

Creekside Cancer Care

Policies & Procedures Manual

December 28, 2014

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Siemens CT

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1.1 Scheduling Patients

Pre-Register patient:

1. Open patient Brower
2. Select Registration Tab
3. To register patient, enter all known information depicted in bold font
 - Name
 - Medical record number
 - Date of birth
 - Sex
 - Height & weight
 - Scan protocol
 - Orientation
4. Choose PRE-PREGISTER

Select Patient for Exam:

1. Open Patient Brower
2. Select Schedule Tab
3. Highlight the patients name you wish to proceed with
4. Choose the Register button on the keyboard
5. Registration box should populate with all pre-entered patient information
6. Enter any data that is missing if applicable (EXAM button will be grey until all required information is entered in correct format)
7. Choose EXAM
8. Continue with patient exam process

1.2 Recording a Voice Command

1. From dropdown menus, select SETUP
2. Select API COMMENT
3. Select NEW ENTRY
4. Choose language
5. Type command and press ENTER
6. Press record

1.3 Machine Warm-Up

Turn Machine On and Complete Check-up Procedure:

1. Press ON button on circular console at desk denoted with symbol ⊖.
2. Assure that there is nothing in the gantry during this procedure, including the table, as this may cause issues with calibrations
3. A message box will prompt you perform CHECK-UP to warm tube, press CHECK-UP
4. When dialog box prompt appears highlighted in blue, press yellow x-ray button on console
5. Wait approximately 7 minutes for CHECK-UP procedure to finish

Complete QA Procedure:

1. In the room, mount the QA phantom
 - (a) Must unlock table top by pressing grey button at foot of table
 - (b) Slide table a few inches toward the bore
 - (c) Lifting up at the center of the table, move table up and over locking mechanism at foot, so that the QA mount is accessible
 - (d) Slide phantom into place at head of table making sure it locks into place
2. While in the room, turn on laser lights and position the hatch marks on the phantom to match the inner set of lasers so that phantom is at isocenter
3. Zero table, leave room, and close door
4. From the dropdown menus at computer console, select SETUP → QUALITY → OK (Wait while systems run a short Phantom Position Check)
5. When START prompt appears highlighted in blue, press yellow x-ray button on console
6. When procedure is complete, check that the message displayed reads RESULTS IN TOLERANCE
 - (a) If a Results not in tolerance message is displayed, ensure gantry is clear of obstructions, run a calibration followed by an additional QA process
 - (b) Contact service if results remain out of tolerance Click OK to finish

**If machine has not been run in over 2 hours, the check-up procedure must be redone:

1. From dropdown menu, select SETUP → CHECK-UP
2. Follow morning checkup steps 1-5

1.4 Exam Process

Complete the following steps from the computer at the CT control console:

1. Register patient or choose patient from Pre-registered list
 - (a) To register patient, enter all information in depicted in bold font: name, medical record number and date of birth; select EXAM to continue
 - (b) If patient has been previously registered, select patients name from browser so that it is highlighted in blue; press register button on keyboard and enter any additional information if applicable; select EXAM to continue
2. Choose RT button and select protocol
3. Verify direction and orientation is correct for exam

Enter CT room and complete the following steps:

1. Position and straighten patient in alignment with CT lasers
2. Move patient into bore so that the area of interested is centered at the inner set of lasers
3. If patient will be treated with Tomotherapy, place BBs at isocenter
4. Press ZERO on control panel on CT machine to zero the tables reference point
5. Move patient inside bore so that the inside laser is set at the most superior edge of what you want to see on your topogram
6. Exit room

Continue procedure from the computer at the CT control console:

1. Select OK
2. Verify Tomogram length, Select LOAD
3. When prompted with yellow arrow, start the first Topogram scan by pressing yellow button on control console; first Topogram will appear
4. Highlight the second Tomogram, Select LOAD
5. When prompted with yellow arrow, start the second Topogram scan by pressing yellow button on control console; second Topogram will appear
6. Pink localizer box will appear; select scanning parameters
 - (a) Click and drag the superior and inferior edges of the box to select scan area as well as field of view
 - (b) OPTIONAL: If a reconstruction will be required, select the scan series and choose RECON tab, select 2 to add a recon, choose desired slice thickness and parameters
7. Select LOAD on computer
8. Select MOVE TO SCAN on control console

9. When prompted with yellow arrow, start CT scan by pressing yellow button on control console

NOTES

- * When a head icon appears replacing the RT icon, you may double click to begin paging though images
- * Page through images with scroll bar on right or page turner in top right corner

1.5 Dual- and Triphase Liver CT

This procedure will scan first arterial phase with contrast in the arteries only and second venous phase normally about 50-70 seconds after the start of the contrast.

If patient is unable to hold still, procedure will not work because ROI may not be monitoring aorta properly after movement.

**For contrast IV, use needle size of at least 20 gauge due to varying protocol based flow rates necessary for scan.

Complete the following steps from the computer at the CT control console:

1. Register patient or choose patient from Pre-registered list.
 - (a) To register patient, enter all information in depicted in bold font: name, medical record number and date of birth; select EXAM to continue.
 - (b) If patient has been previously registered, select patients name from browser so that it is highlighted in blue; press register button on keyboard and enter any additional information if applicable; select EXAM to continue.
2. Choose RT button and select Liver Dual Phase or Liver Tri Phase from list.
3. Verify direction and orientation is correct for exam.

Complete the following steps from the computer at the MEDRAD display console:

1. Select patient protocol from protocol manager
 - (a) Select abdomen as region of interest.
 - (b) Select PT3 weight based liver protocol from the protocol list.
 - (c) Review details of the selected protocol in the Preview Box and make patient specific changes if necessary.
 - (d) Select LOCK on the display.
2. Load proper contrast to MEDRAD power injector

Enter CT room with patient and complete the following steps:

1. Position and straighten patient in alignment with CT lasers.
2. Move patient into bore so that the area of interested is centered at the inner set of lasers.
3. If patient will be treated with Tomotherapy, place BBs at isocenter.
4. Press ZERO on control panel on CT machine to zero the tables reference point.
5. Move patient inside bore so that the inside laser is set at the most superior edge of what you want to see on your topogram.
6. Exit room.

Continue procedure from the computer at the CT control console:

1. Select OK.
2. Verify tomogram length, Select LOAD.
3. When prompted with yellow arrow, start the first topogram scan by pressing yellow button on control console; first topogram will appear.
4. Highlight the second tomogram, Select LOAD.
5. When prompted with yellow arrow, start the second Topogram scan by pressing yellow button on control console; second topogram will appear.
6. Pink localizer box will appear; select scanning parameters.
 - (a) Click and drag the superior and inferior edges of the box to select scan area as well as field of view.
 - (b) OPTIONAL: If a reconstruction will be required, select the scan series and choose RECON tab, select 2 to add a recon, choose desired slice thickness and parameters.
7. Adjust the pink pre-monitoring single slice line to continuously scan through selected area; it will take up to 30 slices at this chosen position as the contrast is being injected.
8. Left mouse click to get an ROI and place on aorta with correct diameter.
9. Choose HF 100.
10. Select ACCEPT.
11. Select LOAD on computer.
12. Select MOVE TO SCAN on control console.
13. When prompted with yellow arrow, start both CT scan and contrast at the same time.
 - (a) Press yellow start button on CT control console.
 - (b) Press yellow start button on MEDRAD display console.
14. Once every two seconds, a CT slice will be taken as specified with the pink line.

2

Quality Assurance

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2.1 Quarterly & Monthly QA

1. Attach the low contrast phantom to the CT table
2. From the dropdown menus at the computer at the control desk, choose OPTIONS → SERVICE → LOCAL SERVICE
3. Remove the password and click OK
4. Choose QUALITY ASSURANCE → CONSTANCY (always choose NORMAL)
5. Make sure all desired QA items are checked
 - (a) Always checkmark PHANTOM
 - (b) Physics will determine what else to include in monthly and quarterly QA
6. Click GO
7. Verify Phantom with ⊖
8. Click GO
9. To obtain a measurement, choose HELP from the dropdown menu, then choose LOW CONTRAST → GENERAL
10. Enter the diameter of the smallest (should be 4)

To obtain results of QA:

1. From the dropdown menus at the computer at the control desk, choose OPTIONS → SERVICE → LOCAL SERVICE
2. Remove the password and click OK
3. Choose REPORTS → QUALITY ASSURANCE

3

Emergencies

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3.1 Sprinkler System Water Leak

If the sprinkler system in the CT develops a leak:

1. Emergency shut-off valves are located in the back of the CT and MRI Electrical Room on the right side.
2. Turn the Gold knob (left side of unit) to close the incoming water supply.
3. Turn large Red knob to drain.

Part II

Siemens MRI

4

Pre-Imaging

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4.1 Scheduling Patients

Pre-Register patient:

1. Open patient Brower
2. Select Registration Tab
3. To register patient, enter all known information depicted in bold font
 - Name
 - Medical record number
 - Date of birth
 - Sex
 - Height & weight
 - Scan protocol
 - Orientation
4. Choose PRE-PREGISTER

Select Patient for Exam:

1. Open Patient Brower
2. Select Schedule Tab
3. Highlight the patients name you wish to proceed with
4. Choose the Register button on the keyboard
5. Registration box should populate with all pre-entered patient information
6. Enter any data that is missing if applicable (EXAM button will be grey until all required information is entered in correct format)
7. Choose EXAM
8. Continue with patient exam process

4.2 iSTAT for Patient Test Procedure

Cartridges:

- Cartridges must be stored between 2 and 8 degrees Celsius; record refrigerator temperature at least every 24 hours
- Cartridges are good only until their expiration date
- Cartridge must sit at room temperature for at least 5 minutes prior to use
- Cartridge will last for a maximum of 14 days at room temperature

Procedure:

1. Turn Handheld ON
2. Press 2 and follow prompts
3. Enter initials
4. Enter patient ID
5. Carefully open patient cartridge packet and scan barcode on packet (hold packet about 5 inches away from handheld)
6. Fill patient blood sample into cartridge within 15 minutes of opening and scanning; fill to blue line and seal the cartridge close by pressing down on outer edge only
7. Insert cartridge into handheld; screen will read cartridge locked
8. Place handheld on flat surface during the cartridge locked period; DO NOT move device around during this time
9. When screen reads results ready press arrow key >>
10. Creatinine level appears
11. To print results, make sure printer is turned on; print results by pointing the receiver of the handheld towards the receiver of the printer and press the print button on the handheld (middle button on the bottom row)

4.3 Machine Warm-Up & Daily QA

Procedure:

1. Turn key to unlock position on power console to left side of desk
2. Press the blue System On button on the power console
3. Go in room, turn lasers on and line up the lasers to the dots on the head coil
4. Ensure that the coils are plugged in properly
5. Press isocenter button to send phantom to center of bore; leave room and close door
6. From the dropdown menus, choose OPTIONS → SERVICE → CUSTOMER QA
7. From menu on left side of screen, Choose HEAD MATRIX COIL
8. Place a checkmark in the box beside COIL CHECK verifying coils are plugged in
9. Click on the GO button at the bottom of the screen
10. Pop-up with phantom picture will appear; note time and wait for 10 minutes for water to become perfectly still in phantom
11. After waiting 10 minutes, Click OK (QA procedure will take about 5 minutes and grey box next to coil check will read RUNNING)
12. After QA procedure is completed will say DONE in grey box if it checks out
 - If QA procedure does not to standards, wait 5 minutes and try again
 - Contact service if results remain out of tolerance
13. Close out of QA procedure by clicking X in upper right corner

4.4 EKG and O₂ Sensors

NOTE: EKG is for patient gating only and is not FDA approved for patient monitoring

Procedure:

1. Area for EKG electrode stickers must be free of hair or shaved
2. Apply the electrodes stickers so that one sticker is on the patients right side above the breast line and two stickers area on the patients left side below the breast line.
3. Apply the EKG leads
 - White lead is attached on patients right side above the breast line
 - Green and Red leads area attached on the patients left side below the breast line; it does not matter which one is more medial or lateral as long as both leads are left of midline
4. Use the grey foam EKG strip to secure the placement of the device and place on patients abdomen area so that sensors are directed toward window in room
5. If O₂ monitoring is needed, place the device on the right patients right index finger and direct the sensors toward the window in room
6. While at computer console display the EKG wave by selecting the EKG button on the lower right
7. Right click in EKG display window to adjust settings or options
8. To display both EKG and O₂ right click in the EKG display window and choose from options
9. When procedure is complete, return monitoring devices to charging station and press firmly into dock so that the charging light illuminates

5

Imaging

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5.1 Correcting Patient Information

1. Open patient Browser
2. Select Name of patient for whom you would like to correct so that the name is highlighted in blue
3. From the dropdown menu, select EDIT → CORRECT → YES
4. Edit select data
 - Note: only some patient information can be edited
 - Items in grey cannot be edited
5. Certain additional information can be edited by selecting each series individually from the patient browser

5.2 Creating a Disk

1. Open the patient browser and highlight patient name, study, and each series you would like to copy.
If you wish to copy all series, you can select only the study in blue and all series from the menu on the right will be copied.
 - Use SHIFT key to select consecutive sequences
 - Use CONTROL key to select nonconsecutive sequences
2. From the dropdown menu, choose TRANSFER → EJECT FROM
3. Place a CD-R disk in the disk drive and manually close drive
4. From the dropdown menu, select TRANSFER → EXPORT TO
5. When prompted, assign a label to the disk. Label must be at least 3 characters long and contain no spaces but may contain underscores
6. Check the box for VIEWING TOOL if disk is to be viewed on a computer without Dicom reader (usually this is for patient use or for an outside doctor to view)
7. Job status can be viewed with icons at bottom of screen
 - Red dot means information is currently being recorded to disk
 - Double click the red dot icon to view details of job status
8. When job status is finished, always eject the disk by choosing EJECT FINALIZED FROM DVD WRITER (otherwise files may become corrupted)

NOTE: An E under the file name means that that file any files in the menu to the right have been exported or sent.

5.3 MRI Contrast Policy

To maintain safety in regard to performing contrast enhanced MRI examinations and address issues relating to the administration of contrast material.

1. Intravenous contrast may only be administered when a physician is physically present in the clinic.
 - IV Contrast may only be administered by a Physician, Registered MRI Tech, or Radiation Therapist.
 - Oral Contrast can only be given to the patient to drink by a Physician, Registered MRI Tech, or Radiation Therapist.
2. Compliance with all federal, state and local laws regarding contrast administration is observed.
3. Thorough screening prior to performing contrast-enhanced examinations is conducted for Nephrogenic Systemic Fibrosis risks, contrast sensitivity and allergies. This is accomplished by reviewing the screening form which contains questions that assess the risk for the conditions listed above. Lab values must have been obtained no more than 30 days prior to exam. If no previous lab values are available, a current creatinine is acquired, the eGFR is calculated and recorded.
 - For an eGFR less than 30, consent must be obtained from the supervising physician before contrast can be given.
 - When a patient has indicated a prior reaction to contrast, this will be discussed with the supervising physician.

5.4 Power MEDRAD System On/Off

Turning On MEDRAD:

1. Turn on system by pressing grey power button on display monitor at computer console
2. It will take about 5 minutes for system to boot up
3. Read warnings and press CONTINUE
4. Home screen will be displayed

Turning Off MEDRAD:

1. From the menu, select SHUTDOWN
2. Select SYSTEM SHUTDOWN
3. Both the display monitor and the injector will be shut down

NOTE: To perform a Hard Shutdown press and hold the grey power button on the display monitor.

5.5 Loading the MEDRAD Contrast Injector

1. Select patient protocol from protocol manager
 - (a) Select region of interest
 - (b) Select protocol from the protocol list
 - (c) Review details of the selected protocol in the Preview Box and make patient specific changes if necessary
 - (d) Select LOCK on the display
2. Attach syringes to the injector by inserting it quickly
3. Attach spikes to the syringes.
4. Attach saline bag to blue side and attach contrast to green side of power injector
5. Press AUTO LOAD button; the volume indicators indicate how much fluid needs to be loaded to support the selected protocol including the amount needed to prime the system.
6. Blue and green indicator lights will flash when ready to load syringes
7. Press both FILL B button and FILL A button and wait for saline and contrast to completely load into syringes and automatic plunger has stopped moving
8. Detach spikes along with empty saline bag and empty contrast vial
9. Attach warming devices to syringes
10. Use knobs at base of injector to manually drive both saline and contrast to top of each vial to that a bead of fluid forms at the top
11. Attach transfer tubing set; the T-connector with the extended line of tubing should be on the green contrast side
12. Attach prime tube to end of tubing set
13. Select PRIME button; this will allow power injector to push any air out of tubing
14. Verify that all air bubbles have disappeared from tubing and that saline is visible in the priming tube
 - (a) Push the ✓ checkmark button to confirm that no air remains in tubing
 - (b) If air is found in tubing, manually turn the knob to advance the piston and continue priming until all air is expelled from tubing set
15. Select ARM button to prepare system for patient contrast injection
 - (a) The system can either be armed from the injector or from the display
 - (b) If system will not arm from the injector, this may mean that the amount of saline or contrast loaded into the syringes is insufficient for the protocol
 - (c) Usually it is acceptable to simply modify the protocol from the display monitor to match the volume in the syringes if the variance is within a few milliliters
16. Arm Lights will illuminate when injector is ready for contrast delivery

5.6 Injecting Contrast with the MEDRAD Power Injector

The full MEDRAD MRI Contrast Injector manual has been included in Section [22.1](#). Here we present an overview of its operation.

1. Flush the IV line with a 10mL syringe of saline to check for any possible obstructions
2. Attach the tubing set from the power injector to the patients IV line
3. Press START on the injector
 - (a) Saline will be injected into the patient
 - (b) Observe injection site to verify saline is safely delivered
4. Exit room
5. Press START on both the contrast display screen and on the CT control panel
 - NOTE: Selected CT protocol must be programmed for proper contrast delay
 - If no contrast delay is programmed in selected CT protocol, the delay for contrast must be manually created by waiting to start the CT scan in the desired time frame
6. During the injection the display screen will display all details pertaining to the injection such as pressure, phase view, elapsed time, pressure limits, reminders, and injection information
7. When the injection is complete, an audible tone will emit from the injector and a summary of the injection will be displayed on the display screen
8. Disconnect the disposable syringes with a simple twisting and pulling motion; the pistons will automatically retract once syringes are removed

NOTE: To abort the injection in an emergency, press the red ABORT button at any time.

5.7 Exam Process

Complete the following steps from the computer at the MRI control console:

1. Register patient or choose patient from Pre-registered list
 - (a) To register patient, enter all information in depicted in bold font: name, medical record number, date of birth, sex, height & weight, scan protocol, and orientation; select EXAM to continue
 - (b) If patient has been previously registered, select patients name from browser so that it is highlighted in blue; press register button on keyboard and enter any additional information if applicable; select EXAM to continue
2. Before entering room, review patient screening form with patient and re-verify that patient has removed all possible metal

Enter MRI room and complete the following steps:

1. Provide patient with earplugs to use during the exam, position earphones & provide patient with panic button to use for emergencies
2. Position and straighten patient in alignment with MRI lasers
3. Select appropriate coil for exam and secure all plugs for that coil
4. Move patient into bore so that the area of interest is centered at the inner set of lasers
5. Press MOVE TO ISO button on control panel on MRI machine; this will move patient inside bore to ideal location within magnet
6. Exit room

Continue procedure from the computer at the MRI control console:

1. Highlight CK protocol
2. Click double arrow << to move protocol into the program control area
3. Select OPEN
4. Select APPLY
5. Localizer scan will begin (note: images will not begin to appear until the entire segment is complete)
6. Use yellow box to select area to be imaged in all three planes
 - Adjust yellow box ONLY by dragging the center of the box
 - If additional slices or slabs are needed, use up or down arrows under the Routine parameter card to adjust number of slices or slabs
 - DO NOT type in the number of slices, must use arrow keys due to required increments
 - NEVER adjust size of yellow box by dragging the edges as this will effect multiple parameters
7. Select APPLY
8. As each segment is scanning, set up the next consecutive segment by highlighting the segment in program control area and repeat step 4
9. Select APPLY for each segment after setting up yellow box

5.8 Miscellaneous MRI Tips

1. If a larger scan area is needed for a particular patient, you can increase the number of slices per slab by using the arrow button next to number of slices and then hit ENTER on keyboard for it to register (DO NOT type in number of slices).
2. If Panic button is pressed by patient and you must pull patient out, choose the CLOSE TO HOME button to that the table does not break the laser plane; this will ensure you do not lose your reference point and you may simply rerun only that segment.
3. To rerun a segment during an MRI scan (for example, if panic button is pressed), right click on the segment that needs to be repeated and choose RERUN.
4. To delete a segment, you can highlight the item and drag it to the trash can icon at the bottom left of the screen

6

Post-Imaging

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6.1 Imaging and Report Timeline

1. All images and appropriate corresponding documentation will be submitted to the Radiologist for review within 6 hours of the examination.
2. All examinations will be reviewed by the Radiologist, dictated, and transcribed within 48 hours of the examination.
3. All final reports will be signed (verified) and dated by the Radiologist within 4 business days of the date of the examination.
4. All reports will contain the following items:
 - Examination title with details of contrast usage (without contrast, with contrast without and with contrast, delayed imaging.);
 - patients full name, date of birth and patients medical record number;
 - examination date;
 - description of the Clinical indication/history;
 - a technique description to include a description of the specific pulse sequences (imaging contrast) and imaging planes used in the performance of the examination (e.g., Sagittal T1, Axial T1, Axial T2 and Axial FLAIR);
 - a mention of comparison examinations utilized (e.g., no images for comparison, images currently unavailable for comparison, or comparison made to prior study including study and date);
 - a description of the specific type and amount of intravenous contrast administered;
 - a comment on the image quality (notation of any factors affecting image quality such as physical or mental disabilities, nervous disorders, claustrophobia or body size);
 - a findings section (body of report);
 - a summary/final impression;
 - typed name of interpreting physician;
 - final signature of the interpreting physician
 - date of the interpreting physicians signature
 - a recommendation for follow up of incidental findings (if applicable).

6.2 3D MPR Reconstruction

Images can be reconstructed from one plane to another (e.g., sagittal to axial).

Procedure:

1. Open sequence to reconstruct patient browser by highlighting the patient name, study, and sequence to reconstruct in blue
2. From the dropdown menu, select APPLICATIONS → 3D → MPR
3. Select PARALLEL RANGES icon (head with grey diagonal lines)
4. From within the Radial Ranges dialogue box, select desired preset reconstruction the dropdown menu
 - If more coverage is needed, deselect CONSTANT NUMBER OF IMAGES icon when defining start and end points
 - Important DO NOT change image thickness or distance between images
5. Position the yellow box over the area to be included in the reconstruction
6. Select START
7. Select SAVE AS icon
8. Name the file under Range Series

7

Quality Assurance

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7.1 iSTAT Electronic Simulator

Requirements:

- Required to run Electronic Simulator each time after required software updates
- Software updates happen twice a year in JUNE and DECEMBER and it is recommended to upload new software on the 1st day of the month, as iSTAT will not run with expired software
- Access the software from the Abbot Point of Care website (tech support can help if needed)

Procedure:

1. Turn Handheld ON
2. Press Menu and access Administration Menu
3. Press 3 for Quality
4. Press 4 for Simulator
5. Enter initials if prompted
6. Scan barcode on box of electronic simulator (different from barcode on simulator itself)
7. Insert electronic simulator into handheld; screen will read simulator locked
8. Place handheld on flat surface during the locked period; DO NOT move device around during this time
9. Within two minutes, results will appear on screen; result should read PASS and a Thermal Differential is displayed such as +0.00
10. This value must be logged into a log sheet; templates can be found through system resources

7.2 iSTAT for Control

Requirements:

- Must check cartridge stability with every new lot AND every month
- Control viles and cartridges must be stored between 2 and 8 degrees Celsius; record refrigerator temperature at least every 24 hours
- Controls are good only until expiration date
- Controls will last up to five days at room temperature
- Control vile must sit at room temperature for 30 minutes before collection from vile
- Cartridge must sit at room temperature for at least 5 minutes prior to use
- A level 1 control must be tested immediately upon collection from control vile

Procedure:

1. Turn Handheld ON
2. Press Menu and access Administration Menu
3. Press 3 for Quality
4. Press 1 for Control
5. Enter initials
6. Scan barcode on control vile
7. Carefully open cartridge packet and scan barcode on packet (hold packet about 5 inches away from handheld); this is the same cartridge used for patients
8. Fill control sample into cartridge immediately; fill to blue line and seal the cartridge close by pressing down on outer edge only
9. Insert cartridge into handheld; screen will read cartridge locked
10. Place handheld on flat surface during the cartridge locked period; DO NOT move device around during this time
11. Within two minutes, results will appear on screen in mg/dL
12. Compare results with chart found at <http://www.abottpointofcare.com>
 - (a) Click on VALUE ASSIGNMENT SHEET (right side of screen)
 - (b) Select appropriate CLEW
 - (c) Select test type: i-STAT Level 1 Control
 - (d) Choose Lot # from drop down list (found on the box of control viles)
 - (e) Check to see if results are within tolerance under Crea Level
13. If result is PASS, continue to use the iSTAT handheld
14. If result is FAIL, run a second control test; if result of second test is FAIL, call technical support and do not continue to use iStat handheld

8

Safety

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8.1 MRI Safety and Pregnancy

Purpose: The following information is provided to pregnant patients and/or personnel to facilitate their decision whether or not to undergo diagnostic MRI or work in the MRI environment.

Policy: Pregnant patients can undergo MRI scans at any stage of pregnancy if, in the opinion of the attending radiologist and the referring physician, the risk-benefit ratio to the patient warrants that the study be performed. It should be documented in the radiology report or the patients medical record that:

1. The information received from the MRI study cannot be acquired via alternative non-ionizing studies, and
2. The information received from the MRI scan is needed to potentially affect that care of the patient and/or fetus during the pregnancy, and
3. The referring physician does not feel that it is prudent to delay diagnostic data until after the patient is no longer pregnant.
4. Gadolinium-based contrast agents should not be routinely given to pregnant patients. Rather, a risk-benefit assessment should be discussed between the patients, the attending radiologist and the referring physician.
5. Pregnant patients undergoing MRI will provide written informed consent to document that they understand the potential risks/benefits of the MRI procedure, know the available alternatives and that they wish to proceed with MRI.

Creekside Cancer Care Imaging Center pregnant personnel: Pregnant health care workers are permitted to work in and around the MRI environment throughout all stages of their pregnancy. This includes but is not limited to positioning patients, scanning, archiving, injecting contrast, entering the scan room in response to an emergency, etc. *Pregnant workers are not to remain within the bore or the MRI room during actual scanning and data acquisition.*

General information: MRI uses a powerful magnetic field and computers to create images of the body. The magnetic field aligns protons that are present in nearly all of the bodys tissues. Radio waves then cause these protons to produce signals that are picked up by a receiver within the MRI scanner and then sent for computer processing to derive anatomic information of the body.

In general, there is no known risk of performing MRI on pregnant patients. However, the risks are not well defined. MRI has been used without known or significant side effects during the second and third trimester pregnancies for many years. Historically, MRI has been used sparingly during the first trimester of pregnancy. MRI studies on pregnant patients are generally performed to address very important clinical problems or suspected abnormalities. Generally, MRI is safer for the fetus than imaging with x-rays.

Current radiology practices discourage the use of gadolinium-based contrast agents during pregnancy because their safety for the fetus has not been proven. While available evidence suggests that it is unlikely that these contrast agents have an adverse effect on the developing fetus, they should not be used routinely but should be reserved for serious clinical problems or emergencies.

Breast Feeding and Gadolinium Contrast: If a patient is breast-feeding an infant during the period of a scheduled MRI exam that requires gadolinium contrast, it is recommended that the patient pump and save her breast milk since the injected contrast will pass into the breast milk. *While the injected contrast takes about 24 hours to clear the body, it is recommended that breast-feeding not resume for 48 hours.*

8.2 Acoustic Noise

As current is passed through the gradient coils during image acquisition, a significant amount of acoustic noise is created. Although these levels are anticipated to be well below the OSHA standards whereby a hearing loss prevention program must be started (80 dB over 8 hours or half the exposure time for each additional 5 dB exposure), it can cause some reversible and irreversible effects. These effects include communication interference, patient annoyance, transient hearing loss and, in patients who are susceptible to hearing impairment, permanent hearing loss.

It is recommended that all patients be provided with earplugs and/or headphones.

8.3 Universal / Standard Precautions Regarding Fluids

Universal/Standard Precautions are a set of infection control practices that everyone should use to reduce transmission of microorganisms. These guidelines are to protect both healthcare personnel and patients from contact with infectious agents.

1. Appropriate use of protective barriers, including gloves for hand contact, mask and gowns
 - Gloves, when required, are changed and hands washed after each patient.
2. Precautions should be taken to prevent injuries caused by needles, syringes, and other contaminated sharp objects.
 - The safety devices on needles and other sharps should be activated immediately after use.
 - Used needles should be discarded immediately after use and not recapped, bent, cut, removed from the syringe or tube holder, or otherwise manipulated.
 - Sharp objects are to be discarded in puncture- resistant red containers with a Biohazard label that are impervious to moisture, and of sufficient strength to prevent expulsion. Do not overfill sharps containers. Discard after 2/3 full or when contents are at the full line, indicated on the containers.
3. Surfaces and equipment contaminated with blood or other potentially infectious materials that will not be sterilized, are cleaned and disinfected after treatment of each patient. Disposable coverings may be used on some surfaces to prevent contamination.
4. Floors, rugs and carpeting that have been contaminated by body fluids will be cleaned by blotting to remove the fluid as quickly as possible, then sanitize by spot cleaning with soap and/or disinfectant or steam cleaned/shampooing the surface.
 - Mops or other equipment that are used to clean up spills should be cleaned with soap and water, rinsed with a disinfectant solution, wrung dry, then allowed to air dry completely.
5. Infectious waste is to be placed in containers labeled with the Biohazard symbol.
 - Containers are located in each treatment, scanning and exam rooms. They will be checked and emptied weekly, and contents placed in collection containers located in a secure location at both 120 and 140. The collection containers are picked up monthly.

8.4 Conscious Sedation / Analgesia

Conscious sedation / analgesia is defined as combinations of pharmacological agents administered by a physician or RN via one or more routes. This will produce a minimally depressed level of consciousness and satisfactory analgesia while retaining the ability to independently and continuously maintain an airway and respond to physical stimulation and verbal commands.

Protocol:

- All patients receiving conscious sedation/analgesia will have intravenous access.
- Emergency equipment and medications including a fully stocked crash cart with an AED, will be immediately available where conscious sedation/analgesia is administered.
- Informed consent is required prior to administering conscious sedation/analgesia. The physician will provide the patient with all information for obtaining informed consent. The RN will reinforce the physicians explanation prior to and during the procedure.
- Only RN with ACLS and have validated current competency in the administration and monitoring of conscious sedation/analgesia will administer and monitor patient. The RNs role includes:
 - pt education
 - administration of drugs producing conscious sedation/analgesia under direct supervision of physician.
 - get baseline assessment before and monitor patient during procedure
 - emergency management
 - documentation
- An RN will have no other responsibilities during the procedure and will not leave the patient unattended or engage in tasks that will compromise continuous monitoring.
 - EKG, BP and Oxygen saturation every 5 minutes
 - auscultation of breath sound and observation of respiratory depth and rate every 5 minutes.
 - level of sedation and mental status every 5 minutes
 - Skin color and condition every 10 minutes
 - pain rating every 10 minutes
- The physician will be present when conscious sedation/analgesia is initiated and throughout its administration.
- Patients who have received conscious sedation/analgesia may be discharged 60 minutes after the last dose of sedative or analgesia drug is administered if all of the established discharge criteria are met.
 - patient is as alert and orient as baseline
 - presence of protective reflexes (swallow and gag)
 - stable vital signs consistent with baseline for 30 minutes after last drug dose
 - cardiac rhythm consistent with baseline
 - BP and heart rate within 20 points of baseline or within normal limits
 - temperature not above 101 F
 - pain rating less or equal to baseline
 - responsible adult will drive patient home and will be able to remain with them

8.5 Sentinel Events

A *Sentinel Event* is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.

Identifying an Sentinel Event:

- Delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose.
- Abduction of any patient receiving care, treatment or services.
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- Assault, homicide, or other crime resulting in death or major permanent loss of function of a patient, staff member, licensed independent practitioner, visitor or vendor.

Reporting a Sentinel Event:

- Submit to the Joint Commission within 45 calendar days a thorough and credible root cause analysis and action plan.
 - The complete root cause analysis, including its findings.
 - The resulting action plan that describes the organizations risk-reduction strategies and measures for evaluating their effectiveness.
 - The root cause analysis and action plan are not to include
- Form accessible through its Joint Commission Connect extranet site. From this site, select Self-Report Sentinel Event from the Continuous Compliance Tools section.

8.6 Cooling Event Warning

If the "Cooling System warning" message appears on the console as in Fig. 8.1, call service:

1. Go to OPTIONS dropdown menu, choose SERVICE → LOCAL SERVICE
2. Service technician will either send a code to enter, or read it over phone
3. Choose Magnet & Cooling option
4. Read Water Temp values (screenshot in Fig. 8.2). Pressure and temperature can also be read from the gauges inside the equipment room (see Fig 8.3).

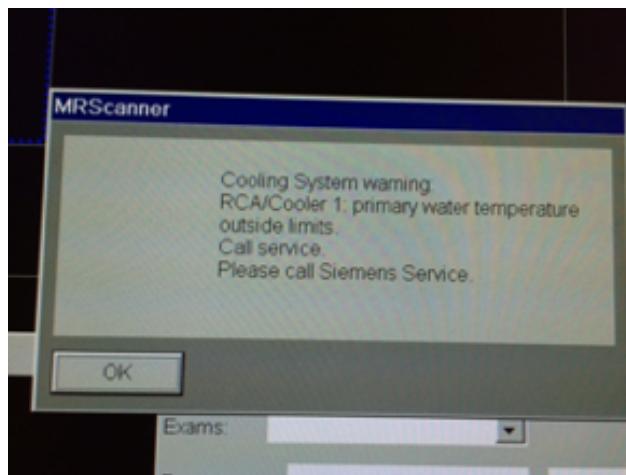


Figure 8.1: "Cooling System warning" message.

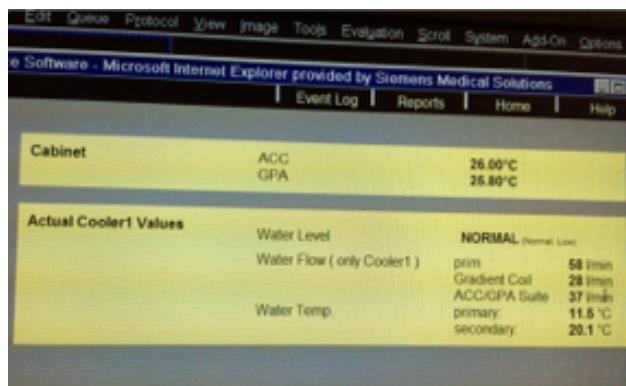


Figure 8.2: Water temperature values from console.



Figure 8.3: Temperature and pressure gauges inside equipment room.

9

Emergencies

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9.1 Sprinkler System Water Leak

If the sprinkler system in the MRI develops a leak:

Emergency Shut-off valve for the MRI has a yellow handle, located back right of room on pipes on ceiling.

9.2 Magnet Quench

Quenching is the process whereby there is a sudden loss of absolute zero of temperature in the magnet coils, so that they cease to be super conducting and become resistive, thus eliminating the magnetic field. This results in helium escaping from the cryogen bath extremely rapidly.

It may happen accidentally or can be manually instigated in the case of an emergency. Quenching may cause severe and irreparable damage to the super conducting coils, and so a manual quench should only be performed in extreme cases when the physician and service engineer are involved in the decision to quench. A fire in the scan room may also be a cause to quench the magnet, so the fire fighting personnel can safely enter the room.

Our system has helium-venting equipment, which removes the helium to the outside environment in the event of a quench. However if this fails, helium will vent into the room and replace the oxygen. Under these circumstances immediate evacuation of the patient and personnel is necessary. In such a case the patient should be immediately evacuated and evaluated for asphyxia, hypothermia and ruptured eardrums.

9.3 Fire in the MRI Room

The following protocol is to provide the MRI staff with the proper and safe procedural guidelines for a fire situation in a MRI environment.

1. Remove patient from the scan room. Use MRI safe fire extinguisher located on wall next to the door of the MRI room. Sprinkler system should be auto activated, if not functional perform Emergency Magnet Rundown procedure (Quench).
2. Press the Emergency Magnet Rundown button located in the magnet room or next to operators console. This results in a rapid reduction of the magnetic field in about 2 minutes. There is a boil-off of cryogen, accompanied by loud crackling and hissing sounds.
3. Evacuate scan room and close scan room door.
4. Call 911, and 7145 to alert fellow employees. Evacuate to the parking lot and guide the Fire department responding to the fire. When the Fire department arrives notify the crew that the magnetic field has been shutdown.

9.4 Riser Room Emergency Water Shutoff

If the water supply to the sprinkler system needs to be shut off in the building:

1. Facing unit- on the left side of the unit close both black knobs, there is an orange flag next to each knob that will rotate as you close valve and an alarm will sound.
2. On the right side of the unit turn red knob 90 degrees to allow the water to drain.

9.5 Code Blue

The following protocol is to provide the MRI staff with the proper and safe procedural guidelines for a Code Blue situation in a MRI environment:

1. Assess the patient

Early assessment, recognition and prevention of potential problems is the key to a safe scan. If the patient is eminently at risk of "coding" while in the scanner, the patient must be pulled out of the scan room immediately.

If the situation is unforeseen, check the patient for responsiveness. If the patient is not responsive, remove patient from scan room immediately to the designated recovery area and call 911.

2. Call a Code Blue

Call 911, give address-140 Old Laramie Trail, and nature of emergency. Call 7145 to alert rest of staff
Instruct a staff member to go out in parking lot to direct Ambulance.

3. Secure scan room door

Make sure the scan room door is closed prior to the arrival of the EMTs.

4. Begin CPR until the EMTs arrive

Begin the CPR protocol until the EMTs arrive. Open the airway, assess breathing. Assess circulation, and begin chest compression if indicated. With Doctor present, start any other life saving measures necessary till the EMTs arrive.

5. Upon arrival of the EMTs, MR technologist to monitor the security of scan room door.

Upon the arrival of the EMTs, the MR technologist informs the EMTs of the patient's situation, reason for exam, any pertinent medical history. Then the technologist stands in front of the closed scan room door, restricting entrance to the room, allowing entrance to the scan room only if the individual is deemed "MR safe".

If patient is transported make sure all belongings go with them.

6. Contact Emergency contacts.

From Patients chart or mobile, contact emergency contact and apprise them of situation.

7. Follow-up

Follow up with patient or their family that day or following day. Restock COR items and supplies. Make sure incident is recorded in patients chart.

Please note that the magnetic field can be quenched during a Code Blue situation, only under the following circumstance: *The patient's life is in jeopardy and is unable to be removed from the scan room due to equipment malfunction.*

Part III

CyberKnife

10

Quality Assurance: CyberKnife

CyberKnife is significantly different than gantry-based systems, and for this reason the standard report from the AAPM Task Group #142 is inadequate. To this end, AAPM set up Task Group #135 to address specific quality assurance issues for CyberKnife, and both Accuray and TG #135 recommendations^{23.2} form the basis of Creekside's CyberKnife Quality Assurance program.

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10.1 Daily QA

Each day before the first treatment, the following Daily QA checks are performed:

- Mechanical and electrical readings
- Robot position checks
- Safety checks
- Output
- Energy
- Symmetry

The details of the daily checks are laid out in detail in the “Treatment Procedures: CyberKnife” [11.5](#) chapter.

10.2 Monthly QA

Monthly QA tests the following items.

- Flatness, symmetry and penumbra
- Energy
- Linac laser alignment
- End-to-end target accuracy
- Dose output
- Imaging system alignment
- Target locating system accuracy
- Treatment couch positioning check
- External laser alignment
- Safety interlocks
- Iris collimator constancy (when Iris in use)

Monthly QA data and reports are stored on the physics laptop under

Desktop\PhysicsBRT\CK\QA - Monthly

The Monthly QA steps are as follows. Enter results in the QA Summary spreadsheet found in the monthly qa subdirectories (cut-and-paste is a good way to start a new qa).

1. Warm up linac if machine has been dormant for ≥ 3 hours (2000 MUs).
2. Warm up x-ray tubes if machine has been dormant for ≥ 4 hours.
3. Insert the isopost and adjust lasers to isocenter (± 1 mm).
4. Load end-to-end plan, and use it to take images of isopost. It may help to reduce kV to 60 or so.
5. Record the center of the isopost crystal as read by imaging system (s/b ± 1 mm).
6. Remove isopost and set up phantom with EBT2 film.
7. Take images and change couch position to 0 angles.
8. Record actual pitch and roll of couch using level to measure.
9. Align phantom according to E2E plan.
10. Record superior/inferior required correction, move couch 1 (or -1) cm anterior, reimage, and record new superior/inferior correction. Expected adjustment should be within 1 mm.
11. Re-align phantom, and repeat last step with left/right, and then anterior/posterior couch motion.
12. Re-align phantom and deliver E2E plan. Analyze E2E plan (after rest of steps completed) using Accuray E2E software, and record RMS difference (s/b ≤ 1.0 mm static, or 1.5 mm synchrony).

13. Set up birdcage with 40 mm collimator and 5 cm buildup (use two of the IRIS QA plastic bases for platform and buildup). Deliver 600 MU. Later analyze this film for flatness, symmetry and penumbra in both x- and y- directions using bfilm by Vega Physics, LLC (or any other means). Specs are flatness $\leq 18\%$, symmetry $\leq 2\%$, and penumbra ≤ 4.5 mm.
14. Set up birdcage with 60 mm collimator and no buildup (only a single IRIS QA plastic base). Mark location of linac laser on film. Deliver 800 MU. Later analyze difference between radiation center and laser center ($s/b \leq 2$ mm).
15. Remove IRIS QA plastic base. Insert PTW N30013 chamber (with buildup) into holder attached to bottom of birdcage, and align center of chamber with linac laser. Attach electrometer, and apply -300 V. Warm up chamber, and record the average of three 200-MU readings. Be sure to apply temperature / pressure corrections to compare with monthly QA baseline (calculations included in spreadsheet template). Tolerance is 2%.
16. By enabling (or pre-enabling, so that Turn on HIGH VOLTAGE to continue message appears on UCC) high voltage in Calibration Check, verify the following interlocks (high voltage should go off, and/or error message displayed, each time): Door e-stop, console e-stop, console HV OFF button, UCC e-stop, wall e-stop (four walls), teach pendant e-stop, robocouch pendant e-stop, and linac fixed collision detector e-stop.
17. Calculate and record average energy deviation ($s/b \leq 1\%$) and trend (last value - first value, $s/b \leq 1\%$) from the Daily QA records (Daily QA).
18. Review and initial all Daily QA results for prior month (Daily QA).
19. Copy the Daily QA spreadsheet (up to the current day) into the Physics Laptop Daily QA folder.

10.3 Annual QA

Annual QA is roughly based on the recommendations Section IV.D. of TG 135^{23.2}. Principal tests encompass the following:

1. EPO button
2. TG 51
3. RDS TLD independent check
4. Beam data checks on at least three collimators, including TPR (or PDD), OCR and output factors
5. Dose output linearity
6. Synchrony E2E test
7. CT density model
8. CT orientation
9. CT spatial accuracy
10. Monthly QA
11. Daily QA

Results are compiled and stored in the Physics laptop. If any discrepancies beyond tolerance are discovered, adjustments must be made in conjunction with a Field Service Engineer (as necessary). Any changes to the beam model necessitate re-commissioning on the TPS.

10.4 Sporadic QA

After every service event or in special cases, various QA tests will be performed at the discretion of the center's Medical Physicist.

The results of sporadic QA tests are recorded in the Physics laptop.

10.5 Calibration

Calibration is done according to TG-51^{23.1} modified for the CyberKnife geometry. The procedure is briefly described in TG-135^{23.2}:

"The key difficulty with employing either method for CyberKnife calibration is the assumption of a 10 cm × 10 cm radiation field for determining the value for k_Q . Instead, a machine-specific reference field, i.e., the 60 mm collimator, is used for CyberKnife. Equivalent field size corrections can be estimated for either $\%dd(10)_x$ or $TPR(20/10)$ using, for example, the BJR Supplement 25 tables. Only a 0.3% error is made if the k_Q from a 6MV linac with $TPR(20/10)$ of 0.68 is used. For consistency, the PDD at SSD = 100 cm for the 60 mm collimator should be measured with the same (small) chamber that is used for the TG-51 calibration. Converting the round field size of the 60 mm collimator and adjusting the collimator size for the extended SSD, an equivalent square field size of 6.75 mm × 6.75 mm results. An interpolation leads to the PDD at 10 cm depth. The PDD at 10 cm depth can be compared with a standard reference such as the British Journal of Radiology (BJR) Supplement 25 for the 6.75 cm square field size. From this value, the equivalent associated PDD value for a 10 cm × 10 cm field can be inferred."

The procedure is also described in more detail in the Physics Manual from Accuray.

10.6 Service

Every service event on the CyberKnife hardware or software, no matter how minor, must be documented with the event details, date, and person(s) performing the service. This is in accordance with Colorado 6 CCR 1007-1 Part 24^{25,6} Section 24.3.10.1 (3).

After every such service event, the readiness of the CyberKnife for patient treatment must be evaluated and documented by Creekside's Medical Physicist. This documentation is to be maintained in the Physics laptop. This is in accordance with Colorado 6 CCR 1007-1 Part 24^{25,6} Section 24.3.10.1 (4).

10.7 Secondary Dosimetry Calculations

Secondary dosimetry calculations are performed for every CyberKnife plan.

The dose in each radiation treatment plan is calculated to CT-voxel precision using Accuray's proprietary ray-tracing algorithm on MultiPlan treatment planning computers. These computations use lookup tables from beam commissioning data to interpolate or extrapolate off-center ratios (*OCRs*), tissue-phantom ratios (*TPRs*) and output factors (*OFs*) for each beam. The secondary calculation check combines plan-supplied beam geometries and MUs with independent beam data interpolations and extrapolations to provide an independent verification of the dose contribution from each beam.

The ray-tracing algorithm computes the dose D_{MP} to a reference point \vec{P}_{ref} using the ray-tracing factor \mathcal{F} as follows:

$$D(\vec{P}_{ref})_{MP} = \mathcal{F} \cdot MU,$$

where

$$\begin{aligned}\mathcal{F} &= OCR(coll, R_{800}, d_{eff}) \cdot \left(\frac{800}{SAD} \right)^2 \cdot TPR(fs, d_{eff}) \cdot OF(coll, SAD), \\ R_{800} &= R_{SAD} \cdot \left(\frac{800}{SAD} \right), \\ fs &= (\text{collimator diameter}) \cdot \left(\frac{SAD}{800} \right),\end{aligned}$$

SAD is the source-axis distance to the reference point, *d_{eff}* is the radiologic depth, *R₈₀₀* is the off-axis distance to the reference point projected at 80 cm from the source, *coll* is the aperture size (whether Iris or Fixed), and *MU* is the monitor units delivered by the beam in question.

For each beam, MultiPlan provides us with its internally generated *coll*, *SAD*, *d_{eff}*, *R₈₀₀*, \mathcal{F} , *MU*, and $D(\vec{P}_{ref})$. Our secondary calculation check uses these MultiPlan-provided values to compute *OCR*, *TPR* and *OF* based on independent interpolation and extrapolation of beam data tables, enabling a quasi-independent calculation of \mathcal{F} and delivered dose to the reference point, D_{Ind} .

Integrity of the Multiplan calculations, beam data, and beam data interpolations would imply that differences between the MultiPlan- and secondary-check-based doses result solely from variations in interpolation methods. The industry-standard expectation is that the dose calculations match to within 5% whenever the product of the ray-tracing factors is non-negligible. For concreteness, we apply the secondary check to all beams where the MultiPlan-tabulated \mathcal{F} is greater than 0.01.

10.8 IMRT QA

Patient-specific QA should be performed for every IMRT plan.

On CyberKnife, a patient-specific QA plan can be created on MultiPlan by overlaying the plan on the head phantom, and delivering the result to the head phantom with EBT2 ball-cube film inserted in the phantom. The reliable response range of EB2 film is 2 - 8 Gy, and as such the patient-specific plan should be scaled appropriately so that the maximum dose falls within this range. This is done with the MultiPlan software.

Analysis of the results is done using a Sun Nuclear MapCHECK module specifically designed for CyberKnife. In essence the software recognizes the positions of certain holes in the pre-cut EBT2 film, and combined with the coordinates of the ball-cube center on the phantom plan, a standard Gamma analysis is possible.

While the small size of the film, and slit in its middle, make the analysis more difficult than one would find with a standard MLC external beam analysis (and accompanying large film / field), these difficulties can be overcome by selecting a region of interest that sculpts around the slit, and avoids the corner holes and cutouts.

Since it is not possible to use a Farmer chamber at the same time as the head phantom, the absolute dose must be determined by calibrating the EBT2 film. The Sun Nuclear software allows for the calibration curve to be entered and used in the dose analysis.

The pass rate for IMRT QA has been set at $\Gamma(\text{absolute dose}, 5\%, 5 \text{ mm}) < 1$ for at least 90% of the points in the ROI, or alternatively $\Gamma(\text{relative dose}, 5\%, 5 \text{ mm}) < 1$ for at least 90% of the points in the ROI combined with a center point in the film differing by no more than 5% the theoretically delivered value.

All results should be stored in both the Physics laptop and CDMS.

11

Treatment Procedures: CyberKnife

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11.1 Patient's First Day on CyberKnife

In EMR, if the form you need to add is not under Treatment Forms, hit reload.

1. Review plan with Physicist and sign Pre-Treatment Therapist form.
2. Review set-up instructions.
3. Create a Pre-Treatment checklist and sign.
4. Create a Completion Data 4 form, it can be found under the Treatment Completion forms.
5. Make sure consent is signed and attached in chart.

11.2 Adding Gas to the CyberKnife System

1. On top of the Sulfur Hexafluoride tank turn silver knob counterclockwise.
2. Watch meter on top left to be sure the red PSI reads 32.
3. Attach hose and slowly turn red handle away from you keeping watch on the SF6 indicator to make sure it does not go above 32.
4. When correct pressure is reached turn the red handle back to starting position and the silver knob on tank clockwise to shut off- then remove hose.
5. Always check later in day to make sure the red PSI has returned to 0.
6. If too much gas has been put into the system- notify Physics immediately.

11.3 Warm-Up

1. Enter Treatment Room:
 - turn on room lights- switch is on right wall as you walk in
 - turn on lasers- switch is on opposite wall of door
 - close treatment room door
2. At Console:
 - Turn cameras on with remote
 - Turn on Treatment monitor
 - Log on to Apple computer- password 303olt.
 - Open MacPractice- Log in- TD, password 303olt
 - Bring Safari up and open Pandora, Daily QA, and Bmatrix
3. Enter equipment room- key is inside 1st cabinet door.
 - record the 1st set of readings before turning machine on
 - Gun Heater, Vac-ION pump, and SF gas pressure
4. At Console turn on machine under Equipment Power
 - when machine turns on record 2nd set of readings
 - Gun Heater, Magnetron Heater, Steering Coil 1, Steering Coil 2 Steering Coil 3 and 4 (are inside the drawer that is kept open), Magnetron tuner, water temp, and water flow rate.
5. Record all numbers into the Daily QA
6. After machine warms up, log into Physics- cccclinician, password: clinician1
 - Run the x-ray warm-up
 - Run the Linac warm-up
 - Choose warm-up, hit enable and high voltage, do the safety checks (pause button, power off, and check door interlock, by hitting partial open, then stop and then close)
 - Run 2000 checking the Dose Rate in equipment room.

11.4 Creating DRRs

Physics will usually create the DRRs. Here is how it is done if not.

1. If we need to load them:
 - go to the CDMS Dashboard Computer
 - Load Plan Administration
 - find patients name and highlight
2. Under Treatment and QA plans:
 - highlight the plan that says deliverable
 - hit the icon with the page and magnifying glass
3. Plan details comes up
 - select the icon with the paper and green check
 - ICD9 details page comes up-click page with pencil on it
 - Sample page (tx site and path) select the appropriate one, If it is an unusual ICD9 we create it by clicking the plus9 sign and find it or the simple green plus and name it ourselves.
4. Follow prompts and answer:
 - OK
 - User if: cccclinician, clinician1
 - OK
 - Auth successful- OK
5. DRR will go from candidate to complete when done.

11.5 Daily QA

1. Make sure the 60 collimator is loaded in machine.
2. Place checkmate on table and turn on.
3. Turn laser on and check floor position under perch, then move robot to Wall 1 position checking BB on wall to make sure robot lines up. Last move robot to Output position. With the laser on in output position, move the checkmate to line up and move table to line up as well (up-down laser should be slightly below the checkmate line).
4. At Console pick phantom, cccclinician, clinician1, then load Checkmate,Two- Daily QA_postupgrade plan then align.
5. Exit and log into physics, linac and calibration. Run 200- 5 times recording the last 3 times in the output section of Daily QA. Place buildup in the middle of checkmate, being careful of bbs placed on top. Run 200- 5 more times-recording the last 3 times. Move robot to symmetry 1 position, run 200- 5 more times recording numbers in Daily QA under Symmetry, and finally move robot to Symmetry 2. While running the final 200 record the Dose Rate A and B.
6. After QA is done move robot back to perch, then load iris or fixed collimator that is needed for the 1st patient.

11.6 CyberKnife Door Emergency Procedures

If door will not open:

1. open panel that is directly across from door by turning lock with coin.
2. On bottom left flip switch to try to reset.

If door will not reset:

1. open cabinet on your left.
2. on black knob push red button and bring handle up.
3. turn crank to manually move door.

11.7 Shutdown

1. Load the 60mm collimator
2. Shut off lasers and lights
3. At control panel
 - select Equipment Power and hit Power Off
 - after all systems shut off- hit continue to return to 7 button window
 - turn main screen off, Synchrony screen and room monitor
4. Make sure equipment room lights are off and lock room.
5. Shut down MacPractice and Safari

11.8 Treatment Book

1. Place Sandisk into tower of CDMS Dashboard Computer
2. Open Report Administrator
 - left upper corner choose treatment book
 - Check Makeup Plans (all others are already checked)
 - click arrow next to Last Name to find patients name
 - click arrow under Last treatment date to pick the plan to import. If pt has more than one plan, do one at a time.
 - click view report at the top left
3. After report is loaded
 - export by clicking on the small disk with the green arrow
 - select Acrobat (PDF) file
4. Removable Disk (F) screen will appear
 - file name TreatmentBook.pdf will appear- rename with pts last name and area treated. (ex treatmentbook.smithrlung)
 - save (watch the scandisk, it will flicker and when it slows down is done)
5. If patient has more than one area treated- repeat steps to export.
6. Pull scandisk
7. Connect on side slot on the white apple keyboard
 - white thumbdrive picture will come up on desktop
 - open by double clicking
8. In Macpractice go to pt icon and type pt name- select enter
 - open attachments and under type select Tx. Book
 - from thumbdrive list pick pts name and drag into the open empty page
 - description: make sure its the correct pt treatment book and type the area treated (ex rt lung)
 - procedure date: when pt finished
 - incident: SRS or IMRT
 - attachment status: attach to ledger
9. When done drag pt tx. book down into locked pt attachments, drag the consent also.
10. Open the EMR
 - check all forms for doctors signatures
 - check each daily treatment record is completed then drag down to locked forms
 - drag Setup instructions, Simulation Request, Pre-treatment Checklist and Pre-Treatment Therapist Review into locked forms
11. On Completion Data form fill in the last treatment date

11.9 Importing Images

When importing images from a CD it needs to be in Dicom format.

1. Select Osixix from the bottom icons on the apple computer.
 - on apple white keyboard hit the Rt upper corner arrow button, this will let us insert the CD.
 - when you hear the fan, CD is importing. You can check activity on the bottom left of the screen
 - exams will pop up under the patients name
 - right click on exam wanted and Export to Dicom Network Node
 - select Destination- N1000_Storage- Creekside CyberKnife-hit send

When importing images directly from hospital:

1. Open Query
 - under Dicom Nodes- make sure Creekside Incoming is checked
 - on the right side make sure any date is checked
 - type in patients name in upper right hand corner
 - exams will pop up- hit the small green arrow to the right of patients name to retrieve images.
 - close out of Query
 - in upper right corner type patients name in
 - exams will pop up under the patients name
 - right click on exam wanted and Export to Dicom Network Node
 - select Destination- N1000_Storage-Creekside CyberKnife-hit send

Loading into treatment planning system

1. On CDMS Dashboard Computer
 - pick image review and import.
2. After images finish downloading
 - Choose the name and then import (small can shaped icon on the top of screen).
 - window will pop up wanting to know if it is a new scan or associate with existing patient. If it is an existing patient it will ask for a password- clinician1
 - next window choose patient not phantom- hit OK
 - 3 Images will pop up, hit the can icon again to save.
 - Imported successfully message will appear

11.10 Skull Tracking

11.10.1 Initial Patient Alignment

1. Acquire image to review initial patient position.
2. Manually align the patient similar to the patient position in CT.
3. Use graphic sliders to get an approximate patient position.
 - look for a easy match point (chin) on DRR. Use mouse to move cross-hairs.
 - On image you took use slide bars to move to same area (If image becomes off center-hit reset to recenter.)

11.10.2 AutoCouch Alignment

1. Open the AutoCouch window.
2. Patient shift will be inputted from the graphic sliders.
3. Click the Move button to position the patient in two steps- Translation 1st.
4. After initial alignment, the patient should be within the tracking range.

11.10.3 Adjustment of X-ray Parameters

1. After correcting translations, acquire another image.
2. Open the Imaging Log to make sure your brightness factors are in range (.98-1.02)
 - adjust KV to reach the desired brightness.
3. Click the Move button to correct for Translations and Rotations.
 - If you are having a problem with table Rotation- try to fix by moving pts head (head up try putting pts chin down.)

11.11 Xsight Spine Treatment

1. Use the following x-ray parameters:
 - C-Spine: 105-125 KV, 100 MA, 100 EX
 - T-Spine: 125 KV, 200 MA, 100 EX
 - L-Spine: 125 KV, 200 MA, 100 EX (use higher MA and EX for larger pts)
2. Once image has been acquired- if spine is not in the middle of image- use slide bars to manually position patient to match CT images.
3. Turn on (check) CT center and Skeletal Mesh.
4. If desired you can choose to use Segmented Viewing mode. On DRR, right click on Image and select segmented.
5. If you are unable to get couch corrections- you can change the following parameters:
 - Target dxAB: default is 2.5. First make sure patient is not rotated. You can increase to 10mm.
 - False Nodes Threshold: default is 50. You can increase this value for lumbar spines and noisy images.
 - ROI height: default is 45. Can be increased or decreased depending on area of spine treated. Increase may be needed for lumbar spine. Range is 40-100mm.
 - Tracking range: default is 40. Decrease if necessary. Range is 4-40m.
 - Live image Contrast Factor: default is 4. It sets contrast between spine and background images.
6. If after 15 mins, you are unable to lock on, return all parameters to default, get the patient up and start over.

11.12 Synchrony Treatment

11.12.1 Patient set-up

1. Position the patient on table, and move couch to the approximate treatment position.
2. Instruct the patient to relax and breathe normally.
3. Evaluate the patients breathing to identify the location of maximum body motion during respiration.
4. In the supine position this is most typically the diaphragm area, but possibly the lower thoracic (for chest breathers) area or the abdominal area (for stomach breathers).
5. Hook BOB up, and put in table slot.
6. Apply the 3 Tracking Markers onto patient at the location of maximum body motion due to respiration.
7. Lower the camera so that it is directly in-line with the patient (not angled from the side of the patient and angled about 45 degrees) and is approximately 6-7- feet from the floor.
8. Keeping the camera low will reduce the incidence of the robot obscuring the Tracking Markers from the Camera Array.
9. Moving the camera Array forward can increase the risk of potential robot collisions with the Camera Array.
10. Continue to adjust the position of the Tracking Markers and Camera Array until the Tracking Markers are visible by the Camera Array, which is confirmed by very fast blinking action from each of the markers. This can best be viewed by standing directly under the Camera Array looking at the Markers.
11. Fiducial identification can now occur.

11.12.2 Motion tracking

1. Align the patient prior to building a model for a Synchrony treatment.
2. Adjust the imaging parameters to have a shorter exposure time and adjust the KVp for larger patients. Adjust slowly as image contrast decreases as KVp is increased.
3. Check the MODELING checkbox, then the Synchrony System will process all ACQUIRE and CORRELATE COMMANDS for use in modeling. The MODELING checkbox must be checked for the fiducial tracking algorithm to use the correlation model as an aid in ROI placement.
4. It requires the acquisition of at least 3 images to build a model. The first two images are used to build a model and the third image is used to confirm the model. A maximum of 15 model points are used. After 15 points the model will start deleting the oldest points each time a new image is taken.
5. Synchrony Alignment controls in the Automatic Patient Positioning window allow the user to automatically move the treatment couch so image acquisition occurs at the center of the respiratory cycle.
 - Click the AutoCouch button in the Alignment and Tracking window.
 - In the Synchrony Alignment section of the Automatic Patient Positioning window, click the Acquire button. Respiratory Center corrections are automatically calculated and displayed.
 - Click the Move button, to move the couch into optimal position.
 - One auto-alignment should be sufficient, if you repeat the process, corrections are averaged.
6. Acquire images for the Correlation Model

- Check the modeling box
 - Acquire an image, Synchrony will monitor the breathing cycle and take the image at the needed time.
 - Locate fiducials using offsets.
 - Hit Correlate to register position.
 - Continue acquiring images and correlating to refine the Correlation Model.
 - You can delete the most recently acquired model point if high correlation errors persist.
 - Right-click on the Correlation Error graph. The graph is located on the Model Graph tab in the main Synchrony Controls window.
 - Select Remove Model Point from the context menu.
 - In the Remove Model Point dialog, click the OK button to remove the most recent model point.
7. Advise Patients that brief motions such as coughing, sighing, etc. are permissible and preferable to having them struggle to suppress such acts, as their respiratory Pattern could change substantially, although dose delivery may be interrupted or the model need to be reset.

11.13 Xsight Lung Treatment

1. Position the patient on the treatment couch and move the patient to the alignment center for initial alignment using the Xsight Spine Tracking System.
2. Use the Xsight Spine tracking System to align the patient translationally and Rotationally. After this step, the treatment couch is at the Xsight Spine Tracking alignment center.
3. Switch from the Xsight Spine Tracking alignment center to the Xsight Lung tracking center by clicking the Go to Xsight Lung button.
4. The Treatment Delivery screen changes to display controls for Xsight Lung Tracking mode. The Go To Xsight Lung button is replaced by the Go to Xsight Spine button. In case during set-up patient moves and you need to realign spine.
5. A window will appear that asks if you want to move couch to treatment center.
6. After hitting yes the treatment couch automatically moves to the treatment center for Xsight Lung tracking mode.
7. Acquire an image. If the tumor was successfully detected in the Live X-ray image and the Display Marker checkbox is enabled, a graphic overlay of the tumor outline appears over the detected location of the tumor.
 - Pressing the Align button on the Alignment and Tracking window shifts the Live X-ray images relative the DRR images using the computed translation offsets.
 - The rotation corrections obtained from initial Xsight Tracking alignment are used to perform rotation adjustments of the LINAC during treatment delivery.
 - If the Xsight Lung Tracking algorithm cannot locate the tumor, the displayed tumor outline in the Live X-ray images will not be aligned with the actual tumor.
8. Modify the X-ray parameters to improve the quality of the image. For tumor location, it is best to maximize the contrast between the tumor and the surrounding tissue.
9. use Offset view mode to drag the tumor outlines and determine translation offsets.
10. If it is not possible to drag the tumor outlines correctly using Offset view mode you can increase the Tracking Range X and Tracking Range Y parameters in the Imaging Parameters window
11. You can also increase the value of the Uncertainty Threshold Parameter.
12. If tumor is visible in one projection but blocked in the secondary projection, or if a large dxAB value and large detection uncertainty are calculated for the secondary projection, you can enable the preferred projection method.
13. If the Xsight Lung Tracking algorithm cannot correctly locate the target using the default segmented DRR images, you can consider using the tumor region DRR images for tracking.
14. If the tumor is located near the diaphragm and exhibits rotation during treatment, you can consider enabling in-plane rotation.
15. After tumor is identified correctly make Synchrony Model.

11.14 Lung Optimized Treatment

1. Position the patient on the treatment couch and move the patient to the alignment Center for initial alignment using the Xsight Spine Tracking System.
2. Use the Xsight Spine Tracking System to align the patient translationally and Rotationally. After this step, the treatment couch is at the Xsight Spine Tracking alignment center.
3. Switch from the Xsight Spine Tracking alignment center to the 1-view tracking Treatment center.
 - The Treatment Delivery screen changes to display controls for 1-view tracking.
 - The go to 1-view Tracking button is replaced to Go to Xsight Spine button. It will be available if needed to realign spine if pt moves.
 - A window will appear that asks if you want to move couch to treatment center.
 - After hitting yes the treatment couch automatically moves to the treatment center of 1-View tracking.
4. Acquire an image. If the tumor was successfully detected in the Live X-ray image and the Display Marker checkbox is enabled, a graphic overlay of the tumor outline appears over the detected location of the tumor.
5. The rotation corrections obtained from initial Xsight Tracking alignment are used to perform rotation adjustments of the LINAC during treatment delivery
6. If the 1-View tracking algorithm cannot locate the tumor, the displayed tumor outline in the Live X-ray images will not be aligned with the actual tumor.
 - Modify the X-ray parameters to improve the quality of the image
 - Use Offset view mode to drag the tumor outlines and determine translation Offsets.
 - If it is not possible to drag the tumor outlines correctly using Offset view mode You can increase the Tracking Range X and Tracking Range y parameters in the Imaging Parameters window.
 - Couch view mode can be used to move the Live X-ray image used for tracking Relative to the corresponding DRR image to determine translation offsets.
 - Increase the value of the Uncertainty Threshold Parameter.
 - Use the tumor region DRR images for tracking.
 - If tumor is located near the diaphragm and exhibits rotation during treatment, you can consider enabling in-plane rotation
7. After tumor is identified correctly make Synchrony Model.

12

ATP & Commissioning

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12.1 Acceptance Testing

Acceptance testing of the CyberKnife machine was completed by Accuray engineers and Creekside Medical Physics consultants according to Accuray manufacturer specifications. Acceptance Testing documents have been compiled into the Physics laptop.

12.2 Commissioning

Commissioning of the CyberKnife was also completed by Accuray engineers, Accuray physicists, and the Creekside Medical Physics consultants according to Accuray manufacturer specifications. Commissioning documents have been compiled into the Physics laptop.

13

Emergency Procedures

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13.1 Linac Emergencies during Treatment

If the linac fails to stop delivering dose at the end of a beam:

1. Press the nearest e-stop button.
2. If delivery does not terminate, press the nearest EPO button.
3. Notify Accuray, Physics and Administration.
4. Do not continue treatment until cleared by Physics.

If the linac or equipment malfunctions because of implosion or explosion:

1. Press the nearest EPO button.
2. Attend to the patient.
3. Notify Accuray, Physics and Administration.
4. Do not continue treatment until cleared by Physics.

If fire, smoke or fumes are detected during treatment,

1. Press the nearest EPO button.
2. Activate the fire alarm in the facility.
3. Attend to the patient.
4. Evacuate everyone from the facility according to facility protocols.
5. If smoke or fumes are coming from the computer equipment, manually turn off the Uninterruptible Power Supply (UPS).
6. Notify Accuray, Physics and Administration.
7. Do not continue treatment until cleared by Physics.

14

Quality Management Program

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14.1 Treatment Planning

Treatment planning should proceed as follows.

14.1.1 (Anyone) Send simulation scans to Osirix in Planning room

Either have them sent directly from the imaging center, or upload them from a CD. All diagnostic scans ultimately need to be uploaded to the Treatment Planning room Osirix, since backups are based on its database (and not, for example, Osirix databases in other offices or reception).

14.1.2 (Anyone) Export planning CT and auxiliary scans to "N1000_Storage"

Whether a CyberKnife or TomoTherapy patient, the simulation CT has to be sent to MultiPlan first. Just select the series' on the Osirix in the Planning room, and Export to N1000_Storage. The format and so forth (like little- vs- big-endian) are set correctly for MultiPlan.

When you export to N1000_Storage, you're actually exporting to the CyberKnife Database Management System, or CDMS for short. From there, the data can be loaded onto any MultiPlan or MD Suite for fusion and contouring.

Other scans (like MRI series) can also be sent to CDMS the same way.

If it's unclear which scans need to be used for planning (for example, if there are multiple diagnostic MRI scans to choose from), it is better to clear this up with Physics and the MD before sending to CDMS, mostly because it becomes much more cumbersome to sort them out once they're in CDMS.

14.1.3 (Anyone) Import scans from CDMS

When the scans are exported to N1000_Storage, they're placed in a queue in CDMS. The next step is to go into Image Review and Import on any MultiPlan, and import them.

14.1.4 (Anyone) Move patient status in BMatrix to "Needs Dosimetry Prep"

"Needs Dosimetry Prep" signifies to Physics that the scans are in MultiPlan and ready for planning.

14.1.5 (MD or Physics) Start a new plan in MultiPlan

To start a new plan, choose "New Plan" in either MultiPlan or MD Suite. You'll be able to choose the simulation CT (this is what the planning is based on), as well as any auxiliary scans you wish to fuse.

You'll also have the option of choosing a template for the plan. This is truly optional, as it just sets up default names for the VOIs and so forth. It has no effect on the actual planning process.

Some cases (such as prostate) may require significant effort in fusion, while others (such as brain) may be very simple, and well done by MultiPlan's automated registration.

Depending on the case and MD preference, the OARs may be pre-drawn by Physics / Dosimetry before the MD begins contouring the target(s).

While we are flexible about the order and persons(s) involved in the loading, fusion and contouring, it is important the physician review the final fusion and contours prior to planning.

14.1.6 (MD) Fill out planning section of Written Directive

This must be done by the MD.

The Written Directive form is found in MacPractice, and must be created / filled out by the patient's MD. If the patient's MD can not fill this out for logistic reasons, it may be filled out by another MD, but only under direction of the patient's MD, and a note must be made to that effect in the Written Directive.

At this stage, the planning section needs to provide information for the planner, including (at the very minimum):

- Number of fractions.
- Patient diagnosis.
- Treatment goals (curative, palliative, benign or functional).
- Machine.
- Modality (SRS, IMRT etc).
- Tracking.
- Target name(s). This must match the names in MultiPlan, including case and whitespace.
- Rx dose, coverage, and IDL range (or max dose).
- OAR name(s). If any need to be drawn by the planner, indicate this.
- OAR DVH constraint points, preferably including acceptable ranges as well as optimal goals.

These might be changed over iterations of the planning process, but the idea is to end up with a record of planning goals and results, that can be verified in the final QA stages of planning.

14.1.7 (MD) Move patient status to “Needs Plan”

This will be an indication to Physics that the planning process can begin.

14.1.8 (Physics) Plan according to Written Directive planning guideline

For TomoTherapy patients, the CT and RTSSET data needs to be exported to TomoTherapy. This can be done from any MultiPlan computer using the “Export” button.

The plans should follow the Written Directive guidelines, but where the constraints are too tight, they need to be noted explicitly in the Written Directive planning section.

14.1.9 (Physics) Move patient status to “Needs Approval”

This is the indication to the Physician that the optimal plan has been generated, and is ready for approval.

14.1.10 (MD) Generate the final plan

The MD should review the Written Directive planning section to see the actual values for each of the constraints, and make adjustments as necessary. Here's where the DVH specifics should be evaluated.

If any changes are needed, they should be adjusted in the Written Directive planning section, the patient status in BMATRIX should be switched back to “Needs Plan”, and the changes should be discussed with Physics.

If no changes are needed, the plan needs to be put into final form by the MD:

- Tomotherapy:
 - Generate final calculation
 - Go to Fractionation tab
 - Authorize plan
- CyberKnife:
 - Perform a high-res calculation
 - Prescribe
 - Save as deliverable

14.1.11 (MD) Complete Written Directive

Once the final plan is saved, data such as DVH values, date and time saved, etc need to be entered into the Written Directive. The Written Directive will serve as the cross-check for all Physics and Treatment QA, so it is extremely important it be accurate and precise.

The Written Directive needs to be thoroughly reviewed:

- Patient is correct.
- Plan goals are correct.
- VOI names match those in the planning system.
- Target and VOI final values accurately reflect the plan.
- Signature.

14.1.12 (MD) Move patient status to “Needs Finalizing”

This is the indication to Physics that the MD has thoroughly reviewed the final plan, and has completed the Written Directive.

14.1.13 (Physics) Finalize plan

The final plan on the planning system needs to be cross-checked with the Written Directive.

Whether TomoTherapy or CyberKnife, all the plan parameters (date, time, etc) and DVH values need to be verified to ensure they match the data in the planning system. Some of the entries in the Written Directive must be checked as verified by Physics.

For CyberKnife, the plan must be authorized (by Physics) in order to generate DRRs.

If anything does not match beyond an insignificant decimal place, the Physician must be contacted for possible revisions.

14.1.14 (Physics) Secondary Dosimetry Calculation

Secondary dosimetry calculations must be performed according to the instructions in the Quality Assurance chapters: CyberKnife^{10.7} and TomoTherapy^{17.8}. The tolerance is 5% for each calculation. The secondary calculation form must be uploaded to MacPractice and signed by both Physics and Physician.

If any calculation is outside 5% of its expected value, the reason must be identified and noted by Physics. If the error is more serious than a numerical rounding problem, for example, the plan must not be delivered until an adequate solution is found.

14.1.15 (Physics) IMRT QA

IMRT plans must be analyzed for dose distribution and magnitude according to standard IMRT QA protocols. Specific techniques are described in the IMRT QA chapters: CyberKnife^{10.8} and TomoTherapy^{17.9}. The IMRT QA results must be uploaded to MacPractice and signed by both Physics and Physician.

Failure of IMRT QA must be explored, root causes determined, and solutions developed before patient treatments continue.

14.1.16 (Physics) Initial Physics Review

An Initial Physics Review consists of compiling screenshots and plan reports, and comparing with the Written Directive to ensure the final deliverable plan matches the Written Directive, and important elements are documented in MacPractice. The Initial Physics Review must be signed by both Physics and Physician prior to treatment.

14.1.17 (Physics) Special Physics Consult

Stereotactic planning requires a Special Physics Consult because of the direct involvement of Physics at all stages. Other special situations (e.g., determination of delivered dose to the fetus during pregnancy; compensation for incomplete prior treatments; plan modifications due to anatomic changes, etc.) may also require a Special Physics Consult.

A letter describing the Physician request and subsequent Physics efforts must be signed by both Physics and Physician and maintained in patient records in MacPractice.

It is important to note that the physics contribution to QA and planning for IMRT treatments is considered by most insurance companies to be included in the planning charges, and not billable as a Special Physics Consult. Consequently, unless an IMRT plan presents unusual complications requiring special physics assistance, a Special Physics Consult will not be included in any IMRT claims.

14.1.18 (Physics) Therapist Pre-Tx Review

Prior to the first fraction delivery, whether TomoTherapy or CyberKnife, Physics must communicate with the treating therapist and describe the particulars of the final deliverable plan. The purpose of this communication is to ensure there is no confusion about the intended target or fractionation scheme, and also to alert the therapist to any potentially difficult setup or delivery conditions.

This communication can be made in person, over the phone, via text messaging or email (provided electronic messages do not divulge PHI). An electronic form in MacPractice must be completed to document that this communication between Physicist and Therapist has indeed taken place, and the form must be signed by the Therapist and Physicist.

14.1.19 (Physics) Move patient status to “Ready for Delivery”

In BMATRIX, the patient status should be changed to “Ready for Delivery”. Therapists should check that this status has indeed changed before initiating any treatment, and if it has not been changed, the status should be verified with Physics.

14.2 Treatment Delivery

Treatment delivery is fully described in the Treatment Delivery chapters: CyberKnife¹¹ and TomoTherapy¹⁸.

14.3 Treatment Verification

Both CyberKnife and TomoTherapy establish patient positioning at least prior to beginning treatment (CyberKnife through stereotactic x-rays, and TomoTherapy through MVCT volumetric imaging). Prior to each fraction, once patient alignment or tracking has been established by the Therapist, the Radiation Oncologist must review and sign a daily note to this effect.

The Radiation Oncologist also meets with each patient at least once per week to review symptoms and progress, and this meeting is documented in MacPractice.

14.4 Continuing Physics

Physics should check each CyberKnife stereotactic plan with 2-5 fractions at some point after the first fraction is delivered, and before the last fraction is initiated, to verify the adequacy of image guidance, treatment delivery, daily treatment notes, and consistency with the Written Directive.

Plans with greater than 5 fractions should be checked weekly.

Continuing Physics checks should be documented in MacPractice, and signed by both Physics and Physician.

14.5 Incident Reporting

Reportable medical events are described in Section 24.6.3 of Part 24 of the Colorado State Regulations^{25.6}. This section is reproduced here for convenience.

1. A registrant shall report any event resulting from intervention of a human patient or human research subject in which the administration of any beam radiotherapy results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
2. Other than events that result from intervention by a human patient or human research subject, a registrant shall report any event in which the delivered dose to the prescribed point or volume:
 - (a) Involved the wrong individual or the wrong treatment site; or
 - (b) Involved:
 - i. A calculated administered dose that differs from the:
 - Total prescribed dose by more than 10 percent of the total prescribed dose, for a total prescribed dose consisting of three (3) or fewer fractions; or
 - Total prescribed dose by more than 20 percent of the total prescribed dose; or
 - Weekly prescribed dose by more than 30 percent; and
 - ii. The event also involved:
 - Malfunction or improper placement of any field definition or beam limiting device, including, but not limited to, a collimator, a mask, a diaphragm, a cone, or a block; or
 - Miscalculation of dose administered to the individual; or
 - Written facility radiotherapy procedures or protocols not being followed.
3. The registrant shall notify the Department by telephone no later than the next calendar day after discovery of the reportable medical event.
4. The registrant shall submit a written report to the Department within 15 calendar days after discovery of the reportable medical event to include:
 - (a) The registrant or licensee's name;
 - (b) The name of the authorized user who signed the written directive and/or who supervised delivery of the prescribed dose;
 - (c) The name(s) of the Registered Medical Physicist(s);
 - (d) The name(s) of the radiation therapist(s)
 - (e) A brief description of the event;
 - (f) Why the event occurred;
 - (g) The room the event occurred in;
 - (h) The type of radiotherapy equipment involved in the event;
 - (i) Copies of written protocols;
 - (j) The effect, if any, on the individual who received the dose;
 - (k) Actions, if any, that have been taken, or are planned, to prevent recurrence; and
 - (l) Certification that the registrant notified the individual who received the dose (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.

5. The report shall not contain the individual's name or any other information that could lead to identification of the individual who received the dose.
6. The registrant shall provide notification of the reportable medical event, no later than 24 hours after its discovery, to the authorized user (and to the referring physician if other than the authorized user).
7. The registrant shall notify the individual who is the subject of the reportable medical event no later than 24 hours after the reportable medical event is discovered, unless, based on medical judgment, the authorized user informs the registrant in writing that telling the individual would be harmful.
 - (a) The registrant shall notify the affected individual as soon as possible if the affected individual cannot be reached within 24 hours.
 - (b) The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the reportable medical event, because of any delay in notification.
 - (c) To meet the requirements of this section, the notification of the individual who is the subject of the reportable medical event may be made instead to that individual's responsible relative or guardian.
 - (d) If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.
8. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants, licensees, and physicians in relation to each other, to an individual affected by the reportable medical event, or to that individual's responsible relatives or guardians.
9. A registrant shall retain a record of a reportable medical event for 3 years, containing:
 - (a) The registrant's or licensee's name;
 - (b) The name of each individual involved;
 - (c) The medical records number or equivalent means to identify the individual who is the subject of the reportable medical event;
 - (d) A brief description of the event and why it occurred;
 - (e) The effect, if any, on any individual who received the dose;
 - (f) The actions, if any, taken, or planned, to prevent recurrence; and
 - (g) Whether the registrant notified the individual (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.
10. A copy of the record shall be provided to the authorized user(s), if other than the registrant or licensee, within 15 calendar days after discovery of the reportable medical event.

15

Tricks and Tips

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15.1 CK: Resetting the CISCO switch

The Cisco switch allows traffic from outside the CyberKnife firewall to the CyberKnife network, including CDMS (e.g., for image transfer) and MultiPlans (connected outside the network). If the switch is shut down for too long, or some other event causes it to reset to default values, it needs to be initialized for the Creekside network. This is done as follows:

On the UCC, switch to Service mode (service / cksvc@accuray.com).

There will be a Unixtype menu. Select the submenu item called CK Services - Network Configuration. It will produce a screen asking to select a CyberKnife network. Choose CK1, and device Cisco 2800 Series Gigabit Router/F. And press ok.

On the next screen, fill in the Hospital Network Information as follows:

- Management IP Address: 10.120.3.231
- Forwarding IP Address: 10.120.3.10
- Subnet Mask: 255.255.255.0
- Gateway IP Address: 10.120.3.1

Click Configure Device. It may take several minutes (with a spinning icon). If successful, it should say success. You may need to repeat once or twice. If this doesn't work, it is possible that the network settings have changed (check IT administration), or that the Cisco switch is broken and needs replaced. Replacing the Cisco switch requires Accuray service involvement.

15.2 CK: Uploading scans directly to MultiPlan

You can upload scans directly to CDMS from any MultiPlan, MD Suite or CDMS Administrator station.

First insert the CD or USB thumb drive with the image data into the computer.

From the main MultiPlan / MD Suite / CDMS Administrator screen, select the Image Review and Import Button.

Then select the Load DICOM Series From Disc icon at the top left, and select the desired subdirectory or images from the CD. The rest of the data import is the same as if the data is sent directly to N1000_Storage.

It may not be obvious which dicom files need to be sent, so you may have to click around the folders, and use a little trialanderror.

An alternative is to find the precise set of images you want on Osirix, and then export the dicom files directly to a USB thumb drive or CD drive from Osirix. **Make sure you only select the series you want to use on MultiPlan.** Then go through the above process with the exported files (a thumb drive can be used instead of a CD to uploaded directly).

15.3 Tomo: Restarting Cobra

When you log onto Tomo and it says Cobra needs to be restarted:

- In Cluster Room:
 - check Tomo Data Server- Top node- if no green light on- hit power button
 - pull out computer and check to see if you have info on screen
 - If screen blank- hit Ctrl, Alt, and Delete.
 - * Log in with lower case: customeradmin
 - * Password: ca\$min
- On bottom of computer screen:
 - Make sure Data Base Status says connected
 - check port to make sure you have numbers- no port or status not connected you will have to hit restart windows operating system.

15.4 Archiving Patient Data on MultiPlan

15.4.1 Overview

Under System Administration → Storage, you can set any location as a storage location for CDMS patient data. The storage location only needs to be accessible to CDMS (e.g., through a shared directory).

15.4.2 Accuray Network Structure

Most of the CyberKnife computers are located behind the Accuray firewall, although MultiPlan and MDSuite can be placed outside. The Accuray IT Guide (stumbled upon online, reproduced in Sec. ??) goes through network details. Note that Creeksides system as of November 16, 2014 is 9.5 / 4.5.

15.4.3 Accessing CDMS through MultiPlan

You can access CDMS through MultiPlan (e.g., to map a shared folder) by running Remote Desktop Connection from MultiPlan:

```
username: techsupport  
password: cksvc@accuray.com
```

The CDMS Server program (icon on CDMS desktop) allows for configuration of CDMS (dangerous!!), but also starting and stopping of CDMS and DRR services (this is not dangerous). Credentials for this program are:

```
username: service  
password: cksvc@accuray.com
```

15.4.4 Setting MultiPlan as Storage Location for CDMS

Overview

You can add MultiPlan as an external storage location in System Administration → Storage. Screenshots in Fig. 15.1 and Fig. 15.2 provide the necessary details. Note that credentials in the location edit widget refer to the credentials of the machine, so for MultiPlan they are:

```
username: accuray  
password: accuray
```

Fixing Windows registry glitch (IRPStackSize)

When attempting to perform transfers of data from CDMS to MultiPlan (through the PARS interface), it is possible that the connections fail, and log errors suggesting space is unavailable, shared directory can not

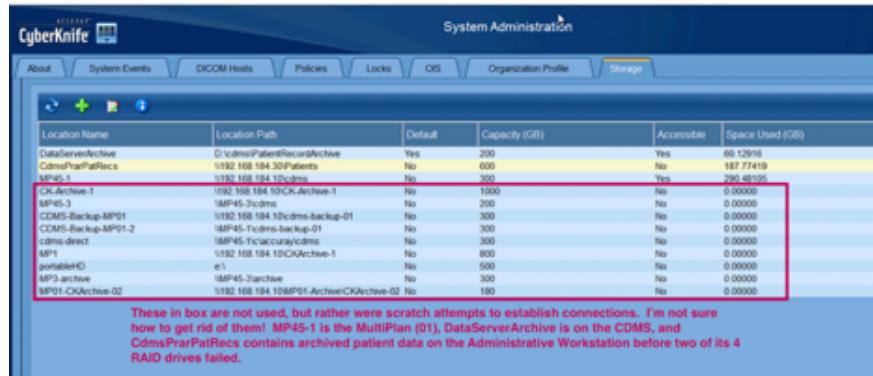


Figure 15.1: System Administration → Storage screenshot #1.

The dialog box is titled 'Update Storage Location' and contains the following fields:

- Name: MP45-1
- Location Path: \\192.168.184.10\\cdms
- Network Credentials:
 - User Name: accuray
 - User Password: [redacted]
- Default: Yes (radio button selected)
- Capacity (GB): 300
- Space Used (GB): 290.48105
- Location Type: Network

* Required

OK Cancel

Figure 15.2: System Administration → Storage screenshot #2.

be found, and so forth appear. On CDMS, it may be impossible to map the shared MultiPlan folder, giving a message about resources insufficient to perform this task.

It turns out this is a known problem when mapping folders between different Windows versions, and has nothing to do with CDMS or drive storage. If this happens, the MultiPlan computer needs to have a registry value - IRPStackSize - changed.

The instructions can be found on several web pages, but a pdf is included in Sec. 21.1 for convenience. I found that while the stated maximum IRPStackSize is 50 (decimal), I still encountered occasional errors transferring, and ultimately set IRPStackSize to 100 (decimal). YMMV.

15.4.5 Storage Locations as of November 16, 2014

Patient data is organized as shown in Fig. 15.3.

MACHINE	PATH	DESCRIPTION	SIZE
CDMS computer	C:\	RAID set #1, four drives	~600 GB
	C:\[...]	CDMS OS	
	C:\cdms	"CyberKnife" in PARS	
	D:\	RAID set #2, four drives	~1 TB
	D:\cdms\backup	"CyberKnife" backup	
	D:\cdms\PatientRecordArchive	"PatientRecordArchive" in PARS	
MultiPlan-01 computer	C:\	internal hard drive	~450 GB
	C:\accuray\cdms	"MP45-1" in PARS	
CK-Archive-01 USB external drive	E:\ <i>(mounted on MultiPlan 01)</i>	portable hard drive	~1.3 TB
	E:\accuray\backup\cdms20141116	"MP45-1" backup as of 11/16/2014	
Administrative Workstation computer	C:\	RAID, four drives	600 GB
	C:\Patients	"CdmsPrarPatRecs" in PARS	
	<i>In late 2013 two of the drives failed, rendering the archived patient data inaccessible. The two faulty and two remaining drives might be able to be restored by Accuray, but we (Creekside) are unable to do so ourselves.</i>		

Figure 15.3: Storage Locations as of November 16, 2014.

Part IV

TomoTherapy

16

ATP & Commissioning

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16.1 Acceptance Testing

Acceptance testing of the TomoTherapy machine was completed by Accuray engineers, Accuray support staff, and the Creekside Medical Physicist following Accuray manufacturer specifications. The documents for Acceptance Testing have been compiled into the Physics laptop.

16.2 Commissioning

Commissioning of the TomoTherapy machine was also completed by Accuray engineers, Accuray physicists, and the Creekside Medical Physicist following Accuray manufacturer specifications. Because the TomoTherapy unit is so much different than gantry-based systems, commissioning and calibration procedures are unique to TomoTherapy. To help guide physicists with the process, the AAPM produced a report by Task Group 148^{23,4} to specifically cover commissioning and calibration of TomoTherapy. Creekside's TomoTherapy unit was commissioned and calibrated in line with TG 148 recommendations. Commissioning documents have been compiled into the Physics laptop.

17

Quality Assurance: TomoTherapy

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17.1 Overview

TomoTherapy is significantly different than gantry-based systems, and for this reason the standard report from the AAPM Task Group #142 is inadequate. To this end, AAPM set up Task Group #148^{23.4} to address specific quality assurance issues for TomoTherapy, and both Accuray and TG #148 recommendations form the basis of Creekside's TomoTherapy Quality Assurance program.

17.2 Daily QA

TomoTherapy Daily QA tests the following aspects, based on TG-148^{23,4}:

- Output - rotational or static
- Image / laser coordinate coincidence
- Image registration / alignment
- Red laser initialization

The procedures are described in detail in “Treatment Procedures: TomoTherapy.”^{18,5}

17.3 Monthly QA

Monthly QA should be performed every month. Patient treatment shall not proceed if it has been more than 45 days since the last Monthly QA was completed.

Monthly QA data and reports are stored on the physics laptop under

Desktop\PhysicsBRT\Tomo\QA - Monthly

The Monthly QA steps are as follows.

1. Warm up linac if it has been dormant for more than one hour.
2. Helical output with cheese phantom (Daily QA Rot). Tolerance 2%.
3. MVCT output with cheese phantom (Daily QA Rot). Tolerance 2%.
4. PDD10 with solid water for 5 cm width. Solid water reference PDD10 is 0.62. Tolerance 1%.
5. Perform a RotVar test (zzzzz TQA Basic Dosimetry; Calibrate → Run). Rotational output tolerance 2%. Gamma analysis (cone profile) < 1.
6. Record difference in OS counter rates (tolerance 2%).
7. Perform a Step Wedge Helical test (zzzzz TQA Step Wedge Helical; Calibrate → Run). Energy difference tolerance 2%. All other measures Alert1 low or less.
8. Set up solid water and measure static dose 85 SSD, 1.5 depth (Static_FW50mm_Central40LeavesOpen_Profile). Tolerance 2%.
9. Longitudinal profiles for 1.5, 2 and 5 cm field sizes (Topographic Profile FW50mm etc). Tolerance 1%. Verify couch actual motion vs digital in all three axes (< 2 mm).
10. Check couch level in for each rotation plane (< 0.5).
11. Check couch longitudinal motion alignment: < 1 mm in both x- and y- directions over 20 cm longitudinal motion.
12. Verify isocenter sag without any weight (< 5 mm).
13. Interruption procedure: Rotate phantom 90 degrees, and deliver Daily QA Rot with two ion chambers (one at fifth hole toward +z, one at eighth hole toward -z). Compare final doses to those when the same procedure is run with interruption midway, then remainder delivered. Tolerance ± 2%.
14. Perform MVCT imaging tests, imaging Daily QA Rot with various density plugs, and resolution plugs.
15. Review all FSE-generated results for prior month.
16. Review and initial all Daily QA results for prior month (Tomo Daily QA).
17. Copy the Daily QA spreadsheet (up to the current day) into the Physics Laptop Daily QA folder.

17.4 Annual QA

Annual QA is roughly based on the recommendations Section IV.D. of TG 148^{23,4}. Principal tests encompass the following:

1. Mechanical alignments
 - y-jaw centering
 - x-alignment of source
 - y-jaw divergence/beam centering
 - y-jaw / gantry rotation plane alignment
 - Treatment beam field centering
 - MLC lateral offset
 - MLC twist
2. Beam parameters
 - Beam quality (each slice width)
 - Transverse profile (each slice width)
 - Longitudinal profiles (each slice width)
 - TG-51 calibration
3. Misc.
 - Axial green laser (distance and twist)
 - Sagittal / coronal green laser
4. MVCT
 - Imaging / treatment / laser coordinate coincidence
5. Treatment planning system
 - CT data import
 - Dimension of object in TPS
 - CT voxel dimensions
 - CT orientation
 - CT gray scale values
 - Associated text info
 - Structure set import
 - Dimension of structure
 - Location of structure
 - Orientation of structure
 - Dosimetric verification
 - Point dose in low gradient area
 - Point dose in high gradient area

Goals and tolerance limits are specified in the reference.

Results are compiled and stored in the Physics laptop. If any discrepancies beyond tolerance are discovered, adjustments must be made in conjunction with a Field Service Engineer (as necessary). The TomoTherapy planning system beam model is primarily based on a factory gold standard, and as such discrepancies are usually resolved by adjusting the machine to match the gold standard.

17.5 Sporadic QA

After every service event or in special cases, various QA tests will be performed at the discretion of the center's Medical Physicist.

The results of sporadic QA tests are recorded in the Physics laptop.

17.6 Calibration

Calibration is done according to TG-51^{23.1} modified for the TomoTherapy geometry. The procedure is thoroughly described in section V.B.5 of TG-148^{23.4}.

"The helical tomotherapy physical limitations do not permit a 10 cm² field size at 100 cm SSD. However, a 5cm × 10cm field size can be set at 85 cm SSD. In the longitudinal direction, the maximum field dimension is 5 cm. Furthermore, there is a maximum distance of only 28 cm from isocenter to the lowest extend of couch position. This does not allow for an accurate measurement of the photon component percent depth dose at a 10 cm depth at 100 cm SSD since there would not be sufficient phantom material for appropriate backscatter. In addition, since the helical tomotherapy unit does not have a flattening filter, depth dose data are slightly different than the depth dose data for similar nominal photon energies that have passed through a flattening filter. Since the TG-51 geometrical PDD reference conditions cannot be achieved, an alternate method of determining the helical tomotherapy beam quality is needed that will allow the use of the TG-51 tabulated kQ values when performing a reference calibration of the helical tomotherapy unit.

The IAEA-AAPM joint committee proposed a formalism to determine the absorbed-dose to water to a static beam under specific helical tomotherapy reference conditions. This field is called a machine-specific reference (msr) field. The msr field is a static field that uses reference conditions that are achievable on a helical tomotherapy machine, i.e., a 10 cm² field size at an SSD of 85 cm. ..."

For convenience, the TG-51 worksheet adapted for TomoTherapy is included in the Forms chapter.^{??}.

17.7 Service

Every service event involving the TomoTherapy hardware or software, no matter how minor, must be documented with the event details, date, and person(s) performing the service. This is in accordance with Colorado 6 CCR 1007-1 Part 24^{25.6} Section 24.3.10.1 (3).

Specific tests required after various service events are compiled in Table VI of TG-148^{23.4}.

After every such service event, the readiness of the TomoTherapy unit for patient treatment must be evaluated and documented by Creekside's Medical Physicist. This documentation is to be maintained in the Physics laptop. This is in accordance with Colorado 6 CCR 1007-1 Part 24^{25.6} Section 24.3.10.1 (4).

17.8 Secondary Dosimetry Calculations

17.8.1 Helical secondary checks

Helical secondary checks use the following information from the plan:

- Duration (s)
- Gantry Rotations
- Gantry Period
- Expected MU
- Couch Travel (cm)
- Couch Speed (cm / s)
- Field Width (cm)
- Pitch
- Output (MU / min)

Secondary calculations compare couch travel distances in two different ways, as well as total MU:

- Couch Travel #1 = Couch Speed \times Duration. Tolerance 5%.
- Couch Travel #2 = Rotations \times Field Width \times Pitch. Tolerance 5%.
- Expected MU = Output \times (Duration - 10 seconds). Tolerance 5%.

Notice the Expected MU calculation subtracts 10 seconds from the plan report Duration, as the first 10 seconds of any fraction delivery are implicitly used for component warm-up, and beam is not delivered.

A Google Spreadsheet has been created that can be used as a template for these calculations:

[Tomo Rot Secondary Calculation Template \(\[https://docs.google.com/a/vegaphysics/...\]\(https://docs.google.com/a/vegaphysics/\)\)](https://docs.google.com/a/vegaphysics/).

Access to this spreadsheet must be granted by Brian Thorndyke.

17.8.2 TomoDirect secondary checks

TomoDirect plans are composed of one or more static-angle fields. For these plans, the secondary calculation consists of comparing the plan's beam-on time with the calculated beam-on time, based on couch travel and couch speed. This is done for every beam:

- Calculated Beam-On = [Couch Travel (cm) / Couch Speed (cm/s)] + 10 s. Tolerance 5%.

Notice 10 seconds are added to the calculated Beam-On time, again to account for the implicit 10-second component warm-up.

The Google Spreadsheet template for TomoDirect calculations is:

[Tomo Direct Secondary Calculation Template \(<https://docs.google.com/a/vegaphysics/...>\)](https://docs.google.com/a/vegaphysics/...)

Access to this spreadsheet is also granted by Brian Thorndyke.

17.9 IMRT QA

Delivering dose to film:

- Load DQA plan on patient.
- Set up DQA plan like regular patient using cheese phantom. Usually the red lasers are aligned to bbs, but it is necessary to check on console to verify.
- Place Gafchromic EBT2 film in cheese phantom. The little notch in the edge of the film should be on the superior right.
- Make a small circle around the notch. This allows the determination of film orientation during analysis.
- Turn on green lasers. Make sure the film is sufficiently left or right in the cheese phantom so that the two green laser ends can be marked with a felt pen at the end of treatment. Sometimes it helps to cut a small corner of the film to allow it to slip past the pegs a bit.
- Insert farmer chamber into hole just below the film (-0.5 cm).
- Turn on electrometer.
- Image and register.
- Make sure bias of electrometer is +300 V and "start" is pressed.
- Deliver beam.
- Note temperature, pressure and accumulated charge.
- Carefully mark the ends of the green lasers on the film with the felt pen. The closer to the edge of the film, the better. It can be tricky to access the film (especially if one of the green lasers requires the cheese phantom to be opened to access).
- Remove film, and write patient name / date on bottom.

Scanning film:

- Wait at least 15 minutes, keeping film in film box (so no light exposure).
- Place film in Vidar scanner with cutout hole to upper left.
- Open "Film Analyzer" on physics computer (under tomotherapy / tomotherapy).
- Choose digitize from top menu.
- Choose "Pre Scan". Film will enter and return.
- Choose "scan". Film will go through slowly and scan.
- Make sure all film marks are visible. Rescan if they are not.
- Save both .dcm and .img files.
- Place film back in film box.
- Therapists: Transfer images to thumb drive and put in physics/patient qa folder on CK Mac; also scan chamber recordings and put in that folder. Notify physics that IMRT QA is ready.

Processing film:

- Perform QA film analysis using TomoTherapy DQA software. Tolerance is Γ (relative dose, 5%, 5 mm) < 1 for $> 90\%$ of points in ROI.
- Compare chamber measurement with calculated measurement. Tolerance is $\pm 5\%$.
- Store all results in MacPractice.

18

Treatment Procedures: TomoTherapy

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18.1 Patient's First Day on TomoTherapy

In EMR, if the form you need to add is not under Treatment Forms, hit reload.

1. Review plan with Physicist and sign Pre-Treatment Therapist form.
2. Review set-up instructions.
3. Create a Pre-Treatment checklist and sign.
4. Create a Completion Data 4 form, it can be found under the Treatment Completion forms.
5. Make sure consent is signed and attached in chart.

18.2 Starting Up Machine

1. On the PDU switch circuit breaker ON.
2. At the Power Control Panel:
 - Use the power key to turn the System Power switch to Enabled
 - Press the green ON button.
3. As soon as info starts showing on the PCP, go to the PDU and press the UPS button until the UPS indicator light is ON.
4. At the Operator Station, log onto Microsoft Windows:
 - log in: tomotherapy
 - password: tomotherapy
5. Open TomoTherapy icon:
 - log on with user name: tomo, Password: tomo1
6. Wait for the system to finish the initialization process. If it takes longer than 15 mins you will have to shut down and restart system.
7. Check Show Auxiliary Data Box, then check the Supply Water Temp.
8. When Temp reaches 38 °C you can perform the Warmup Procedure.
 - It can take up to 20 mins for correct temp to be reached.

18.3 Water Bath

1. Always keep unit unplugged when not in use.
2. To turn water bath on:
 - set control button to 5 or 6.
 - monitor water temp; it takes about 30 mins to reach 165 degrees.
3. Record water temp for each patient.
4. When done unplug unit.
5. Empty water and clean Water Bath monthly, refilling with distilled water.

18.4 Daily Warm-Up

1. Check water temp- it must be at least 38C to run the warm-up
2. Turn on the TomoElectrometer (5min warm-up time)
3. Enter room and position couch slightly in Gantry Bore, and with end stop not in Beam
4. At console select a 5 min. warm-up procedure from the Pt. Selection, hit disease Then Plan01- hit OK, got to Calibrate-Run. Select a performed procedure and Rt Click to generate QA procedure.
 - QA added successfully-hit OK
 - Prepare Calibration
 - AOM dose checking disabled- hit OK
 - no pt in room warning- hit OK
 - no new adjustment- hit continue
5. Couch control Window will open- press Ready.
 - move couch to the Ready position in Gantry bore?- hit yes
6. Turn the mode switch to treat, when the ready light turns on press the Start button. When the procedure is complete turn the key back to program.
7. Run another 5 min. warm-up- hitting the yellow stop button to verify emergency Stop. Use Tomo and Tomo1 to clear.
8. Select 2 min. Beam Warm-up- Disease name- Plan_01-Calibrate-Run. Right click on performed Procedure and generate QA procedure.
 - QA added successfully- press OK
 - Prepare Calibration
 - No pt in room warning- hit OK
 - No new adjustments- hit continueOriginal AOM for this procedure warning may come up- hit use current equivalent AOM.
9. Couch control Window will open- press Ready
 - move couch to the Ready position- yes

Always perform a 5 min. warm-up when machine has sat idle for more than 1 hour.

18.5 Daily QA

After Warm-up and Air-Scan perform the daily QA.

1. Turn the TomoElectrometer on during warm-up. (5 min. warm-up required). Cancel the warm-up on the tomo console at some point to check the safety interlock.
2. On Treatment Console pick TomoPhant- Disease-Daily QA Rot (Monday-Thursday), or Daily QA Static (Friday).
3. Record whether or not green and red lasers are coincident. If they differ by more than 2 mm, contact physics before continuing.
4. Hit scan tab, pick slices, prepare scan.
5. In Room: Place loc-bar in position #2 and position Cheese Phantom against bar. Line up phantom using red lasers centering on top bb, ant/post bbs, and middle of phantom along z. Turn on Green Lasers and verify that distance is between 8mm and 12mm.
6. place IonChamber #89 in 1st hole down, and connect to cable #3, tape cable to table.
7. place IonChamber #88 in 10th hole down, and connect to Cable #2, tape cable to table.
8. hit Main then Ready to position phantom in gantry.
 - message appears- move couch to ready position- hit yes
 - get temp and pressure readings and exit room.
9. Turn key to image and scan phantom. After image completes:
 - Select Register Tab
 - In Auto Registration Control-pick Bone and Translations only- hit Start
 - Turn on checker and adjust image till well overlapped.
 - record adjustment readings in Daily QA.
 - hit accept
10. Get TomoElectrometer ready:
 - set Bias to 300
 - Zero out charge
 - hit start
11. Select Treat tab and click on a performed procedure to add a QA procedure
 - QA added successfully- hit OK
 - Prepare treatment
 - Warning about no pt in room- hit OK
 - Patient adjustments- hit Apply
12. Couch Control Main Panel opens- hit Set-Up to move Phantom to corrected position- hit yes and verify movement on room monitor screen.
 - After couch moves hit Ready
 - Move couch to ready position- hit yes
13. Turn key to Treat and hit Start Button when it lights up.
 - After treating record chamber #'s in Daily QA.
14. Be sure to set Bias back to zero before disconnecting IonChambers.

18.6 Saving Interruptions to File Folder

1. When you get an interruption:
 - open description to see what problem is
 - hit Print Screen button
2. On Bottom Left hit Start → Program Accessories → Paint
 - go to Edit then paste
 - File → Save as → Desktop\interruptions
 - Put in date and save
3. Exit out of Paint

18.7 Shutting Down Machine

1. At Status Console:
 - Click the tools button and pick Exit System.
 - Shut down Microsoft Windows by hitting start button on left bottom of screen, and choosing Turn Off Computer.
 - Wait for computer to shut down.
2. In treatment room wait until the PCP turns to ice screen.
 - Turn the System Power switch to Disabled
3. On the PDU:
 - Press the UPS Button until the UPS indicator light is off.
 - Switch Circuit Breaker to off.

18.8 Stop Buttons

- Stop Button
 - The stop button is intended to be used in non-emergency situations (e.g., the patient moves during set-up or beam on).
 - Stop Button is located on the status Console and on either PCP.
- Emergency Stop Button
 - An Emergency Stop Button is intended to be used in situations that require power be shutdown to the gantry subsystem. (Radiation does not terminate.)
 - There is one located on the Status Console. 2 Emergency Stop Buttons are also located on the front of the gantry enclosure (left and right).
- Facility Emergency Off Button
 - Intended to be used in situations which require the patient be quickly removed from treatment room or facility (e.g., fire).
 - Button is located behind MacPractice computer.

18.9 Daily Air Scan

1. In the Data Selection Dialog, select a plan under the Aircans patient.
2. Click the Scan Tab:
 - Click Accept Slices, then click Prepare Scan.
 - A message warns you not to deliver the air scan procedure to a patient. Click OK.
3. Couch Control window opens up. Press Ready.
 - Move couch to the Ready position. Hit YES.
4. Turn the mode switch to Image.
 - Press Start button when Ready light turns on.
5. When scan is complete, turn the mode switch back to Program.

Once a week a message will appear that says "Weekly CT Number Calibration has not been performed." Hit OK.

18.10 Scheduling Setup Scans

1. Fill out order sheet for either AMI or Good Sam:
 - Dr. Simpson electronically, and he will sign electronically then save on desktop
 - Dr. McNeely hand written, after signed- scan to desktop
2. Go into patients chart and save to desktop:
 - patient demographics
 - insurance information
 - recent scan reports
3. Schedule patient:
 - For AMI call 303-433-9729, and let scheduler know you are scheduling a TomoTherapy Set-up. They have been told to help us as much as possible with Times we need. Make sure when you schedule you allow hour before scan in Tomo room to make treatment device, and 15 minutes travel time. After patient Scheduled-send all information and order to AMI thru faxing at 3034800405@myfax.com
 - For Good Sam, email Regina at marshallr@exempla.org. In email- give patient information, date needed and what exam will be. She will email back with times. Confirm times and email her the order, and all patient information.
 - On Good Sam order make sure you put down that it is a TomoTherapy setup and therapist will be there during scan with treatment device.
4. In Set-up column in MacPractice: schedule the set-up and scan time- allowing for making of treatment device, travel and registration time.
5. In Bmatrix: if patient is not already on list as a potentially upcoming or Waiting for Consult- create a New plan, and move patients name to Waiting for Setup. In notes Column put Set-up date.
6. In FileMaker Pro: Fill in date under Set-up Date
7. Contact patient and give them all details. Make note in Bmatrix that pt notified.

18.11 Simulation

1. Always schedule patients in Tomo-room hour before you have to leave for scans.
2. At console call up a pt that is being treated in the same area as your sim patient.
 - hit scan tab-select area to scan- Accept slices-prepare scan
 - enter room and hit Main on the PCP- this will get rid of patients name.
3. Always use a vac-bag for Tomo Set-ups, and no pad on table.
 - position pt using red lasers to make sure pt is straight.
 - Patient positioning will depend on area treated:
 - Breast: if possible have both arms up using a headrest in vac-bag and building support under arms
 - Lung: Drs will let you know if arms have to be up or can be kept at sides, use a headrest with vac-bag showing impression so it is always in same position also form vac-bag around shoulders.
 - Prostate: pt FFS, top of vac-bag falls at low back- place knee sponge in position and form vac-bag around 2 sides of it to always have it in the same position.
 - Brain: use the 3.2 mask and always have loc-bar at the #2 position. No pad.
 - Spine: For lower spine set-up like prostate- for upper spine set-up like lung with arms down.
4. After positioning device is made- pick 3 points to tattoo to align every day. You can also use body landmarks- nipples for a mans chest or spine- dropping table to make vertical lasers go right thru nipples. Belly Button can be used for a low spine. Use lasers to mark vac-bag for daily alignment. Again make sure lateral alignment is correct using lasers down middle of body.
5. In CT- always scan the pt in the same orientation they are to be treated- planning system cannot change orientation.
 - position patient and place BBs on tattoos, if using nipples-Physics can identify these and belly button on scan.
 - make sure name is spelled correctly
 - scan can be done at 2.5mm, if a possibility that CyberKnife will be used scan at 1.25mm.
 - scan 10cm Superior and 10cm Inferior to lesion
 - make sure table top is included in scan- it will be used in planning.
 - if using Bolus on a skin lesion- do 2 scans- 1 with and 1 without

18.12 Treatment Delivery

1. Pick patient- Disease- Approved plan. Hit OK- Scan tab should come up
 - choose slice thickness - highlight slices- then hit Accept slices.
 - Hit prepare scan- a message will come up asking you to confirm pt positioning-(FFS or HFS) hit OK. If you need to confirm pt positioning look under EMR under set-up notes, you can also confirm where red lasers were assigned by looking at Initial Physics review at screen shots at the bottom.
2. Bring pt into room, position in vac-bag and hit set-up to bring table to set-up position.
 - Line up lasers to vac-bag-then adjust pt to match vac-bag
 - After pt positioned- hit ready to move patient into gantry for imaging.
3. At console- close door and turn key to image and hit ready light when it lights up. After image is complete- turn key back to program and hit Register Tab. Use Auto Registration Control and pick correct structures to align with.
 - Prostate- Bone & Tissue
 - Spine- Bone
 - lung- Bone & tissue
 - choose Translations, Roll, Pitch and Yaw- hit Start
 - check Pitch and Yaw if correction is below 5 Ok to proceed
 - choose Translations and Roll hit start
4. After Auto is done- check all views and fine tune before calling Doctor to check.
 - After Dr. Oks image corrections, hit Accept and Export Screen
5. Choose Treat Tab and pick a scheduled treatment- hit prepare treatment.
 - Pt adjustment window comes up- mentally remember numbers and hit apply
 - All adjustments use the Tomo Logo on Gantry as an orientation. Towards logo is always +, away is -.
 - Longitudinal Couch movement: + toward gantry, - away from gantry
 - Vertical Couch movement: + up, -down
 - Lateral couch movement: +right, -Left Remember couch can only correct 2cm either way so make sure pt is centered before you scan.
 - Roll: + clockwise, - counterclockwise
 - After you hit apply- lasers will move to adjusted position. Couch control window main panel will come up. Close it- we only use it on QA procedures.
6. Enter room- hit Main- hit Set-Up, Window will come up that asks if you want to move pt to adjusted position- hit yes.
 - lasers should now be back on tattoos. (movement should match the #'s you applied earlier).
 - check both sides and if line-up matches, hit Ready. Window will come up that that asks if you want pt moved into ready position in Gantry. Hit yes.
7. Exit room and close door- Turn Key to Treat, and hit ready when light comes on. Watch table movement and verify that the Longitude is moving. When Tx complete Turn key back to program and open door.
 - hit unload to get pt off table.

18.13 Manually Retract and Lower Couch

1. If power to the system is shut down during irradiation for a procedure, the tabletop is automatically disengaged from the couch
2. Retract the couch tabletop to remove the patient from the bore of the gantry.
3. If necessary, manually lower the couch for the patient.
 - Make sure the couch tabletop is retracted from the bore of the gantry back to the foot end of the couch.
 - Push the Emergency Vertical Release button to lower the couch (located at the Foot of the couch).
 - Push and hold the Emergency Vertical Release button until the couch is lowered to the appropriate height.
4. When power is restored to the system, retract the tabletop to the foot of the couch until it locks into place.
 - Press the Enable button and the longitudinal release button on a Couch Control Keypad.
 - The lamps housed inside both longitudinal release buttons turn On when the Tabletop is disengaged.
 - Pull the couch handle to retract the tabletop away from the bore of the gantry until it locks into place or Press one of the longitudinal release buttons to lock it in place.
5. In the event of an Emergency Stop condition, power must be removed before the Couch may be lowered with the Emergency Vertical Release. Press the yellow OFF Button on the Power Control Panel to remove power to the couch.

19

Tricks and Tips

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19.1 Tomo: Restarting Cobra

When you log onto Tomo and it says Cobra needs to be restarted:

- In Cluster Room:
 - check Tomo Data Server- Top node- if no green light on- hit power button
 - pull out computer and check to see if you have info on screen
 - If screen blank- hit Ctrl, Alt, and Delete.
 - * Log in with lower case: customeradmin
 - * Password: ca\$min
- On bottom of computer screen:
 - Make sure Data Base Status says connected
 - check port to make sure you have numbers- no port or status not connected you will have to hit restart windows operating system.

19.2 Adding Air to TomoTherapy

Always monitor the supply and return water pressure along with the water temperature. Try to keep supply pressure above 70.

Or If you turn machine on and it suddenly gets quiet and you get a Gun-Board Logic error, with a water flow fault, you need to add air to the blue tank:

1. Open back right panel and swing out
2. Open back left panel and locate blue tank.
 - If blue tank is not easily reachable, open small side panel on side of machine to access manual gantry controls. Hit button labeled Serial/Local mode till you are in Local mode. It will read out above button which mode you're in. Once you are in Local mode you can hit the Jog FWD button until blue tank is accessible. Be sure to switch back to Serial Mode
 - If blue tank is not easily reachable, open small side panel on side of machine to access manual gantry controls. Hit button labeled Serial/Local mode till you are in Local mode. It will read out above button which mode you're in. Once you are in Local mode you can hit the Jog FWD button until blue tank is accessible. Be sure to switch back to Serial Mode
3. Use bicycle pump to fill tank to 25.
 - Check outside pressure readings. Supply should be above 60, and return around 35.

Part V

Forms



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Conscious Sedation/Analgesic Consent Form

For the procedure you are to undergo, sedation and analgesic medications may be used. The benefit of sedative and analgesic medication is to allow the safe, comfortable completion of your procedure.

The primary risk of these medications is respiratory depression (decreased breathing effort), which can be serious or even fatal if not treated. This risk is minimized by careful administration of these medications and by the vigilant monitoring of your blood pressure, heart rate and breathing.

Infrequently, allergic reactions to medications can occur. If you are known to be allergic to any medications or have any concerns about receiving sedation/analgesia, please let us know so that we may address your concerns directly.

If you elect to receive sedation and analgesia, by signing below, you consent to allow us to administer, as appropriate, the medications required to complete this procedure.

Patient Name:

Patient Signature:

Guardian Signature:
(if patient under 18)

Date:

Part VI

External Documents

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Public Domain Documents

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How to fix “Not enough server storage is available to process this command” error in Windows XP

March 3, 2011 By [thegift73](#) [98 Comments](#)

‘Not enough server storage is available to process this command’, is an annoying error that I have come across a couple of times when using some of the machines at work and home over the past few years. This isn’t an error that will affect every user, but, if you do come across it, then here are a couple of reasons as to why it can happen:

1. You don’t have a DWORD VALUE for IRPStackSize in your registry
2. You have a DWORD VALUE for IRPStackSize in your registry but the data value is set too low

What might have triggered the error message?



1. You are trying to map a drive?
2. You are trying to access a shared folder over a network that you set up correctly?
3. You are trying to share files/ drives between a Windows 7 machine and a Windows XP machine
4. You are trying to print over a network, where the printer driver resides on another machine on that network. (This was my 2nd occurrence)

Those are just the kind of things I was doing when the error was triggered. The main time that it has come up though is when I have correctly set up file sharing over a network and have had no problems accessing those folders and the out of the blue I would get the error message which would prevent me from accessing those files/ drives. Note, that in your Event logs it may show up as, ‘Event ID 2011’.

At work all of our machines are running XP Pro and normally work perfectly fine. However, every now and then (and it is rare) this issue will throw a spanner in the works. Normally on a busy day, but that’s Sod’s Law. It can also occur when trying to share files/ drives between machines running Windows 7 and Windows XP (this is due to the IRPStackSize on the different OS’s being different by default) If the error does come up when you are trying to share files between a Windows 7 PC and a Windows XP machine, then the IRPStackSize adjustment needs to be increased on the XP machine not the Windows 7 one.

Default value sizes for IRPStackSize in Windows NT | 2000 | XP:

1. Windows NT 4.0 – 11 (default value)
2. Windows 2000 – 15 (default value)
3. Windows XP – 15 (default value)

There are many, many things that can cause the IRPStackSize to become too small, but one of the most common reasons are anti-virus software that has been installed or many different programs such as Acronis TrueImage, AVG, Norton, Microsoft Security Essentials etc. It’s not the programs that are the problem, but the drivers and the IRP slots that they use up, hence overtime you may need to increase the value of the IRPStackSize as you install more and more programs as time goes on. For a detailed look at the issue please refer to the Microsoft official help on the subject [here](#) Or for a

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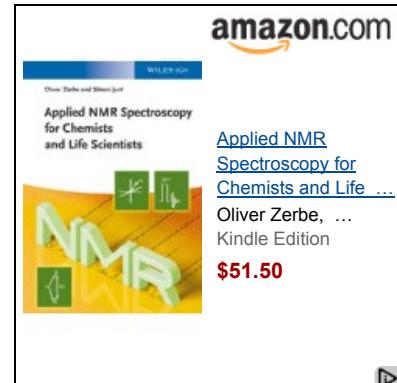


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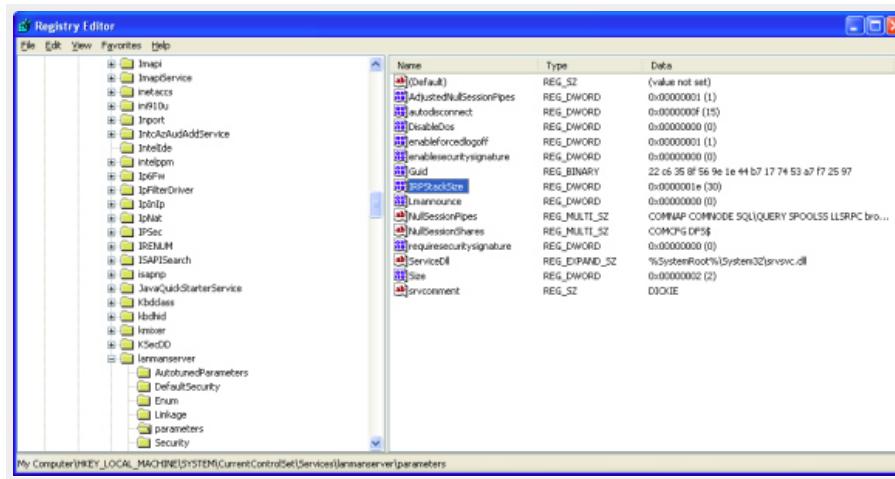
detailed look from a programmers view go [here](#) to learn more about how IRP stacks work.



Right, to try to correct this error message will involve you making some edits in your registry, so please **MAKE SURE** you have backed up your registry before making any adjustments to the registry, as making a mistake in the registry can lead to you having to re-install the OS. The simplest way to make sure that your registry is backed up is to create a Restore Point via System Restore. In Windows XP the easiest way to create one is to go Start>All Programs>Accessories>System Tools>System Restore, check the second button 'Create a restore point' then hit 'Next' and name your restore point in the next window. Something like 'Backed up Reg' (and the date) then just click 'Create'

Now you have done that, you are ready to make your edit. Please note that I am not MVP certified, nor do I work for Microsoft. This is just how I have fixed this issue in the past when ever I have come across it. To get to your registry go Start>Run and type 'regedit' and OK. Now to the part of the registry where you may need to edit the IRPStackSize:

HKEY_LOCAL_MACHINE\SYSTEM\CURRENT_CONTROL_SET\SERVICES\ LanmanServer\Parameters



If you can already see that the IRPStackSize has already been created then you may need to increase its value. Do this in increments of 5 (eg The default value is 15 (Decimal), so try changing it to 20) When you have done this, reboot for the changes to take effect. If this was unsuccessful try increasing it by a further value of 5. The most it can be increased to is 50 (Decimal).

If the IRPStackSize is not present (as was in 100% of my occurrences) you will need to create a new DWORD. With Parameters selected on the left, go Edit>New>DWORD Value enter the word (exactly as I have typed it but without quotes) "IRPStackSize" this will then show up in the window on the left. You now need to give it a value. Try 20 (select the Decimal button) then reboot to see if that helped. If not, try increasing its value by another 5.

Please note that this was done using Windows XP Pro and may be different in Vista or Windows 7.

I hope this has helped some one out.

P.s Please check the comments for additional help added by people who have also had this issue.

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› [Bitstamp stop trading for 24hrs due to mass email phishing attempt](#)

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Comments



Brian J says:

January 5, 2013 at 04:46

Couldn't be clearer and worked like a charm. How do people know this stuff?!

[Reply](#)



Kapitan says:

January 8, 2013 at 15:48

Perfect Man! TNX 1000TImes. XP/W7 works again 2gether... (I think True Image causes the Problem)

[Reply](#)



Patrick says:

January 11, 2013 at 23:15

Yesterday I left a comment about it not working for me. I was not doing it to both the server and the client. It really does work like a charm if you do it to all the systems, not just the one you are getting the error on. Thanks a lot. Saved the rest of my day!

[Reply](#)



Dandolo1204 says:

January 17, 2013 at 12:03

Clear, concise, very helpful indeed. Thank you very much, saved me a great deal of (further) stress. 😊

Cheers from Dorset.

[Reply](#)



David Cole says:

January 18, 2013 at 20:57

Worked for me on my XP machine

[Reply](#)



Brian GH says:

February 26, 2013 at 23:18

You're the man. Thanks

[Reply](#)



TC says:

March 6, 2013 at 01:03

Thanks! Added this dword to my XPpro registry with a value of 20 and it worked.

[Reply](#)



Richard Gailey says:

March 6, 2013 at 01:52

Glad it helped.

[Reply](#)



mandate says:

March 19, 2013 at 17:55

nice one! this worked for me – i had to create the DWORD as it didnt exist

[Reply](#)



Richard Gailey says:

March 19, 2013 at 19:04

Glad it helped 😊

[Reply](#)



MaskFD says:

March 27, 2013 at 12:42

Thanks a lot, that was very helpful to me.

I was suffering for months because of this problem.

Thanks again ^_^.

[Reply](#)



Aloha says:

March 31, 2013 at 02:27

Thank you Richard, I just spent hours going through all kinds of MS "help" and nothing worked, went from one error message to another. I followed your well-documented steps

exactly and it worked perfectly, mahalo!

[Reply](#)



Ajay says:
April 21, 2013 at 18:16

Had to create DWORD parameter in XP home. Worked perfectly. Been hammering at this for Soooooo long. Thank you so much!!!

[Reply](#)



Guest says:
May 1, 2013 at 22:02

I am in the same boat James. Increased to the max size and still getting the error intermittently.

[Reply](#)



PB1 says:
August 14, 2013 at 18:02

Thank you so much for this simple free fix. Having spent over two hours trying everything, a few minutes of your advice sorted it!! If only the world were full of people like you!!

[Reply](#)



Jerry King says:
August 25, 2013 at 06:27

Thank you! I was trying to use a Windows 7 machine to access a large file on an external USB drive connected to a Windows XP machine, and was getting this error. Added the IRPStackSize DWORD per your instructions and the problem went away. Thanks, again.

[Reply](#)



wotnwabbit says:
August 25, 2013 at 19:44

Kudos to dhk who provided the final missing link.

I am running a mixed system:

Windows XP Pro and Windows 7

I followed the tutorial above, modifying the IRPStackSize DWORD on every computer, both XP and 7. That allowed me to see read files on the Win 7 from my XP computer, but I still could not see and read files on the XP from my Win7.

I read the post from who was running a significantly different setup than mine.

"Just wanted to add:

I am running a HP Z800 with 2x10GbE network /

Win 7pro 64bit as a gateway to mount large AVFS drives as SMB shares for
WinXP 32 clients.

I did on the server side as posted before:

Set the following registry key to "1":

HKLMSYSTEMCurrentControlSetControlSession ManagerMemory

ManagementLargeSystemCache

And set the following registry key to "3":

HKLMSYSTEMCurrentControlSetServicesLanmanServerParametersSize"

ON MY XP computers

Does not have:

HKLMSYSTEMCurrentControlSetControlSession ManagerMemory

ManagementLargeSystemCache

But the second part of his post:

And set the following registry key to "3":

HKLMSYSTEMCurrentControlSetServicesLanmanServerParametersSize"

Completed the puzzle. My mixed network is now functioning.

Thank you all!

[Reply](#)



dvernb says:

September 1, 2013 at 14:28

I got this error on a shared folder on a USB drive. Files copied over the network fine (XP to Windows 7) but I kept getting this error whenever I tried to access or delete them from the source folder. Tried everything here to no avail. Turns out the file system had gotten corrupted somehow. I don't know why copying the files worked but accessing or deleting didn't but ran Chkdsk on the drive and all was well.

[Reply](#)



Larry Laginess says:

September 7, 2013 at 23:04

Thank you! Worked like a charm on XP SP3.

[Reply](#)



Bob Kaiser says:

October 20, 2013 at 15:36

The fix described in this article was perfect! Laptop running XP attempted to browse on tower running WIN7, and now it works flawlessly.

[Reply](#)



Ishtar says:

December 3, 2013 at 18:44

Thanks for sharing this piece... it saved us a lot of time! We had a 2003 cluster exhibiting the same error. The resource failed and we could not explain why. We checked the system logs and found: "The server's configuration parameter "irpsStackSize" is too small for the server to use a local device. Please increase the value of this parameter." Event ID 2011, this lead us to your article.

We created the DWORD value at 15 and restarted the server. It worked!

[Reply](#)



Jeff says:

May 19, 2014 at 16:04

Thanks. Worked perfectly !! Your expertise is greatly appreciated.

[Reply](#)



Anonymous says:

November 4, 2014 at 15:05

Tks wotnwabbit – been messing with the IRPStackSize for over a year and wouldn't solve my problem – but the -> HKLMSYSTEMCurrentControlSetControlSession ManagerMemory ManagementLargeSystemCache solved my problem.

[Reply](#)

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Trackbacks

Error: Not enough storage is available to process this command (during Clickonce installation in client machine) » Cyberiafreak says:

February 18, 2013 at 07:17

[...] Already explained here in detail – <http://techfleece.com/2011/03/03/how-to-fix-not-enough-server-storage-is-available-to-process-this-c...> [...]

[Reply](#)

Server Shares Freezing - cannot save or close work - Page 4 says:

June 16, 2014 at 14:52

[...] We have been having issues here where the server is fine but users suddenly cannot access work etc. I also noticed that I couldnt pull large files off and it would come up with "Insufficient Space" type messages (despite 10+G available) reboot and all was fine. It was our IRPStack (which can be knacked when installing/uninstalling things like antivirus software. Might be worth a look... How to fix "Not enough server storage is available to process this command" [...]

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Vendor Documents

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Spectris Solaris® EP
MR INJECTION SYSTEM

**Spectris Solaris EP
MR Injection System**

Operation Manual



CE 0086

202974 Rev. J

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1 - Introduction

This manual applies to the *MEDRAD Spectris Solaris® EP MR Injection System*, Catalog Number 3012011. Read all of the information contained in this section. Understanding the information will assist you in operating the device in a safe manner.

Important Safety Notice

This device is intended to be used by medical professionals with adequate training and experience in magnetic resonance imaging (MRI) studies.

Certifications

This device is equipped to operate at 100-240 VAC, 50/60 Hz, 180 VA (Single), and is designed to comply with EN 60601-1/IEC 60601-1 Second/Third Edition, and EN 60601-1-2 Second Edition and IEC 60601-1-2 Second/Third Edition Standards.

Indications for Use

This system is intended for the purposes of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures.

Contraindications

This device is not to be used in the arterial side of the vascular system, for drug infusion, chemotherapy, or any other use for which the device is not indicated. The system should not be used with a magnetic resonance imaging scanner having a magnetic field strength greater than 3.0 Tesla.

Restricted Sale

Federal (USA) law restricts this device to sale by or on the order of a physician.

Required Training

This device is intended to be used by individuals with adequate training and experience in diagnostic image studies.

Trademarks

MEDRAD, FluiDot, Qwik-Fit, Spectris Solaris, MEDRAD Radiology, Performance for Life are federally registered trademarks of MEDRAD, INC. The trademarks *Becton Dickinson, Daiichi, NSKK, Multihance, Gadovist, Magnevist, Optimark, Prohance, and Omniscan* appear in this manual, and are the property of their respective companies.

Disclaimers

External wiring and modifications disclaimers: MEDRAD disclaims liability for any modifications or interfaces with other equipment which are not in conformity with the specifications and information contained within this manual.

Accessory equipment connected to the device must be certified according to IEC 60601-1 Second/Third Edition standard. Furthermore, all configurations shall comply with system standard EN 60601-1/IEC 60601-1-1. Anyone who connects additional equipment to the signal input or output part configures a medical system and is therefore responsible that the system complies with the requirements of the standard IEC 60601-1-1. To obtain on-site consulting or consulting references, contact MEDRAD Service.

The *MEDRAD Spectris Solaris EP MR Injection System* is not intended for portable use.

The Equipotential Connector (EPC)

The Equipotential Connector (EPC) is an electrically bonded terminal on the injector that is used as a connection point between other medical electrical equipment. The EPC's function is to minimize any voltage potentials differences between all connected equipment. The EPC is not designed to be an electrical safety ground.

Understanding Symbols

The following symbols are used on the *MEDRAD Spectris Solaris EP Mobile MR Injection System* and components.:.



Attention, consult accompanying instructions.



Indicates that this device conforms to the requirements of the European Medical Device Directive 93/42/EEC.



Indicates on/off switch for the Control Room Unit.



Indicates hazardous voltages.



Indicates alternating current.



Identifies a type BF applied part complying with EN 60601-1 standards.

CLASS 1

Indicates the injection system is Class 1 medical equipment as defined by EN 60601-1 standards.

IPX1

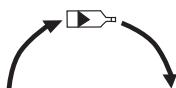
Identifies the degree of protection against fluid as drip proof for the Spectris Solaris EP Injector system.



Identifies connection of the handswitch.



Identifies injector head forward and reverse piston control keys.



Identifies the direction of manual knob rotation relative to plunger movement.



Identifies the ENABLE key.



Identifies polarity of the battery pack terminals.



Indicates DC power supply.



Indicates the current charge level of the system battery.



Identifies Integrated Continuous Battery Charger system activity on Graphical User Interface. When illuminated yellow this indicates that the Continuous Battery Charger system is present and functioning.



Indicates the AIR EXPELLED button on the injector head. When illuminated yellow on the touch screen, also indicates that the operator has acknowledged inspecting the fluid path for air.



Identifies the Equipotential connection.



Identifies the Earth Ground point.

IOIO

Identifies the Service Connection Port.



Identifies the Locking Bracket. Indicates which direction to turn Locking Bracket knob to “lock” and “unlock” the bracket.

TX

Identifies the Communication Cable Transmit connection.

RX

Identifies the Communication Cable Receive connection.



Indicates design for indoor use only.



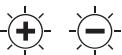
Identifies the Integrated Continuous Battery Charger System power supply connection.



Indicates the presence of no serviceable parts.



Indicates the presence of AC power at the battery charger.



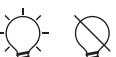
Identifies the Control Room Unit brightness controls.

P109

Reserved for future use.



Indicates the status of the battery charger. When a battery is properly inserted, the LED will illuminate while charging, and extinguish when the battery is fully charged.



Pushing Prohibited. Do not push at or above this point on the Injector.



This manual contains important information about use of the **MEDRAD Spectris Solaris EP MR Injection System**.

MEDRAD urges you to read this manual carefully, become familiar with the procedures and system functions that it describes, and follow its recommendations to assure proper use of the system.

Labels on the system or statements in this manual preceded by any of the following words and/or symbols are of special significance, intended to help you to operate the system in a safe and successful manner:



WARNING: Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the injection system.



CAUTION: Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device. Read and understand the cautions before operating the injection system.

Note: Indicates that the information that follows is additional important information or a tip that will help you recover from an error or point you to related information within the manual.



Warnings

Patient injury may result from a system malfunction. If a system malfunction occurs, immediately remove unit power (by pulling the battery from the Scan Room Unit), and disconnect the unit from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the injection system. Call MEDRAD for assistance.

Patient injury could result from leaks or ruptures during an injection. To prevent leaks or ruptures in the event of a blockage, use only catheters and connectors with pressure ratings compatible with this system.

Explosion hazard. The **MEDRAD Spectris Solaris EP MR Injection System** is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Fire hazard. To avoid an electrical fire, assure the correct type of fuse is used for replacement. The fuse must be replaced with Type F, 250 V, 2.5 A fuse by qualified personnel only.

Electrical shock hazard. Hazardous voltages exist within system components. Do not remove or open any enclosure.

Electrical shock hazard. Avoid fluid entry into system components. Do not immerse any components in water or cleaning solutions. Use a damp cloth when cleaning on or around the battery and the Integrated Continuous Battery Charger system power supply.

Electrical shock hazard. Serious injury or death may result from exposure to hazardous voltages existing within the system. Disconnect the Battery Charging System from line power and remove the battery from the Scan Room Unit before cleaning.

Electrical shock hazard. Equipment must only be connected to a supply mains with protective earth.

Ventilation hazard. To avoid a build up of hydrogen gas from the battery, assure the room is well ventilated while battery is charging.

Improper disposal of the battery pack may result in explosion, leakage, or personal injury. Do not open, or dispose of in a fire! Follow all local regulations concerning the disposal of spent lead-acid based batteries, or contact MEDRAD for assistance.

System electronic assemblies contain potentially hazardous materials. Dispose of system components or accessories properly. Follow local regulations for proper disposal or contact MEDRAD Service for assistance.

Unsafe operation may result from using improper accessories. Use only accessories and options provided by MEDRAD designed for this system.

Chemical burn hazard. Always carry the battery pack firmly by the battery pack hand grips. Damage to the housing may result in a chemical burn hazard. Do not use if the housing is severely cracked or damaged.

Voltage hazard from worn cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, do not disassemble the injection system in any way. Worn cabling also creates voltage hazards. If any worn or damaged cables are detected, do not use the injection system. Contact MEDRAD for service or replacement.

The MEDRAD Spectris Solaris EP MR Injection System is a dual syringe system. Always ensure that the proper syringes are loaded with contrast media and flush solution prior to the injection. Failure to properly load and install the syringes may require the procedure to be repeated. Syringe A is designated for contrast agent use only. Syringe B is designated for flush solutions only.

Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/magnet room components.

Patient injury and/or catheter damage may result from using connector tubing (LPCT) that is too short. Operator must consider tubing length and stretch limitations when moving the injector or the patient.

Serious injury or death may result from syringe failure. Do not retract pistons with connector tubing installed. Retracting the pistons with the connector tubing installed on syringes will create a vacuum in the syringe due to the check valve in the connector tubing. This vacuum may accelerate the plunger rapidly toward the tip of the syringe when it is removed from the injector causing the syringe to break.



Cautions

Condensation may cause electrical damage to the injection system. Do not use the system immediately after it has been brought indoors from extreme outside temperatures. Allow the system to stabilize at room temperature before use.

Injector may disarm or fail to operate upon exposure to high electromagnetic fields that may be generated by radio transmitters or cellular phones, or upon exposure to high levels of electrostatic discharge.

This injector system is in compliance to IEC-60601-1-2 / Second and Third Edition Standards. Special precautions regarding ElectroMagnetic Compatibility (EMC), are required for installation and use of this injector system. Detailed EMC information can be found in the MEDRAD Injector Service Manual - Addendum, (label number: 202559).

Damage can occur as a result of incorrect voltage. Before plugging in the system, check the following:

- Verify that the voltage and frequency marked on the serial tag on the back of the unit matches the voltage and frequency of the electrical outlet.
- Verify that the Control Room Unit and the Battery Charger power supply have the appropriate power cord plugs for the power outlet.

Additional warnings, cautions, and notes are located throughout this manual, where applicable.

2 - System Basics

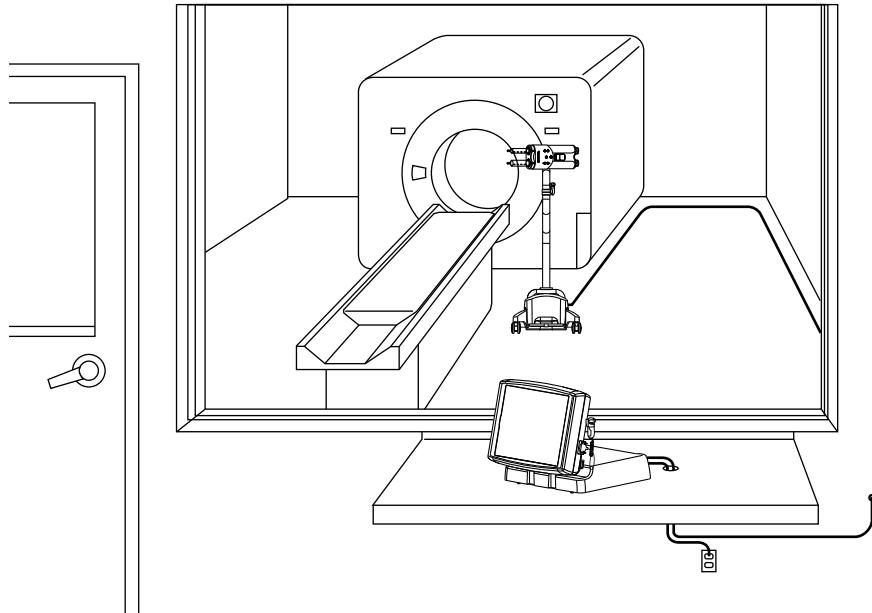
About the Injection System

The *MEDRAD Spectris Solaris EP MR Injection System* is a programmable, dual syringe system, designed to accurately administer controlled doses of intra-venous MR contrast agents and common flushing solutions to patients undergoing a contrast enhanced MR scan.

The system consists of two basic components that communicate by a direct connection of fiber optic lines.

- The Control Room Unit houses the Touch Screen and electronic components used to program the injection system.
- The Scan Room Unit, positioned near the magnet bore, contains the Injector Head, system battery pack, and the mechanical assemblies required for fluid delivery.

A battery charger is also supplied with the system, used to charge the Scan Room Unit battery pack. For convenience, the charger can be used in the control room, but should never be installed or operated in the scan room.



Note: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Pressure Safety Limit

The *MEDRAD Spectris Solaris EP MR Injection System* is designed to allow varied flow rates for contrast injections. By automatically reducing the flow rate, the system can limit the pressure produced during an injection to prevent damage or failure of any connecting devices or tubing. This feature is called *Pressure Safety Limit*.

Inability to maintain the desired flow rate while remaining below the Pressure Safety Limit can be caused by various conditions including contrast viscosity, catheter sizing, connector tube sizing, and stopcock restrictions. If the system is unable, for a period of three seconds, to maintain a flow rate of at least 10% of the programmed rate, the system will disarm due to a stall condition.

If unable to automatically achieve the required level of flow rate reduction, thus reaching the Pressure Safety Limit, the system will terminate the injection and move to a disarm state.

Response to Occlusions

When injecting into an occlusion, a stall condition (flow rate less than 10% of programmed rate) will result. A stall condition lasting more than 3 seconds (3 minutes for programmed rates less than 0.1 ml/sec) will result in the injection being automatically terminated.

If an occlusion occurs during KVO (Keep Vein Open) the system will detect the condition after 4 or less KVO boluses fail to be delivered. This will correspond to from 1 minute with a KVO interval of 15 seconds configured, to 5 minutes with a KVO interval of 75 seconds. Refer to the Setup screen to determine the current KVO setting.

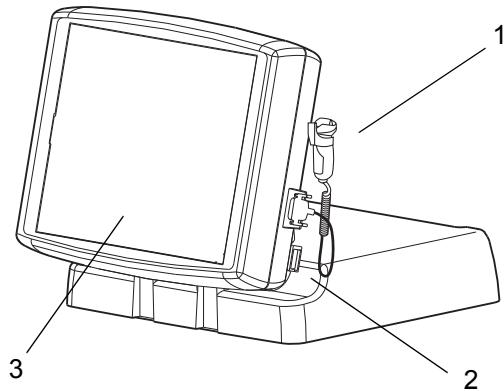
If a stall occurs due to an occlusion, and the blockage is subsequently removed, less than 10 ml will be delivered as the pressure in the administration set dissipates.

Volume and Rate Protection

The following means are provided to protect against over and under volume or rate conditions:

- Warnings displayed on the Safety screen and during the arming sequence remind the operator to check the programmed injection parameters prior to the system being armed.
- An onscreen indication of insufficient volume is provided whenever the total volume programmed to be delivered is greater than the amount of fluid in the syringe.
- Injection monitoring is performed to detect over rate or over volume conditions due to system faults. If either of these conditions is detected, the injection will be stopped before an additional 10 ml of fluid above programmed volume is delivered.

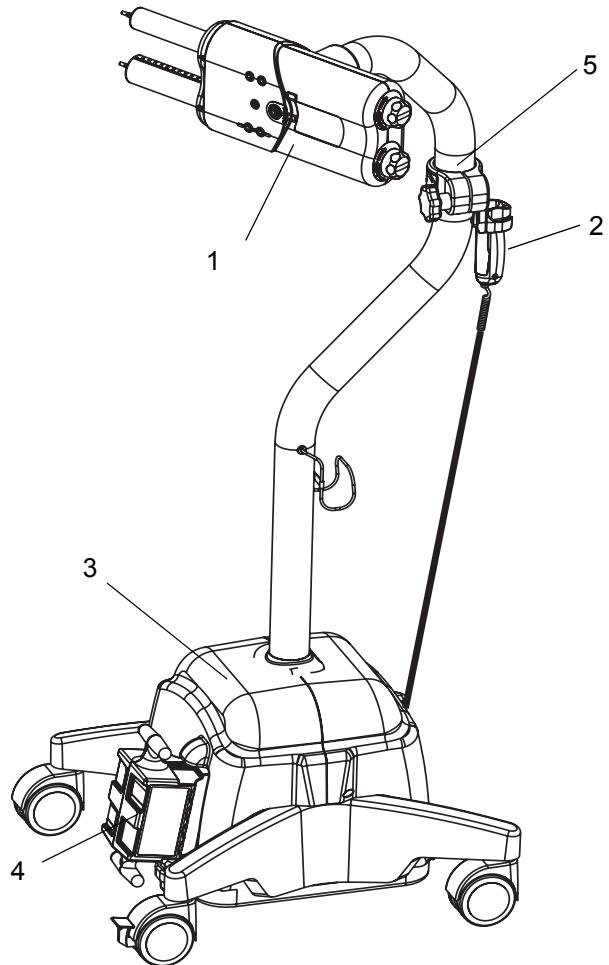
Control Room Unit



1. Handswitch
2. System Power Switch
3. Touch Screen

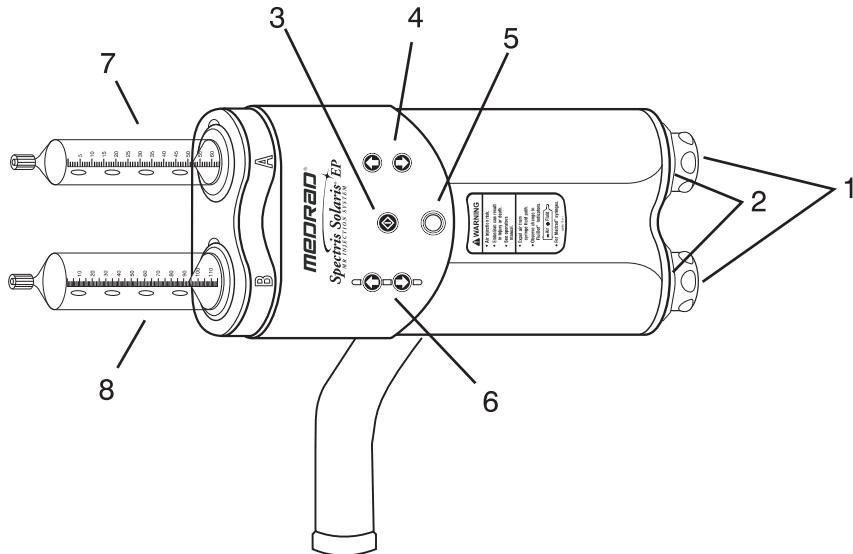
At rear of Touch Screen Assembly - Display Contrast Controls

Scan Room Unit



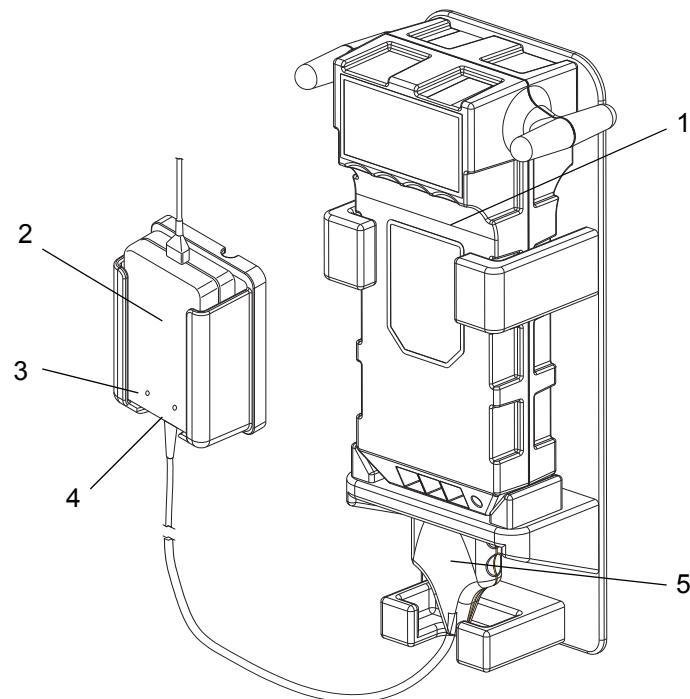
1. Injector Head
2. Handswitch
3. Lower Console
4. System Battery Pack
5. Middle Pivot Clamp

Not shown - Contrast Holder (optional)

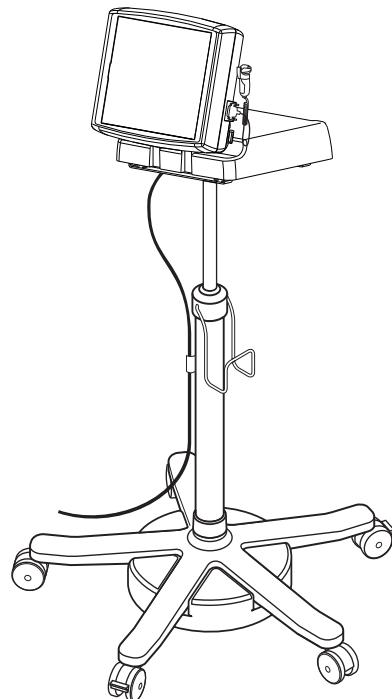
Injector Head

1. Manual piston movement knobs
2. Armed indicator lights
3. ENABLE button - Used to activate the forward/reverse controls - the appropriate direction must be selected within 5 seconds.
4. Syringe A forward/reverse controls
5. AIR EXPELLED button/indicator
6. Syringe B forward/reverse controls
7. Syringe A: Contrast agent
8. Syringe B: Flush solution

Battery Charger



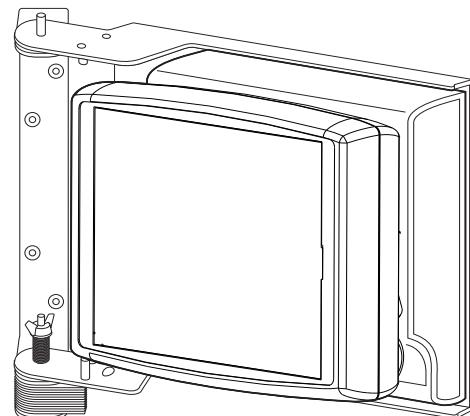
1. Battery Pack
2. Battery Charging Unit
3. Charging Indicator - Amber
4. Power Indicator - Green
5. Battery Charger Head

**Optional Control
Room Unit
Accessories**

Adjustable Height Pedestal



WARNING: Injury or equipment damage may result if the adjustable height pedestal is taken into the scanner room. Do not take the adjustable height pedestal in the scanner room. It contains ferrous material that could be attracted toward the magnet.



Wall Mounting Bracket

Note: These accessories contain ferrous material and are designed to be used in the Control Room only. Do not install or operate in the Scan Room.

Touch Screen Calibration

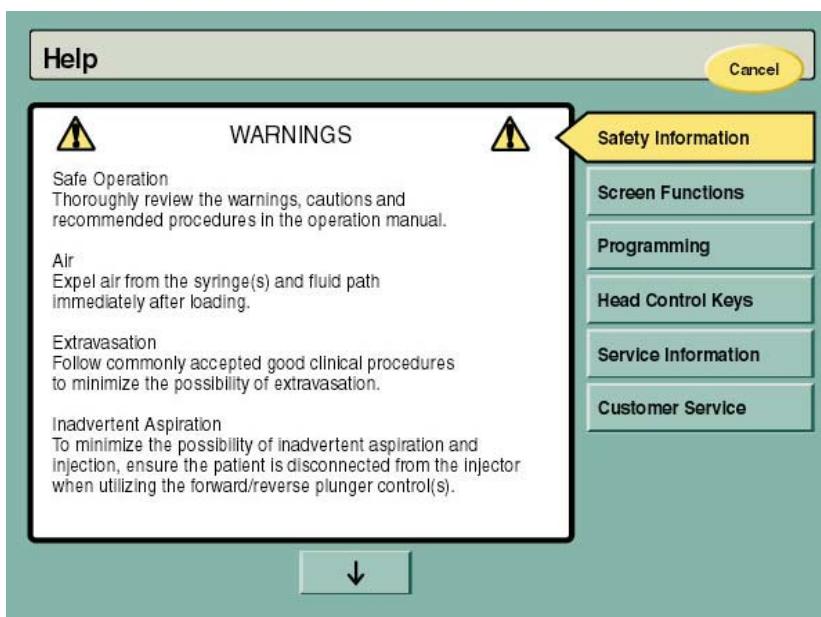
To enter Touch Screen Calibration mode, simultaneously press both the Contrast UP and DOWN keys on the rear of the touch screen housing. A series of screens with instructions to press the appropriate calibration circles will appear.



CAUTION: Do not touch the screen with a sharp object in order to perform the calibration.

Help Mode

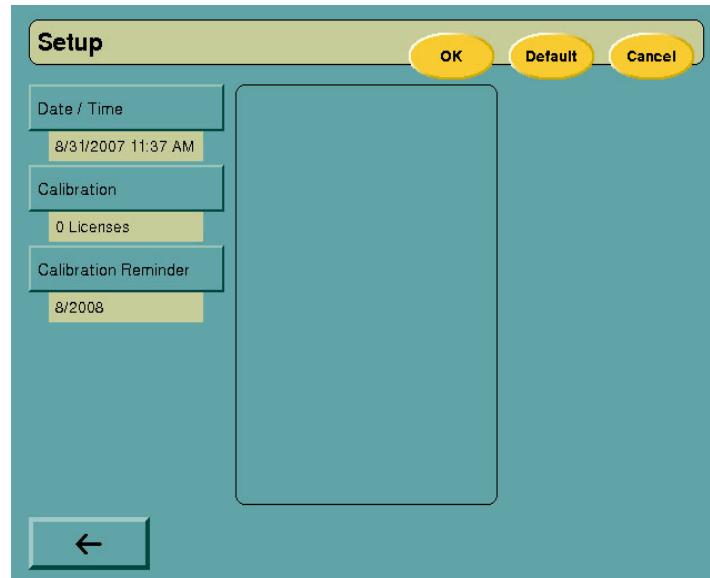
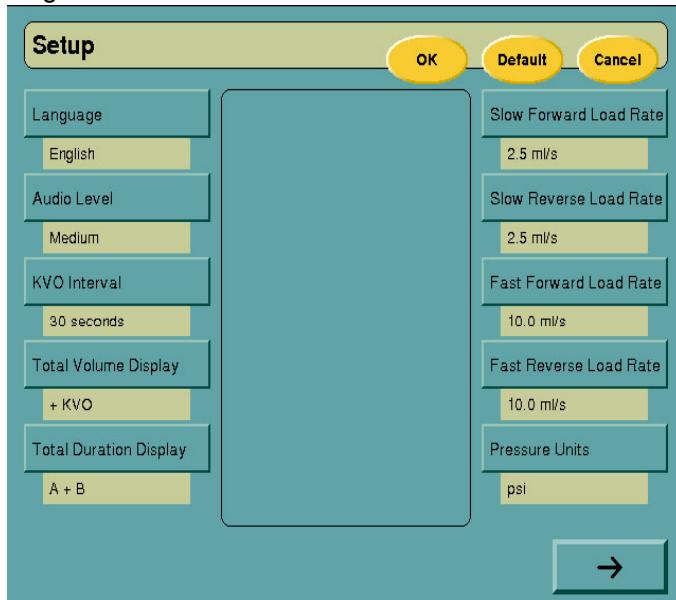
The Help screen can be accessed by pressing the HELP button on the lower right corner of the Main screen. Besides safety information, the Help screen displays a variety of topics as displayed below.



Setup Mode

The Setup screen can be accessed by pressing the SETUP button at the lower right corner of the Main screen. The Setup screen allows user configurable options and preferences to be selected, along with setting of date and time parameters.

Select the appropriate option, then choose from the available selections in the display window. Select the DEFAULT key to return all options to original factory settings.



The system provides a calibration and maintenance reminder. This reminder will be displayed on the System Logo screen at each startup, beginning 30 days before the system is due to be recalibrated. The duration of time from one calibration to the next is programmed during system installation or by selecting the Calibration Reminder key and entering the correct due date.

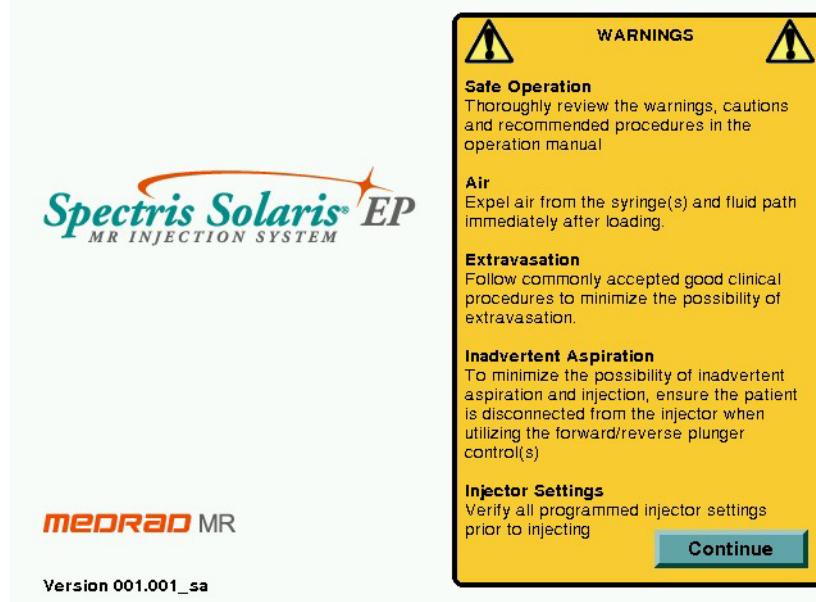
3 - Preparing to Inject

Applying Power

Place the power switch located on the right side of the Control Room Unit in the ON position. The System Logo screen will appear while the system performs a series of self diagnostic tests.

Note: Do not touch the screen or activate any controls while self diagnostics are in progress. If this occurs, diagnostic tests will interpret this activity as a hardware failure and halt the system. The system must then be powered down/up to reset the error.

After diagnostics have successfully completed, the System Logo screen will be replaced by the Safety screen



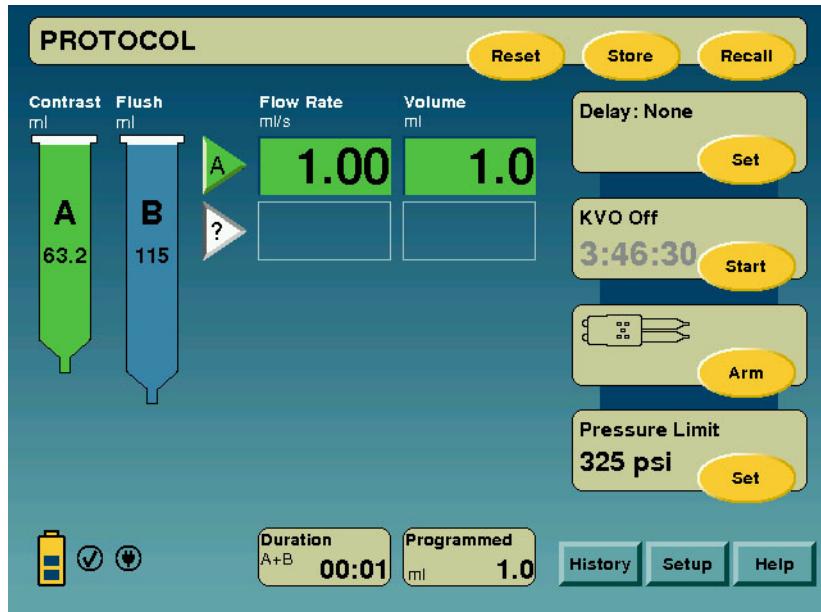
After reading the Safety screen, press CONTINUE to view the Main screen.

Apply power to the Scan Room Unit by inserting the battery into the receptacle on the bottom of the Scan Room Unit. Upon power up of the CRU and SRU, verify that the indicators, lamps, and speaker are operational.

Note: The Control Room Unit can be programmed for an injection without power applied at the Scan Room Unit.

Main Screen

The Main screen is entered from the Safety screen after power-up. The Main screen is used during programming, arming, and injecting, with applicable screen controls made visible based on the task currently being performed.



Battery Maintenance



WARNING: Explosion Hazard. Serious injury or death may result from improper use of the battery charger. The battery charger, MEDRAD Catalog Number 3012424, is intended for use in a well ventilated area, with the injection system battery, MEDRAD Catalog Number 3012070, only. Do not use the charger with non-rechargeable batteries.

When the Main screen appears, check the status of the system battery in the lower left corner of the screen. The battery icon will contain three horizontal bars when indicating full charge, two when indicating medium charge, one for low charge, and no indicators in the icon when the battery is fully depleted, not connected, or communication is not detected between the Control Room and Scan Room Units.

- | | |
|--|---|
| | • Full Charge |
| | • Medium Charge |
| | • Low Charge |
| | • Fully Depleted
• Not Connected
• Communication Not Detected |

If the depleted battery is not replaced when only one bar is displayed, the system will complete any injection that is in progress. However, the system may not initiate a single or multi arm injection, the forward and reverse controls on the injector head may not function and system communications may be lost.

Each battery pack should last for 4 to 6 typical injections using a 20 minute KVO, or approximately 5 hours in an idle state before requiring a recharge. Monitor battery status per injection and on a daily basis. Each battery is capable of being recharged approximately 300 times. When the life of a battery pack becomes shortened, noticeably sustaining fewer injections per charge, this signals that battery life is expiring and the battery pack should be replaced. Call MEDRAD Service for battery pack replacement.

To charge the battery, place the 3-pronged, charging head into the battery, then connect the charger to AC power. A green LED on the charger indicates that AC power is applied. An amber LED indicates that the battery is charging. The amber LED will turn off when full charge is reached. Battery charge time is approximately 5 hours.

Syringe and Disposable Accessory Installation

Retracting the Pistons

Fully retract each piston by using the reverse switches on the injector head.

Note: When using the reverse switches, first press the Enable switch; then within 5 seconds, press the reverse switch(es). Both pistons may be reversed simultaneously.

The forward and reverse switches have dual speed capabilities:

When the switches are partially depressed, the pistons will move slowly. When fully depressed, the pistons will move quickly. Forward and reverse piston speeds are fully configurable (1 to 10 ml/sec) in the Setup mode.

The manual knobs may also be used to move the pistons in the forward or reverse direction. Turn the knobs clockwise to advance the piston, counterclockwise to retract.

Installing a Syringe



WARNINGS:

Patient or operator injury may result if damaged components are used. Do not use damaged components. Visually inspect all components before use.

Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components. Do not store pre-loaded syringes.

The use of single-use disposable devices on more than one patient is a biological hazard. Do not reuse single-use disposable components.

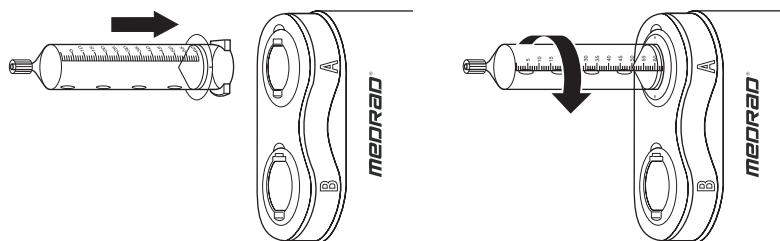
Patient injury could result if the syringe is not properly engaged.

Ensure the alignment marks on the syringe and injector head are properly aligned, and the piston and plunger are interlocked. Improper engagement may cause syringe damage or under-volume delivery.



CAUTION: Improperly engaged syringes may leak or be damaged. Ensure proper engagement of syringe and injector. Syringe and injector engagement points must align.

Note: Syringe A is intended for contrast media, and Syringe B is intended for flushing solution only.



1. Align the flanges on the syringe with the notches in the injector head. (The syringe is keyed to properly fit in only one way.)
2. Insert the syringe.
3. Twist 1/4 turn clockwise until the syringe snaps into place. (Graduations will be facing the front of the injector head.)



WARNING: Air embolism can cause patient injury or death. Expel all trapped air from the syringe(s), connectors, tubing, and catheter-over-needle before injecting.

Note: Do not hit or tap the syringe to remove air bubbles.

To reduce the volume and size of air bubbles drawn into the syringe during loading, a MEDRAD Fluid Dispensing Device (FDD or “spike”) is recommended. Air removal from the syringe(s) will be much more difficult if a small diameter tube, such as a catheter-over-needle, needle, or a tube longer than 10 inches (25 cm), is used for loading.

Operator vigilance and care, coupled with a set procedure, is essential to minimizing the possibility of an air embolism. The injector head should be pointed upward during loading, enabling any air to accumulate at the syringe tip and to be expelled. The injector head should be pointed downward during an injection, enabling any small air bubbles which could still be in the fluid to float to the rear of the syringe(s).

To help avoid air injection, MEDRAD syringes are equipped with FluiDot indicators. These FluiDot indicators should be observed as part of an arming procedure. When the FluiDot is viewed through an empty syringe, the dots appear as small narrow ellipses as illustrated below in figure 1. However, when viewed through a full syringe, the dots become larger, almost round (or wider than round) as illustrated below in figure 2.

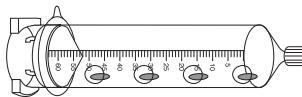


Fig. 1 Empty

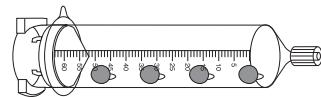


Fig. 2 Filled

FluiDot indicators must be viewed in a properly illuminated environment, with a light source behind the operator providing enough light to permit easy viewing.

To minimize air embolization risks, ensure that one operator is designated the responsibility of filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that the fluid path is purged of air.



WARNING: If a blockage occurs, disposable components with a lower pressure rating may leak or rupture. Use only catheter and connectors with ratings that are compatible with the *MEDRAD Spectris Solaris EP MR Injection System*.

During installation of the low pressure connector tubing (LPCT) with T-connector to the syringe(s), and before arming, manually advance the syringe plunger(s) to provide a very slow flow of fluid at the connection. An absence of flow is an obvious indication of air or a blockage in the fluid path.

Loading a Syringe



WARNINGS:

Remove all trapped air from the syringe, connector tubing, and catheter-over-needle before connecting the patient to the injector.

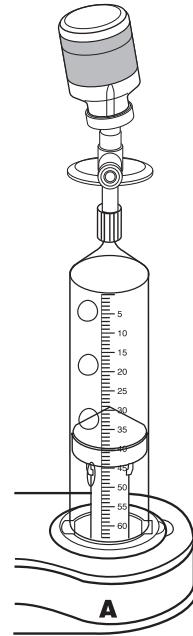
Syringe sterility will be compromised, and patient infection may result, if the plunger is removed from the syringe. Do not remove the plunger to fill the syringe.

Bacterial contamination can occur if syringes are used to store contrast media. Use loaded syringes immediately. Do not store loaded syringes for later use. Discard any unused syringes.

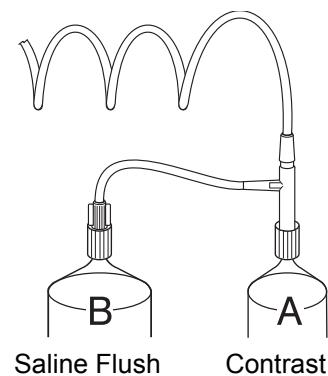
Note: The presence of rounded FluiDot indicators does not indicate the total absence of air bubbles in the syringe tip.

Note: FluiDot indicators must be viewed in a properly illuminated environment, with a light source behind the operator providing enough light to permit easy viewing.

1. Position the injector head so that the syringes are pointing upward.
2. Fully advance each piston plunger. The plungers may be advanced simultaneously after pressing ENABLE.
3. Attach a sterile filling device (spike or Female-to-Female Adaptor - MEDRAD Catalog Number FFA 50) onto the tip of the syringe. If loading contrast media and/or saline from a bag or bottle, use a spike. If loading contrast media from a pre-filled syringe, use an FFA 50.
 - A. If using a spike, open the bottle(s) of contrast and/or bag(s) of flushing solution, then draw the contents (contrast for syringe A; flush for syringe B) into the syringe(s) by depressing ENABLE, and then the reverse load button for each syringe.
 - B. If using the FFA 50, attach it to the tip of syringe A, then attach the pre-filled syringe to the FFA 50. Draw the contents from the prefilled syringe into syringe A by pressing ENABLE, then the reverse load button.
4. With the filling device still attached, advance the plunger to expel any air that may remain in the top of the syringe; then, if necessary, draw more fluid into the syringe to replace fluid loss.
5. Remove the filling device and expel any air bubbles from the syringes.



6. Attach the long end of the T-connector to syringe B.
7. While the injector head is still in a vertical position, attach the short section of the T-connector to syringe A.
8. Starting with syringe A, then syringe B, prime the T-connector, then fill the connector tubing with the appropriate fluid. Ensure that all air is expelled from the entire length of the tubing.



Note: A MEDRAD SSIT 96VLD low pressure connector tube (LPCT) holds approximately 7 ml of fluid. If syringe B is used to flush, use at least 8 ml of flush to deliver this volume to the patient.

Note: If the connector tube is filled with saline, contrast will be delivered to the patient with a delay dependent on the flow rate selected for syringe A.

Note: When the connector tube is filled with contrast the volume remaining displayed on the protocol screen is approximately 7 ml less than what was loaded into the syringe.

9. *Tilt the injector head downward before attaching to the vascular entry device in the patient. After attaching the connector tube to the vascular entry device verify that the connector luer fittings are secured. The injector head must be maintained in this position during the injection.*



WARNINGS:

Patient injury could result from movement of the Scan Room Unit after the patient is connected to the fluid path. Lock the casters at the base of the unit and the Middle Pivot Clamp to prevent unintended movement.

Patient injury and/or catheter damage may result from using connector tubing (LPCT) that is too short. Operator must consider tubing length and stretch limitations when moving the injector or the patient.

10. Secure the Scan Room Unit by locking the casters and the Middle Pivot Clamp, then verify that all air has been expelled from the fluid path by carefully inspecting all tubing and syringe(s). Acknowledge that the inspection has occurred by pressing the AIR REMOVED confirmation button/indicator on the injector head. The Air Removed Indicator will then illuminate yellow on the touch screen.

Note: Reverse movement of the pistons after the AIR EXPELLED button has been pressed will cancel the Air Expelled status. Re-check the fluid path for air, then press the AIR EXPELLED button again to continue.

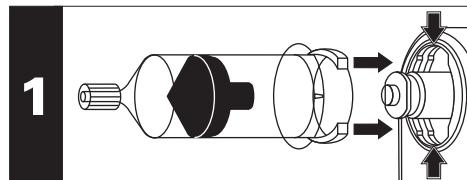
Reinstalling a Syringe



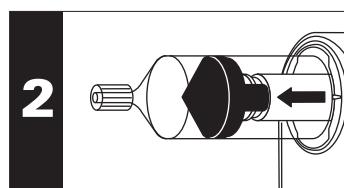
WARNING: Patient injury could result if the syringe is not properly engaged. Ensure the alignment marks on the syringe and injector head are properly aligned, and the piston and plunger are interlocked. Improper engagement may cause syringe damage or under-volume delivery.

If you remove a syringe from the injector, and then wish to reinstall it, perform the following steps:

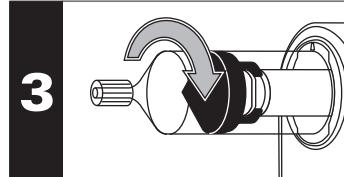
1. Insert the end of the syringe in the horizontal cutouts in the injector head.



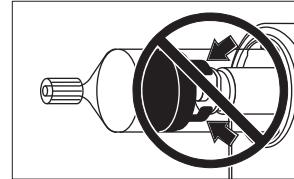
2. Advance the piston until it is past the plunger feet and the piston/plunger interlock.



3. Rotate the syringe 1/4 turn clockwise until the syringe locks and alignment marks are positioned.



4. Proceed as normal by aspirating and dislodging any air bubbles.



Note:

If bubbles appear in the syringe **DO NOT** hit the syringe to remove them. Reverse the plunger 3 to 5 ml, then rock the head on the pivot to gather and accumulate the small bubbles. Expel the remaining air.

Programming

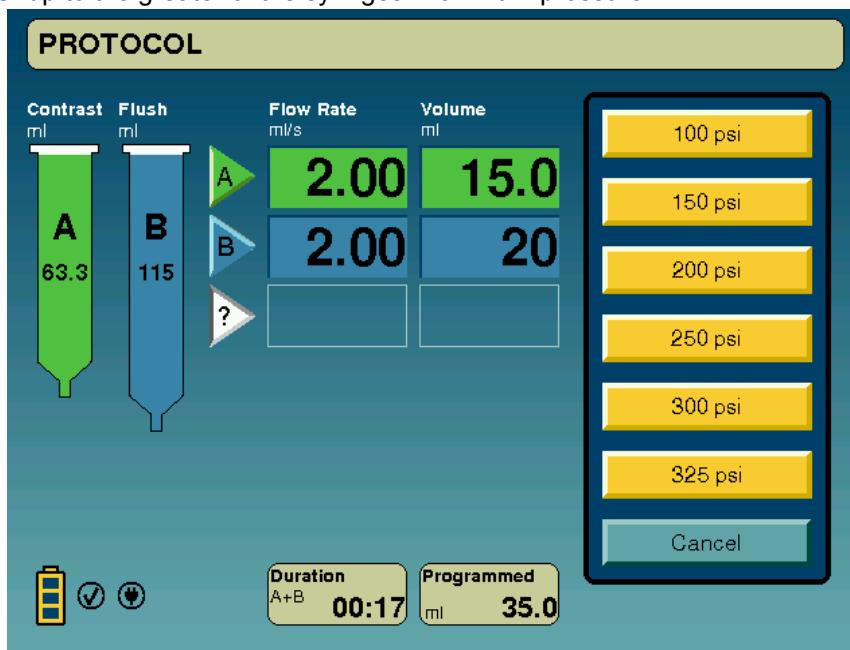
If a program has not been previously entered or stored on the Main screen when the unit is powered up, the Main screen will display default settings; 1.0 ml/s flow rate and 1.0 ml volume, KVO off and No Delay.

Flow Rate and Volume

Begin programming by selecting any programmable block, such as FLOW RATE or VOLUME. When a programmable block on the screen is touched, a keypad will be displayed to permit the selection of numeric values. The numeric keypad is displayed when a Flow Rate, Volume or Delay value is selected. The keypad window will also display the appropriate programmable range for the parameter selected. To lock in values, press ENTER. Press << to edit a selection, or CANCEL to eliminate a selection if an error is made.

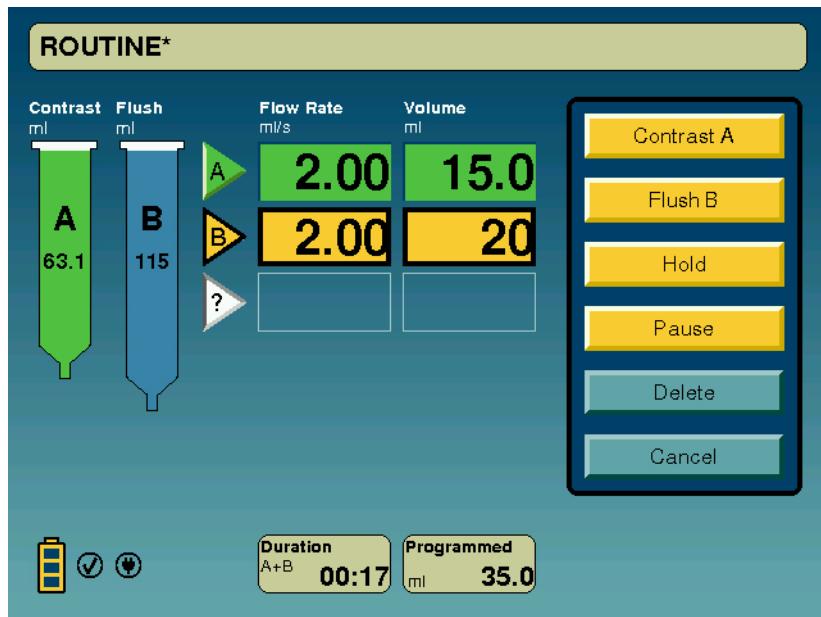
Pressure Limit

The pressure limit can be programmed by choosing a value between 100-325 PSI up to the greater of the syringes' maximum pressure.



Multiple Phases

If appropriate, select a second phase for the injection protocol by pressing the triangle block below the first phase of the injection. The Phase Type selector will appear in order to select the function of the new phase.

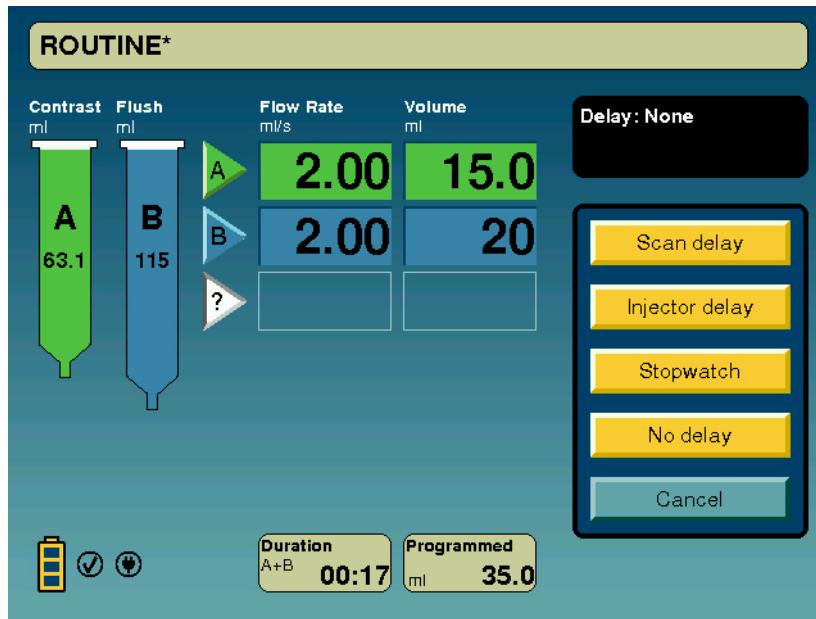
**Hold and Pause Phases**

A Hold or Pause phase can be programmed into a multi-phase injection. A Pause phase will stop the total injection process for a preprogrammed length of time, while the Hold phase will stop the injection until input from the operator resumes the injection. A Hold phase can be maintained for up to 20 minutes, at which time the system will disarm.

After selecting the phase type, continue programming by entering Flow Rate and Volume values for the new phase.

Programmed Delay

After entering Flow Rate and Volume parameters, press SET in the Delay Timer field to select the delay type (Scan Delay, Inject Delay, Stopwatch, or No Delay.)



Note: There is no direct interface between the scanner and the injector. The scanner cannot trigger the injector, nor can the injector trigger the scanner.

Scan Delay

Scan Delay time will elapse in the timer block on the screen. The time remaining before the scan should be activated will decrement in one second intervals. (The scan delay countdown will continue through multiple arm injections.) When countdown is complete, the system will emit 5 beeps.

Inject Delay

Inject Delay will also countdown in one second intervals, commencing when the handswitch is pressed. The clock will display, in one second decrements, the time remaining before the injection will begin. *When inject delay is chosen and the handswitch is pressed, the injection will automatically occur unless the injector is disarmed.* When countdown is complete, the system will emit 5 beeps and the injection will automatically begin.

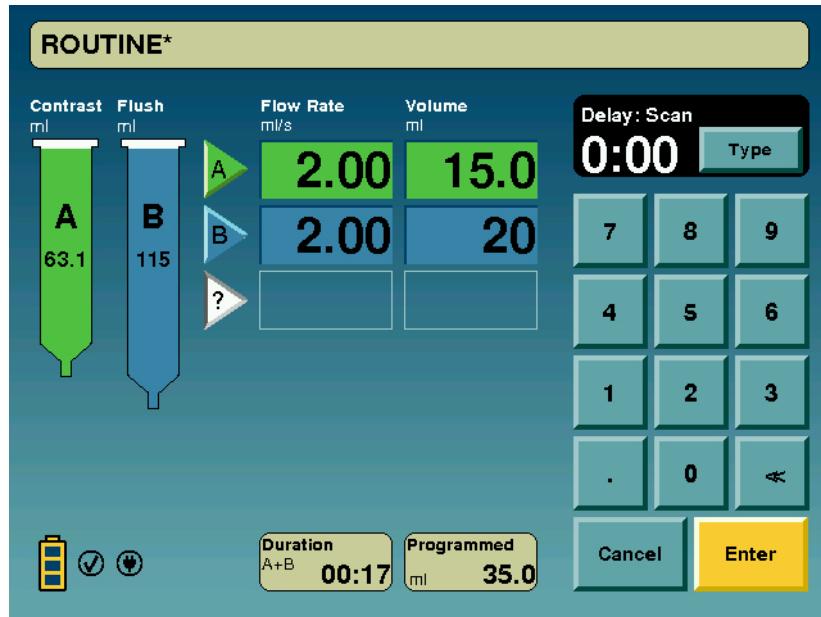
If Hold is activated during an inject delay or a scan delay, the timer will stop during the hold interval and resume when the handswitch is pressed.

For scan or inject delays that are longer than 3 minutes, the unit will beep 30 seconds before the delay is to terminate, then will beep every second from 5 seconds through 1 second before the delay is due to terminate.

Stopwatch

The Stopwatch function initiates an incremental count of elapsed time from initial fluid injection.

After selecting the delay type, enter the delay duration on the numeric keypad. To lock in values, press ENTER. Press CANCEL to eliminate a selection if an error is made.

**KVO (Keep Vein Open)**

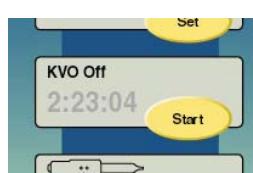
The KVO function delivers small boluses of fluid from syringe B at configurable intervals. KVO can run during:

- Programming
- Pre and post injection
- Between multiple injections
- During Pause and Hold

The delivery interval can be selected in the Setup mode, which is accessed using the Setup button on the Main Screen.

After an initial KVO pulse of 2 ml, KVO delivery intervals include 0.25 ml pulsed every:

- 15 seconds
- 20 seconds
- 30 seconds (*default*)
- 45 seconds
- 60 seconds
- 75 seconds



The KVO field displays the time available to support KVO based on the configured interval and the volume remaining in syringe B less any volume programmed from syringe B in the protocol.

Starting KVO:

On the Main Screen, press START in the KVO field to initiate KVO. When KVO is running, “KVO” will appear, and the KVO Injecting arrows will flash in the Syringe B touch screen indicator.

KVO will function during Pause, Hold and/or inject delay periods. KVO will resume post-injection until no fluid remains in syringe B, or until STOP KVO is pressed in the Injection Complete window.

Note: Volume displayed in the Volume Delivered window can be configured in the Setup mode to include the total KVO volume delivered in addition to volume delivered by the programmed injection.

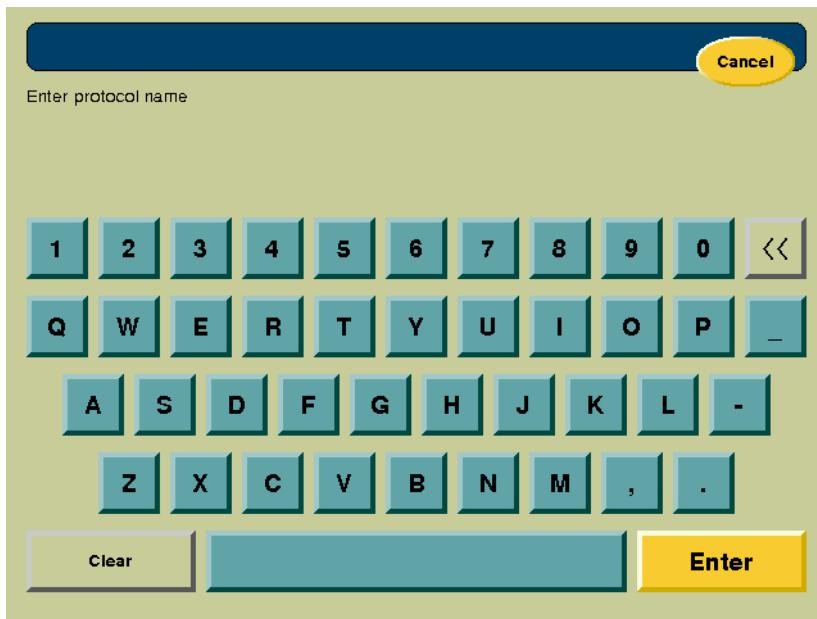
KVO may be stopped at any time by pressing STOP in the KVO field, or by pressing any injector head control button (this will also disarm the system and terminate any injection in progress). Other actions that disarm the injector, such as syringe removal, disarm button press and injection stall, will also stop KVO.

KVO and Occlusions:

If an occlusion occurs during KVO the system will detect the condition after 4 or less KVO boluses fail to be delivered. This will correspond to from 1 minute with a KVO interval of 15 seconds configured, to 5 minutes with a KVO interval of 75 seconds. Refer to the Setup screen to determine the current KVO setting.

Storing a Protocol

To store a protocol for future use, press the STORE button on the upper right corner of the Main screen.

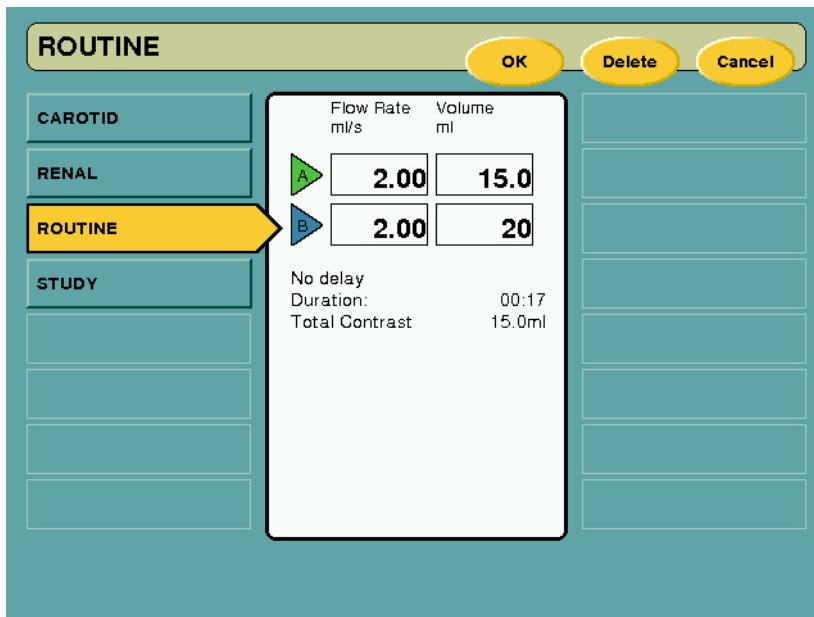


An alpha-numeric keypad will appear with a flashing cursor in the title block. Type in a title of up to 20 characters, including spaces. Use the arrow key to backspace, individually erasing characters, and the CLEAR key to clear a string of text. When title entry is completed, press ENTER.

To exit the Store screen without making changes, press the CANCEL button in the upper right corner.

Recalling a Stored Protocol

To access program memory, press RECALL on the Main screen.



Select a previously stored injection protocol by pressing one of the names on either side of the screen. Key parameters of the selected injection will be displayed in the center of the screen. Once selected, the protocol can be deleted by selecting DELETE at the upper right corner of the screen, or brought to the Main screen by selecting OK.

4 - Arming and Injecting

Before beginning the arming process, ensure that the casters on the Scan Room Unit are locked, verify that all air has been expelled from the fluid path, and that the programmed parameters are correct. Carefully inspect all tubing and syringe(s), then acknowledge that the inspection has occurred by pressing the AIR EXPELLED button/indicator on the injector head. A yellow illuminated Air Expelled Indicator on the touch screen confirms that the button has been pressed.



WARNINGS:

Air embolization can cause death or serious injury to the patient.
Do not connect a patient to the injector until all trapped air has been cleared from the syringe and fluid path.

Patient injury could result from high flow rate venous injections.
Use extreme care when selecting flow rate and duration. Before arming the injector, verify that high flow rate injection parameters have not been unintentionally programmed.

Patient injury could result from inadvertent aspiration. To minimize the possibility of inadvertent aspiration and injection, ensure the patient is disconnected from the injector when utilizing the forward/reverse plunger control(s).

Extravasation can cause injury to the patient. Follow commonly accepted good clinical procedures to minimize the possibility of extravasation.

Arming

To begin the arming and injecting process, press ARM on the Main screen. If necessary, changes can be made to programmed injection parameters after the arming sequence is complete. Select the required parameter, then enter the correct value with the on-screen keypad. Pressure safety limit programmed by the user is indicated to the user and cannot be changed when the injector is armed.

Note: If the AIR EXPELLED button on the injector head has not been pressed, the system will request user confirmation that air has been expelled before proceeding.

Single and Multi-Arm

Select either a Single or Multiple arming sequence by pressing either SINGLE or MULTI. (The default is Single arm.)

A *single arm* injection will perform the protocol once, then disarm.

A *multi-arm* injection allows the protocol to be repeated, creating a series of injections. After the protocol is completed, the system will automatically re-arm in preparation for the protocol to be repeated. Each injection in the series must be started with the handswitch.

Insufficient Volume

If an insufficient volume condition occurs during a multi arm sequence, the system will remain armed to permit the injection of the remaining volume. However, the screen will update to display only the phases that are achievable with the volume that remains. In a single arm sequence, the screen will update when arming occurs to display only the phases that are achievable.

While the system is armed, pressing DISARM or activating any injector head controls will return the system to the idle state.

Injecting

After the system has been armed, press the handswitch to begin the injection. Additional presses of the handswitch will alternately “hold” and resume the injection. The maximum duration for Hold is 20 minutes. If the maximum hold time is exceeded the injection will abort automatically.

If an inject delay has been programmed, pressing the handswitch will activate the countdown timer. The programmed injection will automatically begin when the timer counts down to zero. If the handswitch is pressed during an inject delay, the countdown timer will stop counting until the switch is pressed again, or the Hold time is exceeded.

If a scan delay is programmed, the scan delay countdown and the injection will start simultaneously. During the injection, additional presses of the hand switch will alternately “hold” and resume the injection and the scan delay timer.

If KVO is running: KVO will function during Pause, Hold and/or inject delay periods as long as sufficient fluid remains in syringe B to complete the programmed injection. KVO will run post-injection until no fluid remains in syringe B, or until STOP KVO is pressed in the Injection Complete window. To stop KVO the operator can also press any injector head control buttons.

If a Hold phase is entered, parameters for the remaining portion of the injection protocol can be altered.

On the Injecting Screen:

- As each phase is activated, the phase parameters will be highlighted to display injection progress.
- The Duration window will also increment to display elapsed time.
- The Delivered window will increment as the injection proceeds to display volume delivery (including KVO volume, if selected in Setup mode).
- The Volume Remaining display will decrement.
- The Programmed pressure limit and the current pressure will be indicated on the display. If a pressure limit condition occurs, it will indicate on the display.
- If KVO is selected, the time available for KVO will decrement in the KVO Time Remaining window while KVO is active. (During an injection, KVO will stop and the time display will not count-down.)

On the Injector Head:

- While injecting, indicator lamps on the back of the injector head will be illuminated (white for syringe A, blue for syringe B). The appropriate lamps will be lit solid while injecting, and flash while either Armed or on Hold.
- If multi-arm is selected, the indicator lamps will flash when the system rearms.
- During KVO the blue indicator lamp for syringe B is illuminated.
- AIR EXPELLED Indicator is illuminated.

Disarming

Pressing DISARM, activating any injector head controls, or touching any portion of the touch screen while the system is injecting, will cause the system to disarm.

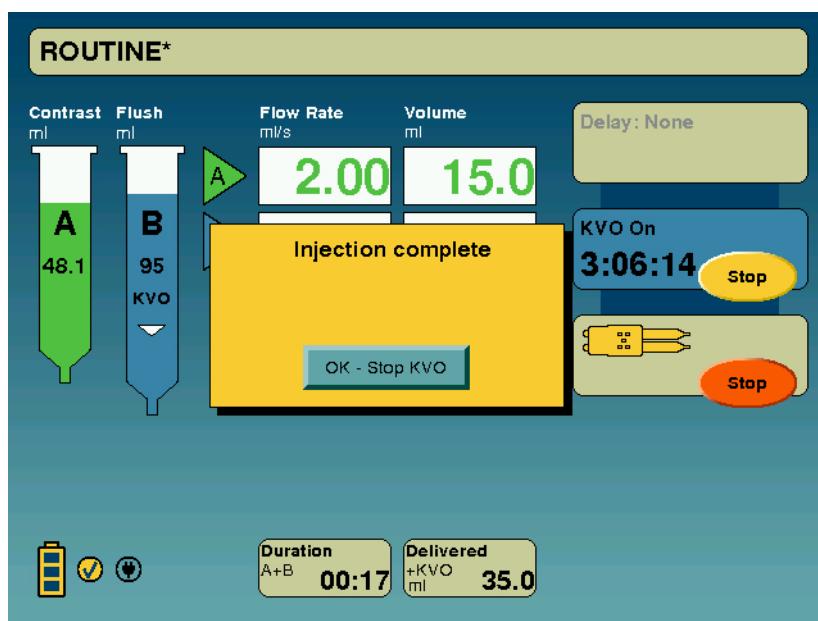
The Hold mode can be entered at any time during an injection by pressing the handswitch. The system will remain in this state until the handswitch is pressed a second time, or the maximum hold time of 20 minutes is exceeded.

Note: A MEDRAD SSIT 96VLD low pressure connector tube (LPCT) holds approximately 7 ml of fluid. If syringe B is used to flush, use at least 8 ml of flush to deliver this volume to the patient.

Note: If the connector tube is filled with saline, contrast will be delivered to the patient with a delay dependent on the flow rate selected for syringe A.

Note: When the connector tube is filled with contrast, the volume remaining displayed on the screen is approximately 7 ml less than what is present in the system.

When an injection (single or all multi-arm sequences) is completed, the following window, with a brief summary of the injection parameters, will be displayed.

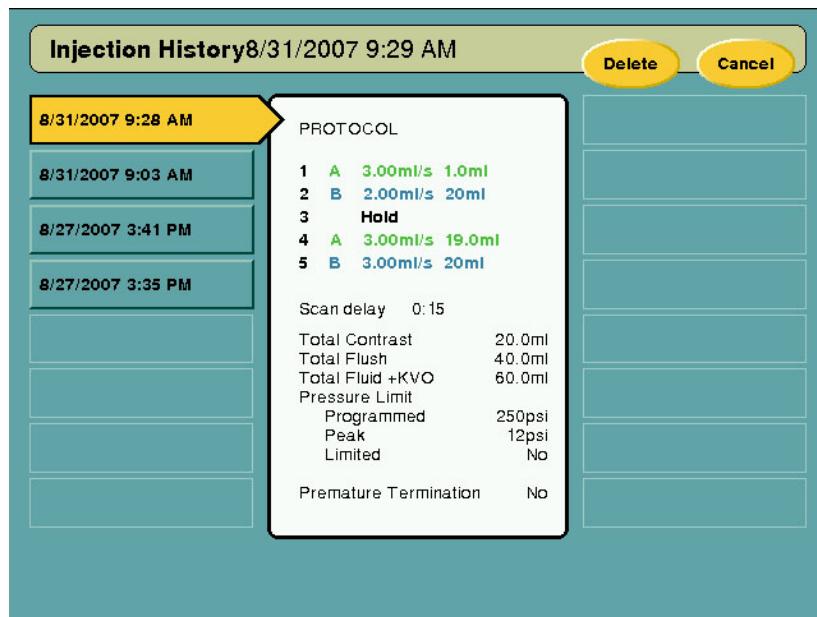


Injection History

To review injection parameters used in a procedure, along with actual achieved values for the injection, press the HISTORY button on the Main screen.

The Injection History screen displays an injection summary block containing the following data:

- Time and Date Started
- Programmed Flow Rate
- Programmed Volume
- Programmed Protocol
- Total Fluid (plus KVO)
- Delay Type
- Delay Duration
- Pressure Limit Programmed
- Peak Pressure
- Pressure Limit Status (YES/NO)
- Premature Termination Status (YES/NO)



The system maintains status information of the 20 most recent injections, sorted by date and time.

To delete any injection protocol history from the system, press DELETE while the protocol is selected. To scroll to the next page of protocols, press the ARROW key. To exit the Injection History screen, press CANCEL.

Clean Up

Note: Do not resterilize or reuse any disposable items.

When cleaning the injector, remove and discard all used disposable items. (Syringes **should** be removed without retracting the pistons.) It is not necessary to remove the connector tubing when removing and discarding syringes.



WARNING:

Serious injury may result from syringe failure. Do not retract pistons with connector tubing installed.

- Disconnect the Control Room Unit from line power and remove the battery from the Scan Room Unit before cleaning.
- Avoid fluid entry into system components. Do not immerse any components in water or cleaning solution.
- Do not remove any covers or disassemble the injector. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact MEDRAD Service for repairs.
- Retracting the pistons with the connector tubing installed on syringes will create a vacuum in the syringe due to the check valve in the connector tubing. This vacuum may accelerate the plunger rapidly toward the tip of the syringe when it is removed from the injector causing the syringe to break.



CAUTIONS:

System malfunction may be caused by failure to perform regular maintenance. Regular preventive maintenance is recommended to ensure that the system stays calibrated and functions properly. Refer to Appendix B of this manual or contact MEDRAD for additional information.

Do not expose system components to excessive amounts of water or cleaning solutions. Wipe components with a soft cloth or paper towel dampened with cleaning solution.

Do not use strong cleaning agents and solvents. Warm water and a mild disinfectant are all that is required. Do not use strong industrial cleaning solvents such as acetone.

Note: For all body fluid spills, follow institutional decontamination procedures.

Note: If contrast medium has leaked inside any component of the system, the affected subassembly should be disassembled and cleaned by MEDRAD Service personnel or returned to MEDRAD Factory Service.

Scan Room Unit

Using a soft non-abrasive cloth, warm water, and a mild disinfectant, carefully clean the assembly, paying particular attention to the following:

- Injector Head
- Syringe Piston Plunger
- Syringe Interface
- SRU Lower Console covers

To clean the injector head, piston, and syringe interface:

1. Fully advance the piston.
2. Remove the battery from the Scan Room Unit.
3. Place the injector head in a vertical position.
4. Clean the piston with a soft cloth or paper towel dampened with cleaning solution.
5. Thoroughly dry the piston with a paper towel.
6. Re-install the system battery, then fully retract the piston.
7. Remove the battery from the Scan Room Unit again.
8. Clean the inner area of the syringe interface with a soft cloth or paper towel dampened with cleaning solution.
9. Wipe the injector head case and control panel with a soft cloth or paper towel dampened with cleaning solution.
10. Thoroughly dry the injector head case and control panel with a paper towel.

Control Room Unit

CAUTION: Do not spray cleaning solutions directly onto the touch screen. To prevent damage, wipe the touch screen with a soft non-abrasive cloth or paper towel dampened with cleaning solution.

Appendix A: System Messages

The system will display messages on the screen as conditions or events occur. There are three basic types of messages:

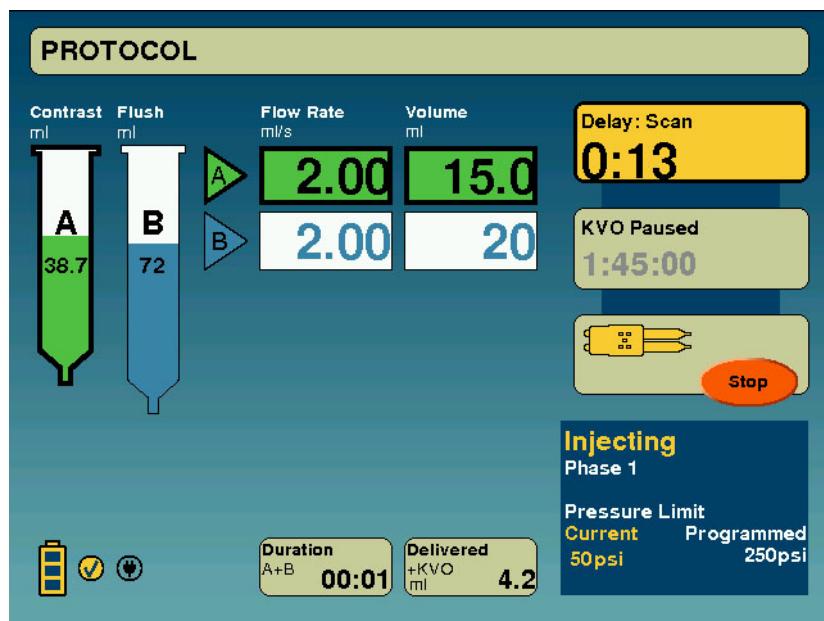


WARNING: Patient injury may result from a system malfunction.

If a system malfunction occurs, immediately remove Scan Room Unit power (by pulling the battery from the head stand), and disconnect the system from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the injection system. Call MEDRAD for assistance.

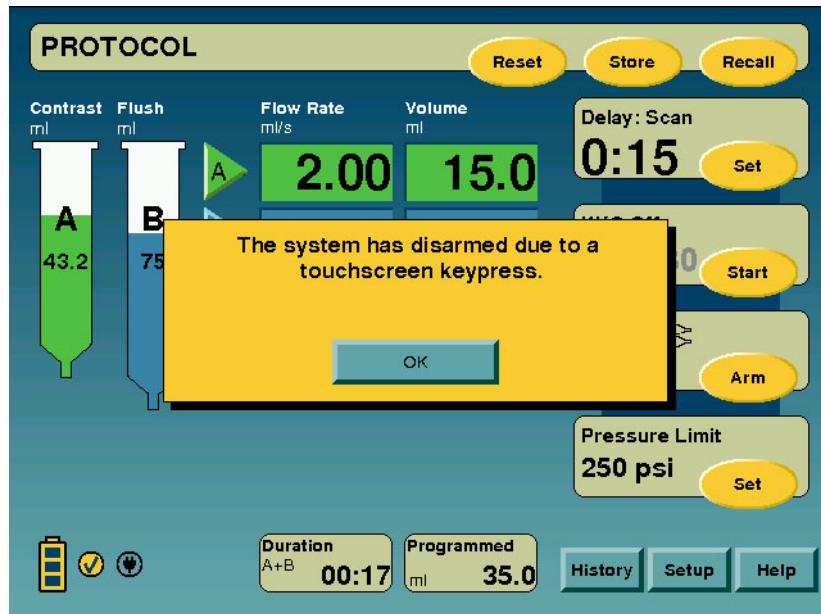
Type 1 Messages

Type 1 messages are messages which provide information regarding the current status of the system, and will clear automatically from the screen. These messages are typically displayed in the lower right corner of the screen.



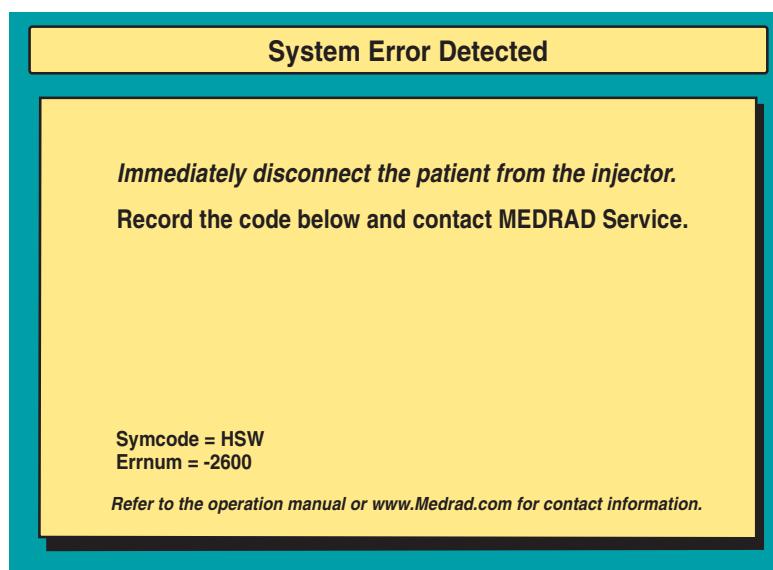
Type 2 Messages

Type 2 messages are messages that convey information that must be explicitly acknowledged before proceeding. The message is displayed within a yellow dialog box - a button (or buttons) must be pressed to acknowledge and remove the message from the screen.



Type 3 Messages

Type 3 messages are system malfunction messages which require power to be removed from the system. Some Type 3 messages provide suggestions to prevent the condition from recurring. If the condition cannot be corrected, record the code and number from the lower left corner of the dialog box, then call MEDRAD Service for assistance.



Appendix B: Maintenance and Checkout

This section contains recommended procedures for maintenance, and an operational checkout of the *MEDRAD Spectris Solaris EP MR Injection System*. Routine maintenance and inspection will:

- Ensure continued performance of the injection system
- Reduce the possibility of equipment malfunction

Recommended Maintenance Schedule

Your *MEDRAD Spectris Solaris EP MR Injection System* must be properly maintained to ensure that it is in peak operating condition. Your individual maintenance system and schedule depends upon how your injection system is used, the type of procedures performed, and frequency of use. The following maintenance schedule is recommended for the system:

Daily:

The piston rod should be thoroughly cleaned after each use. Before use each day, the system should be cleaned and inspected, using the procedures outlined in this section. Ensure that all system safety and warning labels are in place and are legible.

Monthly:

Once a month, the entire system should be thoroughly inspected and cleaned, and an Operational Checkout should be performed.

Annually:

As part of an annual maintenance program performed by a qualified MEDRAD Service Representative or authorized dealer, both Electrical Leakage and Ground Continuity checks should be performed.

NOTE: Local regulations or hospital protocol may require electrical leakage checks at more frequent intervals. If this applies, local regulations for leakage must be followed.

MEDRAD also recommends that a complete system calibration and performance checkout be performed annually. Contact MEDRAD Factory Service, or your local MEDRAD office for complete details.

In the United States, Canada, and Europe, the MEDRAD Service Department offers Preventive Maintenance Programs. These annual programs greatly assist in maintaining accuracy and reliability, and can also extend the life of the system. Contact MEDRAD for details. In Europe, contact your local MEDRAD office or your local authorized dealer for further information. Refer to the back of the title page of this manual for address, telephone and FAX information.

NOTE: Failures which occur due to lack of proper maintenance will not be covered under warranty.

MEDRAD Service

MEDRAD Service will make available upon request:

- Circuit diagrams, component parts lists, or other information that will assist qualified technicians to repair components classified as repairable.
- On-site consulting or consulting references upon request.

Inspection Procedures

The following procedures are recommended for *daily* inspection of all components in the *MEDRAD Spectris Solaris EP MR Injection System*. If any defects are detected, either repair the system, or call MEDRAD for service. Do not use the system until the problem is corrected.

Scan Room Unit

1. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
2. Inspect *all* cables connected to the unit: Look for cuts, cracks, worn spots or other obvious damage to the cables. Ensure that all connectors are properly seated.
3. Inspect for contrast media build-up in the syringe interface area. Follow the cleaning guidelines outlined in this section.
4. Inspect the stand, base, and support arm for cracks and other defects that could weaken the structure.
5. Ensure that all mounting bolts and screws are secure.
6. Ensure that all locking mechanisms on the casters are functional.
7. Inspect the pivot points. The head and support arm must pivot freely. The injector head should rotate on the support arm no more than 330°. The support arm should not rotate on the center post more than 350°.

NOTE: All relevant guidelines for institutional, local, or national safety recommendations related to cable routing and installation should be followed.

Control Room Unit

1. Inspect *all* cables connected to the unit: Look for cuts, cracks, or worn spots, or other obvious damage. Ensure that all connectors are properly seated.
2. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.

- | | |
|-----------------------------------|---|
| Wall Mount Bracket | <ol style="list-style-type: none">1. Inspect all parts of the bracket for cracks and other defects that would weaken the assembly.2. Ensure that the bracket is securely attached to the wall.3. Ensure that all cables are secured to the display control unit and do not interfere with the movement of the mounting bracket. |
| Height Adjustable Pedestal | <ol style="list-style-type: none">1. Inspect the stand, base and support arm for cracks and other defects that could weaken the structure.2. Ensure all mounting bolts and screws are secure.3. Ensure that the casters roll smoothly with no binding or scraping.4. Ensure all locking mechanisms on the casters are functional.5. Verify that the vertical height adjustment of the column shaft moves freely without binding or scraping. |
| Battery Charger | <ol style="list-style-type: none">1. Inspect <i>all</i> cables connected to the unit: Look for cuts, cracks, or worn spots, or other obvious damage. Ensure that all connectors are properly seated.2. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.3. Inspect all parts of the wall mounting bracket for cracks or other defects that would weaken the assembly. If applicable, ensure that the bracket remains firmly attached to the wall. |
| Communication Link | <ol style="list-style-type: none">1. Inspect the cables for cuts, cracks or worn spots. Ensure that the connectors are properly seated. |

Cleaning Guidelines

Deposits of contrast media can interfere with proper operation of the *MEDRAD Spectris Solaris EP MR Injection System*. The following guidelines should be followed when removing deposits, or cleaning any portion of the system.



WARNING: Serious injury or death may result from exposure to hazardous voltages existing within the system. Disconnect the system from line power before cleaning or attempting to perform any maintenance. Ensure that the system is completely dry before connecting to the power source and applying power.

CAUTION: Improper or careless cleaning methods may result in equipment damage. Do not soak or immerse any part of the injection system in water. While cleaning any outside portion of the system, avoid allowing any water to leak inside system components.

- If contrast medium has leaked inside any component of the system, the affected subassembly should be disassembled and cleaned. This cleaning procedure can be done in the field by trained MEDRAD Service personnel, or returned to MEDRAD Service. If the cleaning will be performed in the field, do not disturb any internal wiring or components.
- Care must be taken not to get water or cleaning solutions inside any system components. Do not use strong industrial cleaning agents or solvents such as acetone. Warm water and a mild disinfectant such as antibacterial hand soap are all that is required.
- To clean the syringe interface area of the injector head, fully retract the piston. Using a paper towel moistened with warm water or a mild disinfectant, gently wipe the inner syringe installation area. Do not insert any sharp instruments into this area during the cleaning process.
- Check all System Safety and Warning Labels for legibility. Ensure that the labels are not damaged or missing.

Operational Checkout

A basic functional checkout of the *MEDRAD Spectris Solaris EP MR Injection System* should be included as part of regular maintenance. Verifying proper operation of the injection system will help in detection of any problems that may not be noticed in day to day operation. The following procedure represents a suggested series of activities which encompass typical operation of the system. Read the following procedure carefully before beginning the checkout. If problems are detected, contact MEDRAD Service.

NOTE: Any problems detected during this or any other procedure should be corrected before using the injection system in patient procedures.

System Labels

Ensure that all system safety and warning labels are in place and legible.

Power Up

Apply power to the system. Verify that the Safety screen is displayed after system diagnostics occur. Press OK to acknowledge the messages on the Safety screen. Upon power up of the CRU and SRU, verify that the indicators, lamps, and speaker are operational.

Programming

After the Main screen is displayed, verify that the following controls are functioning properly.

At the rear of the Control Room Unit, Press the **Lighten Display Contrast** key until the screen is lightened to its fullest extent. Press the **Darken Display Contrast** Key until the screen is darkened to its fullest extent. Adjust the screen appearance to return to a desirable contrast level.

Fully advance and reverse the pistons by using the ENABLE key and the forward/reverse controls. Verify that both pistons respond to the forward and reverse controls.

Enter the following protocol:

		<u>Flow Rate</u>	<u>Volume</u>
Phase 1:	Syringe A:	10 ml/s	20 ml
Phase 2:	Syringe B:	2.5	10
Phase 3:		PAUSE	5 seconds
Phase 4:	Syringe A:	5.0	10
Phase 5:	Syringe B:	0.1	1
		No Delay	
		KVO Off	

Arm in single injection mode and inject. In one of the phases, activate the HOLD feature for at least 10 seconds.

Verify that the injection completes normally.

When the injection is complete, access the Injection History screen and verify volume accuracy; actual volume and programmed volume should be the same (41 ml).

Add a 15 second inject delay to the program and activate KVO.

Install syringes and fill them with water.

Arm in single injection mode and inject.

Verify that:

- A. When the handswitch is pressed, the inject delay begins counting down.
- B. The inject delay beeps 5 times when the delay timer elapses and that the injection begins automatically at that time.

Verify that when the injection completes, KVO resumes.

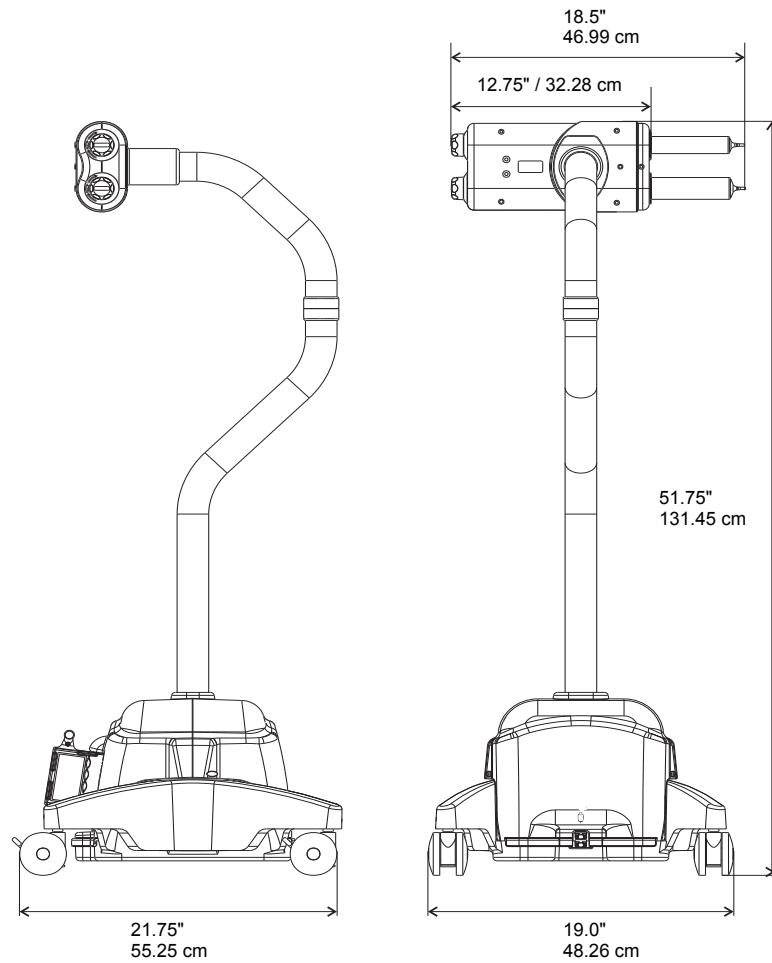
Remove and discard the syringe.

Remove power from the system.

Appendix C: Specifications

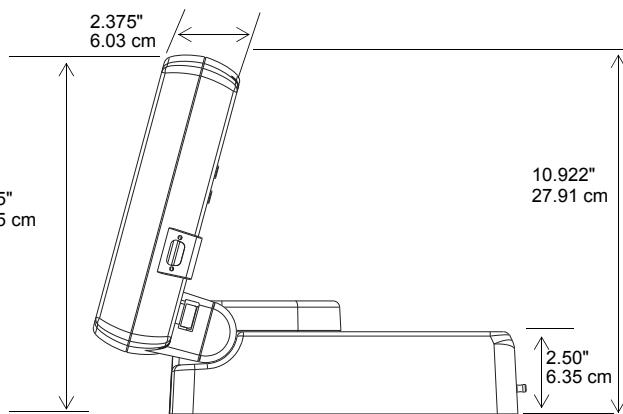
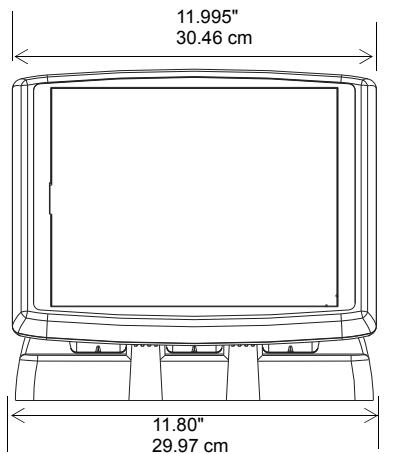
Scan Room Unit

Weight: 60 lbs. (27.3 kg.)



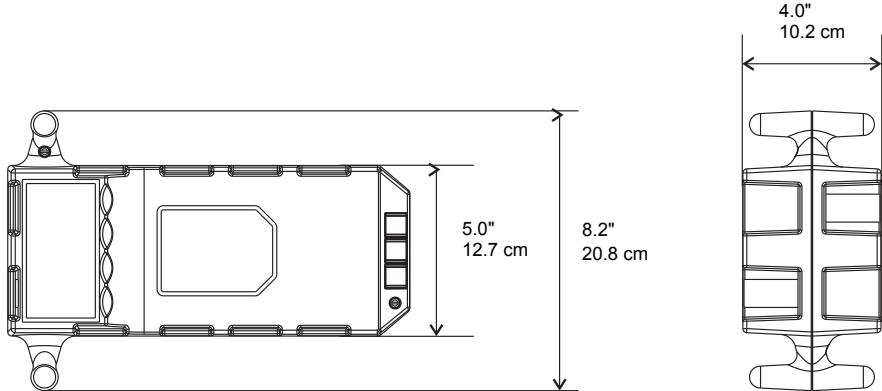
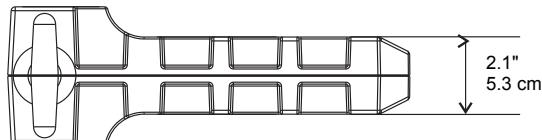
Control Room Unit

Weight: 15 lbs. (6.8 kg.)



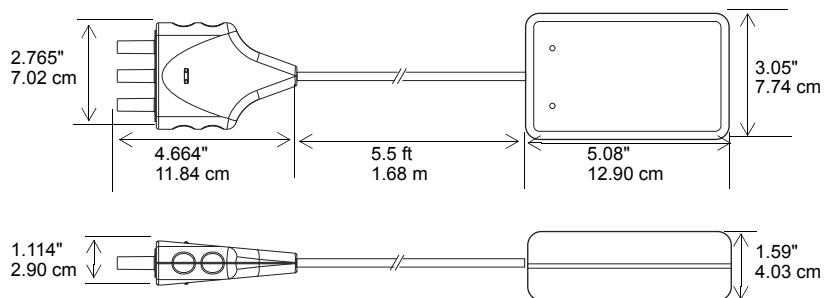
Battery Dimensions

Weight: 7.7 lbs. (3.5 kg.)



Battery Charger

Weight: 2 lbs. (0.9 kg.)



Power Cords

American 12 ft. (3.6 m), Continental 9.8 ft. (3 m)

System Capabilities

SYRINGE A:	Disposable 63 ml
SYRINGE B:	Disposable 115 ml
VOLUME:	Syringe A: 0.5 ml to max. syringe volume in: 0.1 ml increments between 0.5 and 31 ml 1 ml increments for 31 ml and above
	Syringe B: 1 ml to max. syringe volume in 1 ml increments
FLOW RATE (Programmable):	0.01 to 10 ml/s in: 0.01 ml/s increments between .01 and 3.1 ml/s 0.1 ml/s increments between 3.1 and 10 ml/s
KVO (Programmable):	15 seconds 20 seconds 0.25 ml pulsed every: 30 seconds (default) 45 seconds 60 seconds 75 seconds
PRESSURE SAFETY LIMIT:	Factory set below 325 psi (2240 kPa)
PROGRAMMABLE PRESSURE LIMIT (PSI/kPa):	100/690 150/1035 200/1380 250/1725 300/2070 325/2240 (default)
DELAY:	1 to 300 seconds in 1 second increments
PAUSE PHASE:	1 to 900 seconds in 1 second increments
INJECTION CAPABILITIES	6 phases per protocol
STORAGE CAPACITY	32 Protocols of up to 6 phases each

Protocol and User Configuration memory is maintained when system power is off.

Executable Flow Rates

These Flow Rates, with pressure safety limit set to 325psi/2240kPa, are achievable with the *MEDRAD Spectris Solaris EP MR Injection System*, using the Becton Dickinson* catheters listed below and the SSQK 65/115VS MEDRAD Syringe/Disposables Kit.

	18 g IV Catheter BD pn 381144	20 g IV Catheter BD pn 381134	22 g IV Catheter BD pn 381123	24 g IV Catheter BD pn 381112
Multihance*	7.0	5.8	4.0	2.6
Gadovist*	7.3	6.0	4.2	2.7
Magnevist*	9.0	7.2	5.2	3.2
Optimark*	9.7	7.8	5.5	3.7
Prohance*, Omniscan*	10.0	8.3	5.8	4.0
Saline	10.0	9.1	6.1	4.3

* Becton Dickinson (BD) is a trademark of Becton Dickinson, Inc.

Multihance, Gadovist, Magnevist, Optimark, Prohance, and Omniscan are trademarks of their respective companies.

System Performance

Volume Accuracy:	Syringe A: +/- (1% + 0.1 ml) Syringe B: +/- (5% + 0.1 ml)
Flow Rate Accuracy	+/- (10% + 0.005 ml/s) when rate is 0.01 to 0.99 ml/s +/- (10% + 0.02 ml/s) when rate is 1 to 10 ml/s
Programmed Delay/ Pause Accuracy	+/- (5% + 0.2 second)
Displayed Pressure Accuracy	+/- 10 psi
KVO Volume Accuracy	+/- 0.05 ml, averaged over 10 consecutive boluses
KVO Flow Rate Accuracy	1 ml/s +/- 0.2 ml/s

Forward and Reverse Controls

Low Speed: 2.5 ml/s (default)

High Speed: 10 ml/s (default)

Low speed is selectable from 1.0 to 10.0 ml/s in 0.5 ml/s increments

High speed is selectable from 1.0 to 10.0 ml/s in 0.5 ml/s increments

EMI/RFI	<p>The MEDRAD Spectris Solaris EP MR Injection System is designed to be in compliance with IEC/EN 60601-1 Second/Third Edition, EN 60601-1-2 Second Edition and IEC 60601-1-2 Second/Third Edition.</p>
Electrical Requirements	<p>100-240 VAC 50/60 Hz Scanner Room Unit (Powered by Integrated Continuous Battery Charger): 100VA Control Room Unit: 50VA</p>
Power Supply DC Output Voltage	Nominal 15.5 VDC
Electrical Leakage	Unit < 100 microamperes Patient < 10 microamperes
Ground Continuity	The resistance from the earth ground connector at the plug-end of the AC mains power cord to any exposed metal on the Control Room Unit shall be less than 0.2 ohms.
Environmental Specifications	<p>Non-Operating: (Transportation and Storage)</p> <p>Temperature: -25° C to 70° C (-13° F to +158° F) Humidity: 5% to 100% R.H. Air Pressure: 48kPa to 110 kPa (6.96 psi-16 psi)</p> <p>Operating: (The system may not meet all performance specifications if operated outside of the following conditions.)</p> <p>Temperature: +10° C to + 40° C (+50° F to +104° F) Humidity: 20% to 90% R.H., non-condensing Air Pressure: 69 kPa to 110 kPa</p>

Classifications

Protection Against Electrical Shock: Per IEC/EN 60601-1, the *MEDRAD Spectris Solaris EP MR Injection System* is designed as Class 1 equipment with Type BF applied parts.

Type BF corresponds to the degree of protection against electrical shock via the applied parts. Class 1 applies to equipment which includes a means for the connection of the equipment to protective earth in such a way that accessible metal parts cannot become live in the event of failure of basic insulation.

Flammable Anesthetics: The *MEDRAD Spectris Solaris EP MR Injection System* is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Protection Against Ingress of Fluids: Per IEC/EN 60601-1, the Scan Room and Control Room Units have been classified as drip proof equipment. The components of the *MEDRAD Spectris Solaris EP MR Injection System* Scan Room and Control Room Units are provided with an enclosure that prevents the entry of such an amount of falling liquid as might interfere with the safe operation of the injector, indicated by the IPX1 designation. The battery charger is not classified for protection against the ingress of fluids.

Mode of Operation: Per IEC/EN 60601-1 the mode of operation for the Control Room Unit is continuous operation. It will operate under normal load for an unlimited period, without excessive temperature being developed.

The Integrated Continuous Battery Charger power supply will operate under normal load for an unlimited period, without excessive temperature being developed.

The mode of operation for the Scan Room Unit is continuous operation with intermittent loading. Although power is applied to the Scan Room Unit continuously, intermittent use for loading and injecting will result in an internal temperature less than continuous load operating temperatures, but greater than no-load operating temperatures. Under normal operating conditions with a minimum of 10 minutes between injections, the internal temperature of the Scan Room Unit will not rise enough to degrade system performance or reliability.

Appendix D: Options and Accessories

		Catalog Number	Part Number
Power Cord	American Continental	SPC 300A SPC 300C	535-0243-012 535-0127-012
Integrated Continuous Battery Charger System		3012080	3012080
Battery Charger Kit		3012424	3012424
Enhanced Battery Pack		3012070	3012070
Handswitch		SSMR START	3006265
Contrast Holder Tray (optional)		CHD 100 MR CHD 400 MR	404002295 404003227
Control Room Unit Mounting System Height Adjustable Pedestal Wall Mounting Bracket		SDP 300 SDW 300	401001277 401000775
Service Manual		SSMR-SERV	200880

Appendix E: System Installation



WARNINGS:

Serious injury or death may result from exposure to hazardous voltages existing within the system. Use of an unapproved extension cord, adapter, inverter, or multi-outlet strip may compromise electrical safety. Plug the system directly into a properly grounded AC outlet or contact MEDRAD for installation assistance.

Injury or equipment damage may result from improper placement of the Battery Charger. Do not install the Battery Charger in the Scan Room. Install the Battery Charger in the Control Room, or any convenient location other than the Scan Room.

Serious injury or death can result from placing the Adjustable Height Pedestal in the Scan Room. Do not install or operate the Adjustable Height Pedestal in the Scan Room.

Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/magnet room components



CAUTIONS:

Condensation may cause electrical damage to the injection system. Do not use the system immediately after it has been brought indoors from extreme outside temperatures. Allow the system to stabilize at room temperature before use.

Damage can occur as a result of incorrect voltage. Before plugging in the system, check the following:

- Verify that the voltage and frequency marked on the serial tag on the back of the power supply matches the voltage and frequency of the electrical outlet.
- Verify that the injector has the appropriate power cord plug for the power outlet.

Damage can occur to fiber optic cabling due to mishandling during installation. Install following proper handling procedures or contact MEDRAD Service for further assistance.

Unpacking the Injection System

The entire standard configuration of the *MEDRAD Spectris Solaris EP MR Injection System* is shipped in one shipping carton. The optional Control Room Unit mounting accessories, the Adjustable Height Stand and the Wall Mounting Bracket, along with the optional IV Pole, are packaged individually and shipped in separate cartons. Prior to beginning installation, verify that the following items are present:

Standard:

- Scan Room Unit
- Control Room Unit and power cord (110V or 220V)
- Fiber Optic Interconnection Cable - 200 ft. (60.96 m)
- Battery Charging Unit and power cord (110V or 220V) - with mounting bracket and all hardware
- System Batteries (2)
- Hand Switch - with mounting bracket and all hardware
- Syringe Kit (w/ 65 and 115 ml syringes)
- Operation Manual

Optional:*

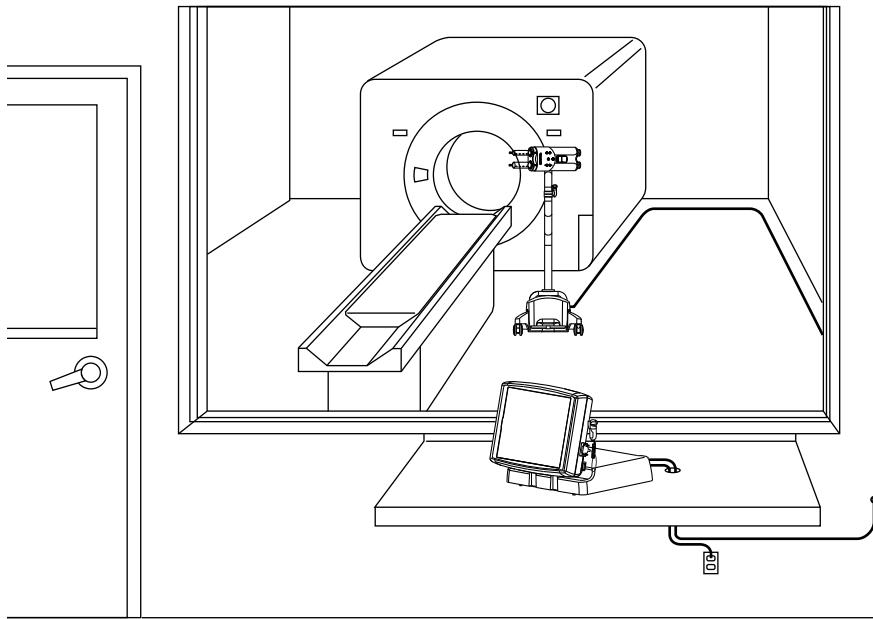
- Additional Battery Charging Unit and power cord (110V or 220V) - with mounting bracket and all hardware
- Additional System Battery
- Additional Hand Switch - with mounting bracket and all hardware
- Service Manual

Optional (packaged separately):*

- Adjustable Height Pedestal for Control Room Unit
- Wall Mounting Bracket for Control Room Unit
- IV Pole for Scan Room Unit Mounting
- Integrated Continuous Battery Charger System

*Refer to "Instructions For Use" sheets for accessory and optional equipment installation.

Installation Considerations



WARNING: Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/magnet room components.

NOTE: System Installation requires that the suite have a 1.5 inch (3.81 cm) minimum tuned port (either separate or within the penetration panel) available for connections between the Scan and Control rooms.

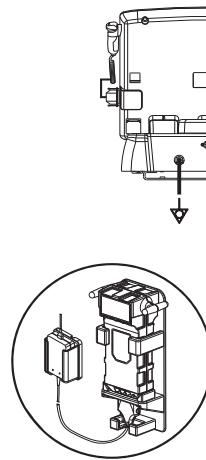
NOTE: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Tools Required: Non-magnetic #2 Phillips Head Screwdriver

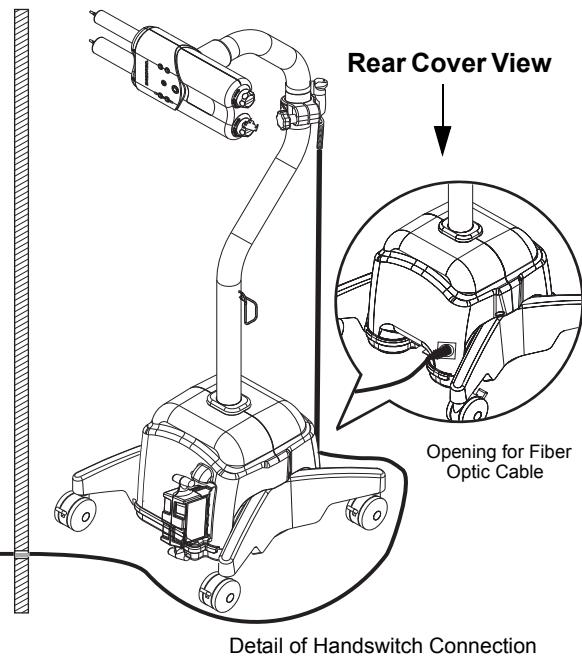
Review the following general connections prior to installing the **MEDRAD Spectris Solaris EP MR Injection System**. Be sure to consider all specifications and requirements outlined in Appendix C of this manual, and follow all applicable regulations of your locality.

NOTE: When using the Spectris Solaris EP MR Injector with a Siemens MAGNETOM Avanto 1.5T or Siemens MAGNETOM Espree 1.5T, it is recommended that the Spectris Solaris EP be placed a minimum of 18 inches from the facade of the scanner.

Control Room



Scan Room



Detail of battery Charger Assembly

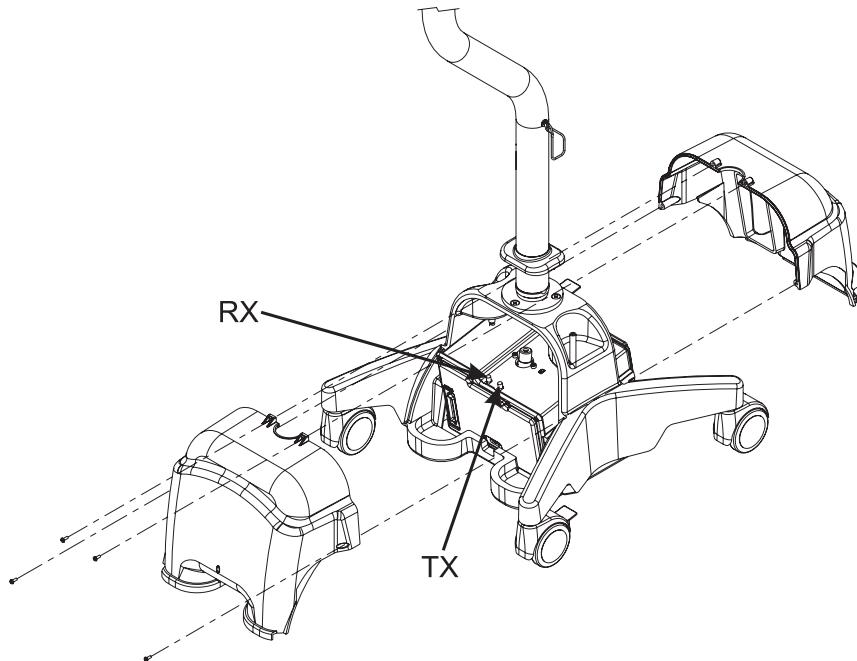
Fiber Optic Cable Installation

Connection at the Scan Room Unit:

Special care should be taken with routing the fiber optic cable to ensure:

- there is no bend radius less than 1 in. (2.54 cm)
- the connector dust caps are not removed until connections are made
- the cable does not run across any sharp edges
- the cable is run across a low traffic area of the floor
- established standards for fiber optic cabling installation should be followed if routing through conduit.

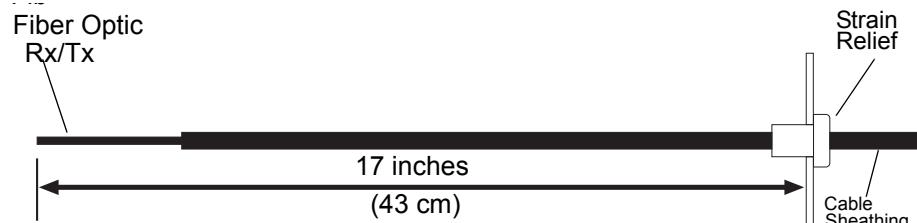
1. Remove the four screws that secure the covers to the lower console of the Scan Room Unit.



2. Install the strain relief 17 inch (43 cm) from the tip of the fiber optic cable.
3. Route the fiber optic cable (the end with the strain relief) through the hole in the lower corner of the rear console cover and snap the strain relief into the hole.
4. Remove the caps from the fiber optic cable connectors, then establish the connections at the lower console - TX to TX, and RX to RX.
5. Carefully re-position the covers on the lower console and secure with the four screws previously removed. Ensure that there are no tight bends in the fiber optic cable.
6. Gather and loop any extra fiber optic cable, then hang the loop from the cable hanger on the Scan Room Unit column.

Strain Relief Location

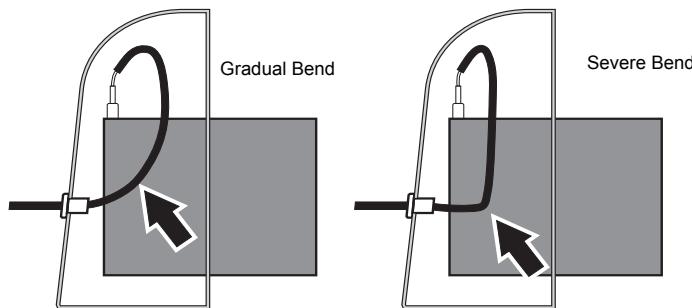
The strain relief should be placed 17" (43 cm) inches from the end of the Fiber optic connectors. This ensures there is sufficient length to maneuver the cable and minimize severe cable bends, which may damage the Fiber Optic cable.



Recommended Routing

The recommended Routing of the FO cable after it enters the SRU rear cover is as follows:

1. Route the cable to the right side of the Electric box
2. Next, route the cable up about 4-6 inches (10-15 cm).
3. Make a gradual bend and connect the FO cable to the Electronic box. (left side of drawing shows a gradual bend, right side of drawing shows a severe bend)



Cable Routing:

Route the fiber optic cable from the Scan Room Unit through the tuned port in the wall between the Scan and Control Rooms. (The tuned port may be part of the penetration panel connecting the two rooms).

NOTE: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Control Room Unit Setup

1. Position the Control Room Unit near an appropriate AC power outlet.
2. Remove the caps from the fiber optic cable connectors, then establish the connections at the rear of the Control Room Unit - TX to TX, and RX to RX.
3. Connect the Handswitch at either the Scan Room Unit, or Control Room Unit Handswitch connection port.

NOTE: Refer to the following procedure for Handswitch mounting hardware installation instructions.

4. Attach the power cord to the Control Room Unit power inlet.
5. If required by local codes, connect the optional equal potential cable to

the equal potential stud, and the equal potential bus.

6. Plug the AC power cord into an appropriate AC power outlet.
7. Insert a fully charged system battery in the Scan Room Unit battery receptacle
8. Apply system power at the Control Room Unit power switch, then perform an system operation checkout as outlined in Appendix B of this manual.

Handswitch Mounting

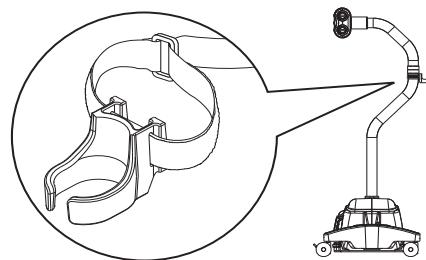
To allow convenience in use, the handswitch mount can be mounted in one of the following ways:

On the wall:

Attach the mount to the bracket using the two screws supplied. Apply the supplied double sided adhesive tape to the back of the solid side (without holes) of the mounting bracket. Affix the mount/bracket assembly to a properly primed wall to ensure maximum adhesion.

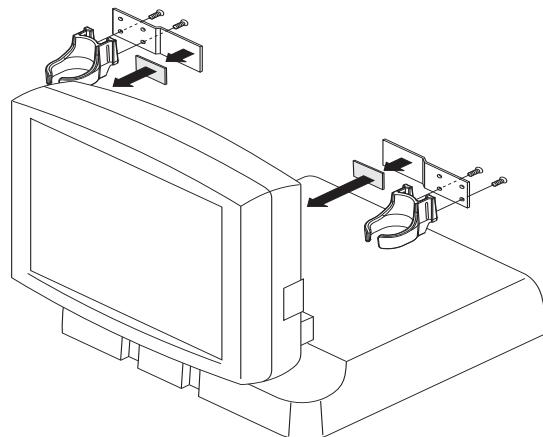
On the Scan Room Unit:

Route the supplied strap through the recesses in the back of the mount. Secure the mount and strap to the upright column of the Scan Room Unit.



On either side of the Control Room Unit:

Determine which side of the unit the mount and bracket will be attached to. Secure the mount to the bracket using the two screws supplied. Apply the supplied double sided adhesive tape to the front of the solid side (without holes) of the mounting bracket. Affix the mount/bracket assembly to the backof the Control Room Unit display.





CYBERKNIFE I.T GUIDE

WI 1022517

REV C

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APPROVAL

DEPT. MANAGER: B. TIEN

DATE: See Agile

Revision History

Rev.	ECO #	Description of Change	Revised By	Date
A	7152	Initial Release.	T. Chieng J. Moran	12/17/12
B	7421	Delete additional Definitions section and minor corrections.	T.Chieng	4/10/13
C	ECO-00292	Added section 8 on Patient Archiving. Updated section 9 on Disaster Recovery. Fixed CK 10.X network diagram. Fixed typos and minor corrections.	T.Chieng	3/20/14

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1 Purpose

- 1.1 The purpose of this document is to create an overview of the CyberKnife network as reference for Hospital IT departments, Accuray Installation & Site Planning departments, and Accuray Field Service – CyberKnife.
- 1.2 This document is applicable to CyberKnife version 8.x and higher.

2 Responsibilities

- 2.1 Field Service – CyberKnife is responsible for updating and maintaining this document.

3 Definitions

- 3.1 CDMS: CyberKnife® Data Management System: The subsystem that manages the data of the CyberKnife.
- 3.2 UCC: User Control Console. The computer that performs treatment delivery on patients.
- 3.3 VLAN: Virtual Logical Area Network. An OSI model layer 3 construct designed to separate one network into many logical networks. CyberKnife networks have switches using VLANs to separate critical devices (e.g. CDMS, UCC) from non critical treatment devices (e.g. MultiPlan).

4 Reference Documents

- 4.1 WI 1024437A CK10.X NETWORK INSTALL AND CONFIGURATION

5 CyberKnife® System Network

5.1 Description

The Accuray CyberKnife® Robotic Radiosurgery System is an FDA cleared medical device. As such, we are limited in what changes we can allow to the approved configuration of the system, which includes all internal connections and networking which allow the system to operate properly. All devices that are a part of the CyberKnife® System should be considered as a black box environment and part of an approved, tested configuration.

The CyberKnife® System is composed of several computers running Windows and Red Hat© Enterprise Linux operating systems. They are connected to a managed switch, which contains the traffic of the various devices within various VLANs. The switch is attached to a router, which connects the CyberKnife® System to the hospital network. The Treatment Planning devices may be connected to the CyberKnife® System or to the hospital.

Imposing any specific controls on the connection to the CyberKnife® System will be at the full discretion of the hospital, however, the CyberKnife® System devices themselves cannot be modified, and the requirements listed under section 15 must be fulfilled to maintain full operation of the CyberKnife® system. Accuray will abide with hospital policies to the point that the system configuration is not changed.

If you have any questions or feedback regarding the CyberKnife® System, or about this document specifically, please contact Accuray Customer support by email at customersupport@accuray.com or by calling **1.877.668.8667**.

5.2 System Overview

The CyberKnife® LAN contains the following parts:

- UCC: User interface to Treatment Delivery System
- IFCC: Controls communications between robot and Linear Accelerator.
- MTS: Synchrony (motion tracking)
- TLS: Imaging System
- CDMS Data Server: Database server
- MultiPlan™ (may exist outside LAN)
- MD Suite™ (optional, may exist outside LAN)

5.3 Network Overview

The CyberKnife® System network configuration is controlled by two devices:

<u>CK 9,x Network Hardware</u>	<u>CK 10,x Network hardware</u>
<ul style="list-style-type: none"> • <u>Cisco ASA 2821 Firewall</u> • <u>HP ProCurve 2824 Switch</u> 	<ul style="list-style-type: none"> • <u>Cisco ASA 5510 Firewall</u> • <u>Cisco 2960 Switch</u>

The Cisco router/firewall contains rule lists that separate the hospital LAN from the CyberKnife® System LAN, so as to prevent computers not explicitly allowed with CyberKnife® System treatments from accessing the CyberKnife® System LAN.

The network switch uses VLANs to divide its ports. VLANs allow for a higher degree of control in the CyberKnife® System LAN, and it separates the user devices, such as MultiPlan™, from the control devices, such as the CDMS Data Server.

In one treatment network, there are three VLANs: the primary VLAN 185, the secondary VLAN 184, and the CDMS VLAN 183. The primary VLAN contains the treatment delivery system, whereas the secondary VLAN contains all the user devices, like MultiPlan, and finally, the CDMS VLAN only contains the CDMS. The use of VLANs provides another layer of security for the CyberKnife® System LAN, however, it adds a restriction where each device connects to a specific port on these switches.

Each network device uses Category 6 Ethernet cables, to provide up to 1 Gbps, or 1000 Mbps, bandwidth.

Each network has special port-forwarding rules to allow the communication of various devices within the CyberKnife® network with devices located on the hospital LAN:

Hospital traffic (Local)

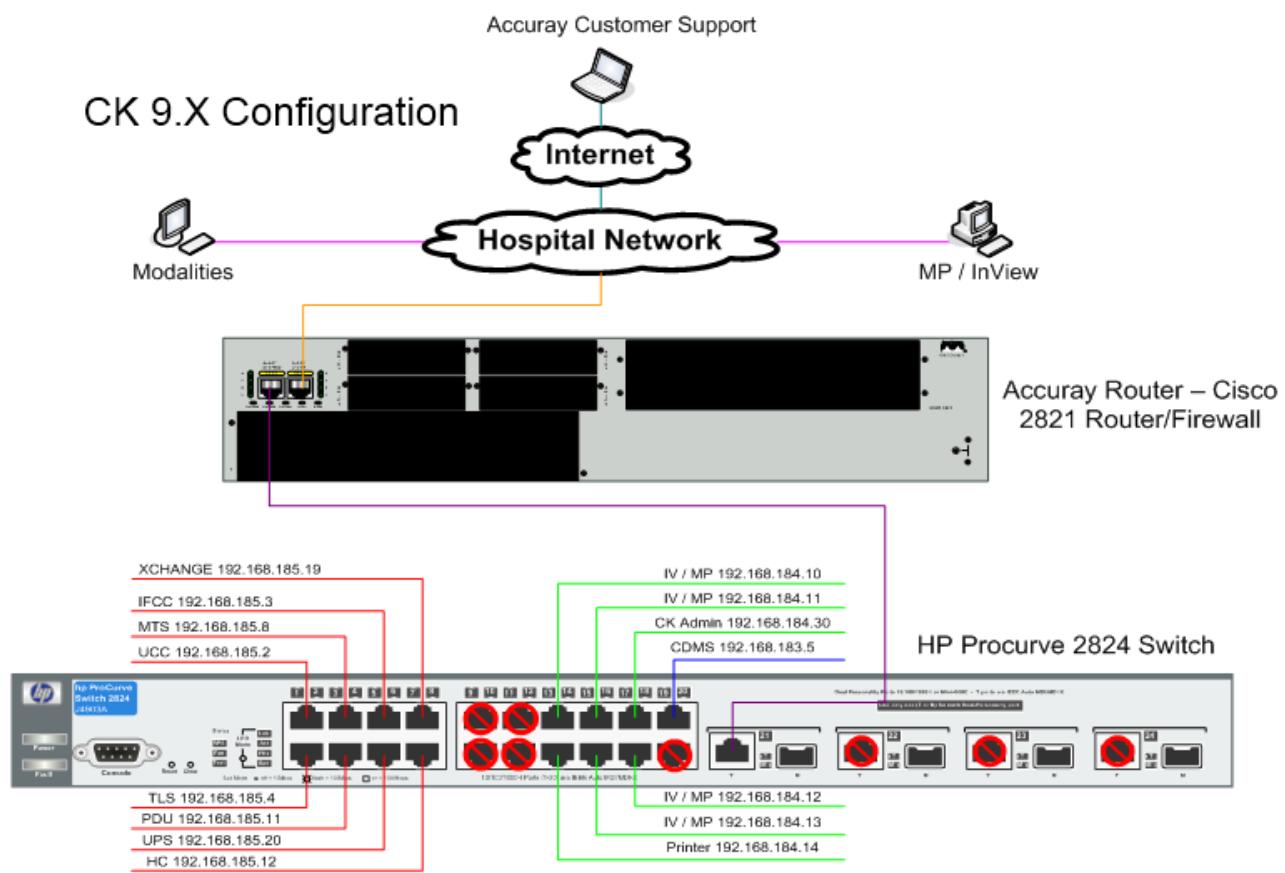
- DICOM: Medical image transfer with CyberKnife® System devices and hospital modalities, e.g., PACS, CT, PET, etc.
 - Traffic is initiated either inbound or outbound, based on the initiator of the traffic.
 - Uses TCP/104.
- CDMS: Stores and retrieves all CyberKnife® System related data, including planning/treatment.
 - Traffic is initiated inbound to the CyberKnife Data Management System.
 - Uses TCP/4000-4099. Primary port is TCP/4027.

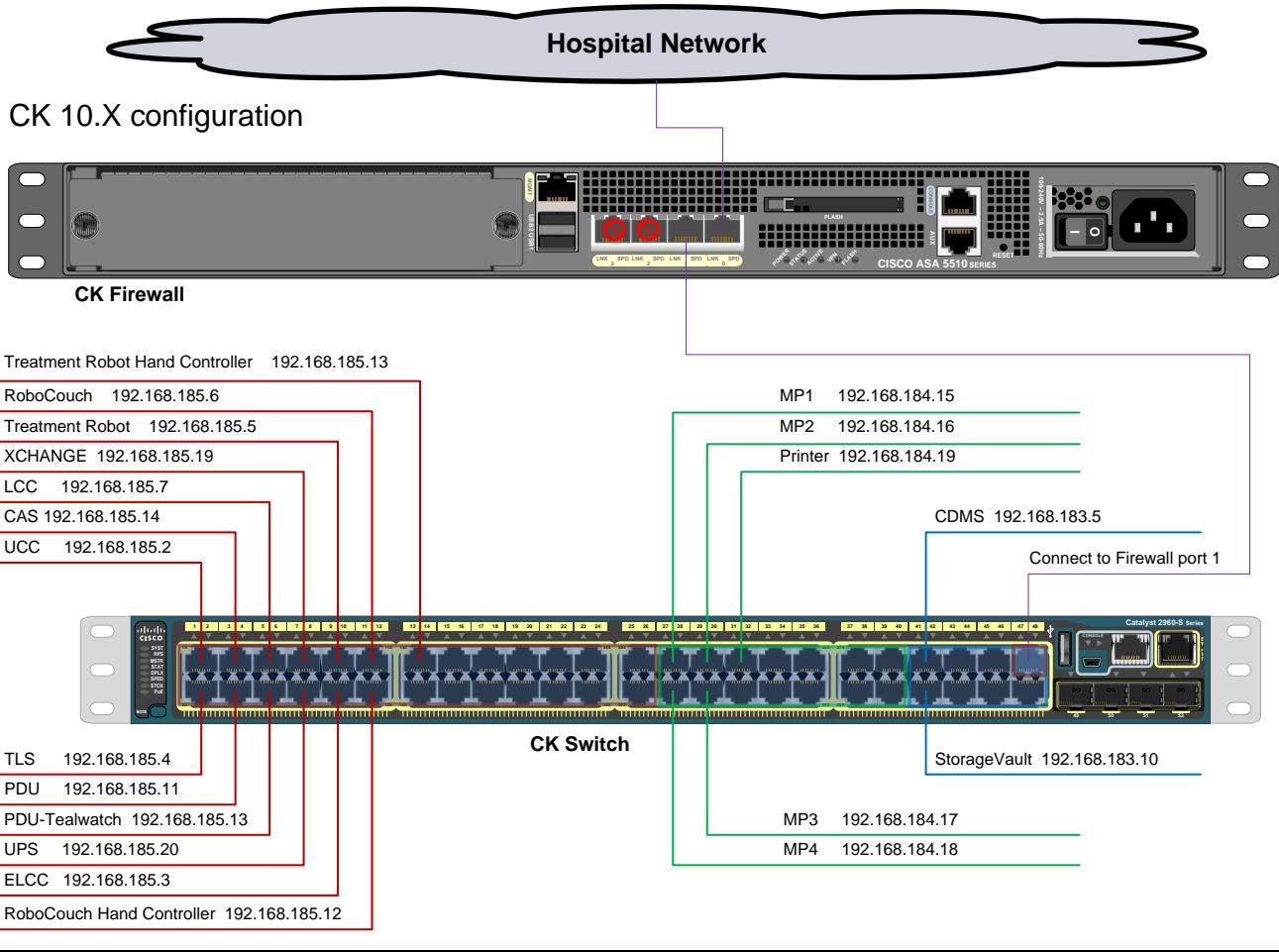
- OIS: Oncology information systems
 - Traffic is initiated outbound to OIS devices.
 - Uses configurable Port Addresses per vendor.
- Miscellaneous: FTP, telnet and SSH access to the treatment delivery system.
 - Traffic is initiated inbound to CyberKnife® System.
 - Uses TCP/21 for FTP, TCP/22 for SSH, and TCP/23 for telnet.

Internet traffic (Remote)

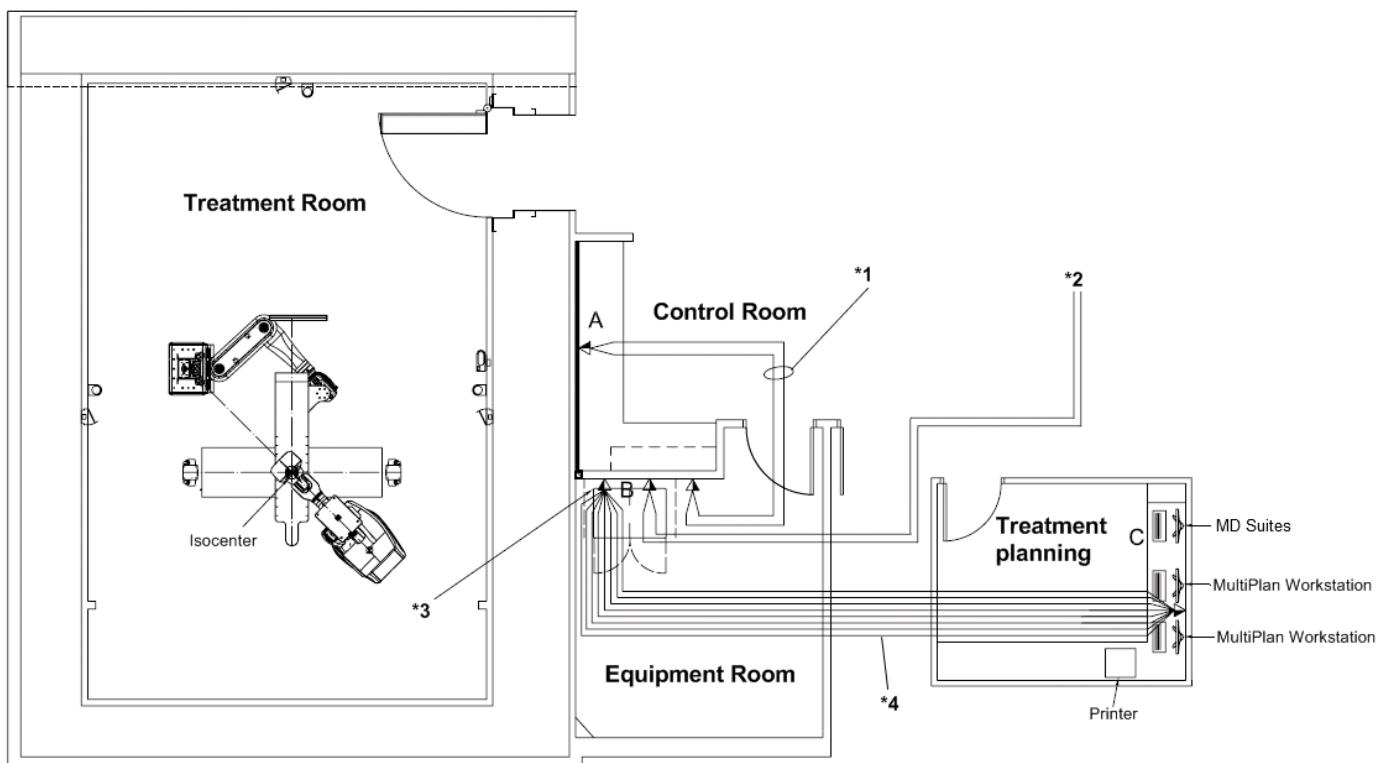
- FTP: Transfers diagnostic files from the CyberKnife® System to Accuray for diagnostics and troubleshooting purposes over an encrypted channel.
 - Secure FTP is initiated outbound to ftps.accuray.com.
 - The public address assigned to ftps.accuray.com is 67.108.13.71.
 - FTPS transfers data in passive mode on TCP/990, 2000 - 2011.
- Symantec Anti-virus definition updates: Provides anti-virus definition update services to Symantec anti-virus clients installed on Multiplan and MD Suite planning workstations.
 - Traffic is initiated outbound to araysep.accuray.com.
 - The public address assigned to araysep.accuray.com is 67.108.13.94
 - Uses TCP/443 or TCP/8014.
- CyberKnife Access™ Remote Service: Provides real time remote access to support the CyberKnife® System remotely.
 - Traffic is initiated outbound to www.cyberknifeaccess.com.
 - The public address assigned to www.cyberknifeaccess.com is 209.202.167.23.
 - Uses TCP/443 or TCP/17002.
- MultiPlan® Remote Access: Accuray and/or authorized hospital personnel can connect to planning stations remotely, and perform necessary planning tasks.
 - Traffic is initiated outbound to www.gotomypc.com and poll.gotomypc.com
 - The public address assigned to www.gotomypc.com is 66.151.158.183.
 - The public address assigned to poll.gotomypc.com is 66.151.158.177.
 - Uses TCP/443 or TCP/8200.
- GoToAssist: Accuray Customer Support personnel may log in remotely, with customer's permission, to access the system to diagnose and troubleshoot issues that may occur.
 - Traffic is initiated outbound to www.gotoassist.com and broker.gotoassist.com.
 - The public address assigned to www.gotoassist.com is 216.115.210.200.
 - The public address assigned to broker.gotoassist.com is 216.115.210.202.
 - Uses TCP/443 or TCP/8200.

5.4 CyberKnife® System Network Configuration





5.5 CyberKnife® System Treatment Network Plan



CyberKnife® System Network Plan Notes:

1. Patched connections from equipment room to control room for field service access and spare.
2. Connection to facility network. Two (2) direct connections (RJ-45 drops) from hospital switch to equipment room. 1 Gbps recommended.
 - a. Connection 1 patched into Cisco router. Provides inbound and outbound communications to/from hospital modalities.
 - b. Connection 2 left as spare or patched into Control Room for field service engineer's access.
3. Router/firewall and switch in 19" rack. (Location may vary. Accuray supplied)
4. 8 direct connections for MultiPlans, Administration Workstation (optional), MD Suites, Printer, and future upgrades.
5. Use Category 6 cabling for 1 Gbps (1000 Mbps) connectivity.
6. Require 3 static IP address for:
 - a. Treatment Network (Forwarding IP)
 - b. Firewall Management
 - c. Field service connectivity

6 Internal Networking Port Diagram

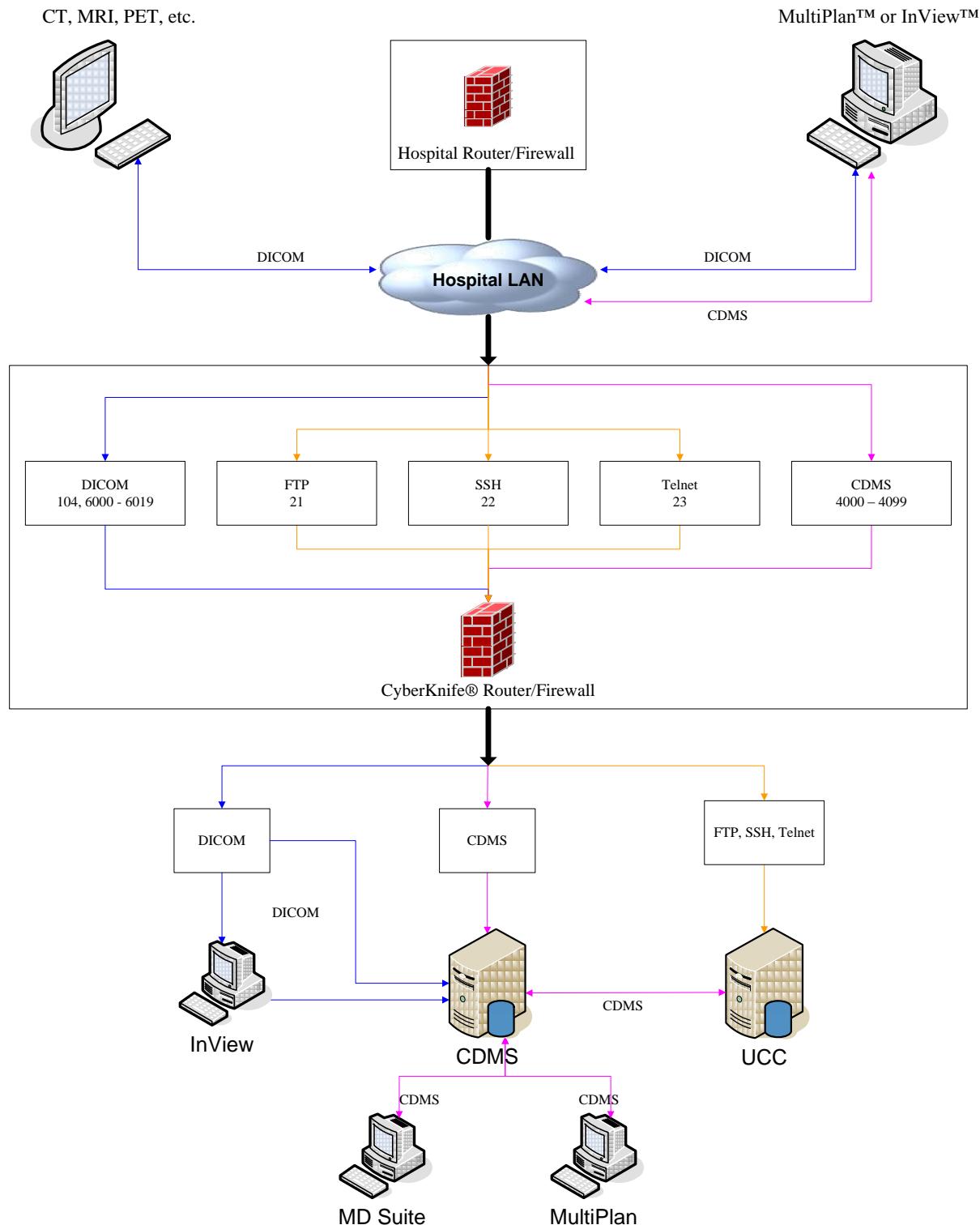


Figure 3.1 – CyberKnife® Network Port Flow Diagram – Incoming

Figure 3.1 shows which ports and protocols that the router forwards to the appropriate device. Please note Accuray supports the MultiPlan, InView and MD Suite devices either being inside and/or outside the CyberKnife® System network.

7 CyberKnife® Data Management System

The CyberKnife® Data Management System (CDMS) provides patient data management to the CyberKnife Systems. CDMS provides applications that allow the user to add, access, modify, export, delete, and validate CyberKnife patient-related data.

The CyberKnife® Data Management System includes the following components:

7.1 Data Server

The data server hosts the CyberKnife® System database, DICOM server, and DRR Generation server. All of the data on this server pertains to currently active patients. It is located in the Equipment Rack in the Equipment Room.

The CyberKnife® System Data Server is configured with two sets of redundant hard drives, or volumes. Each volume is in RAID 5 (Interleaved Parity) configuration for redundancy in case of hard drive failure:

1. 600 GB volume for live database and OS
2. 1000 GB (1 TB) volume for database backups.

The CyberKnife specific data on the first volume is backed up to the second volume every two hours for the purposes of data redundancy.

The Data Server supports the Disaster Recovery solution.

7.2 Administration Workstation (option)

The Administration Workstation (Admin Workstation) option includes a computer, monitor, keyboard, and mouse. The Admin Workstation includes a suite of applications to manage and interface with the data on the Data Server. (These applications are also installed with the MultiPlan and MD Suite workstations.) The suite of applications provides the following functionality:

1. User Administration
2. DICOM Administration
3. Patient Record Archive and Restore
4. Patient Administration
5. Image Review and Import
6. Beam Data Import
7. Plan Administration
8. Report Administration
9. System Administration

The Administration Workstation can be specified as a network storage location for patient archiving since it contains a redundant volume, RAID 10, with approximate total of 1 TB (1000 GB) storage. The Admin Workstation may be located anywhere based on the needs of the site, although it is recommended to be located on the CyberKnife network.

The Administration Workstation supports the Disaster Recovery solution.

7.3 Storage Vault (option)

The Storage Vault option is a set of features for the management of CyberKnife data. It includes a professional grade network attached storage (NAS) device, called the Vault, with approximately 10 TB (10,000 GB) of fault-tolerant storage space. This device is designed to operate with the CyberKnife, and is not meant as an external means of storage.

The Storage Vault will intelligently determine if the CyberKnife is running out of space, and will move the patient record off the CyberKnife onto the Vault. If the patient record is needed later, the system will automatically move it back to the CyberKnife. The records can be moved manually, if so desired. Thus, there is virtually no need to move patient records. However, patient records can be moved to an external network storage location as desired, or if the Vault is filled up with patient records.

The Storage Vault supports the Disaster Recovery solution.

8 Patient Record Archiving

Patient record archiving is the process of moving a patient record from active state (on data server) to archive state (on network shared folder) once treatment has completed for that specific patient; thus, freeing up space on the data server for new patients.

For sites without an admin workstation or storage vault, it is a requirement during planning stages to consult with hospital IT staff to allocate space on their servers for patient archiving. We recommend an initial minimum of 1 TB for this purpose. For sites with an admin wkstn and/or storage vault, this requirement can be delayed until needed.

9 Disaster Recovery

The Disaster Recovery solution is a built-in feature that provides data mirroring of critical devices in the CyberKnife system to hospital or facility network resources. Although not a requirement, we recommend sites implement disaster recovery to protect against data loss due to hard drive or system failures. Refer to the table below for configuration and space requirements. (Note that this space requirement is in addition to the space requirement for patient archiving noted above.)

Configuration	Space Required
System without Admin Wkstn and Storage Vault	1 TB
System with Admin Wkstn	2 TB
System with Admin Wkstn and Storage Vault	Up to 12 TB
System with Storage Vault	Up to 11 TB

Once provided with the network location and credentials, the Disaster Recovery solution will be configured on each critical machine, which will provide a quick path to recovery from a disaster scenario.

10 DICOM

The DICOM 3 Conformance Statement for the CyberKnife® System can be obtained by contacting Accuray Customer support and requesting the latest revision to document P/N 019055.

The following is a list of supported image studies:

Type	Supported Patient Positions
Computed Tomography (CT)	Axial HFS, FFS, HFP, FFP
Magnetic Resonance (MR)	Axial HFS, Sagittal HFS, Coronal HFS
Positron Emission Tomography (PET)	Axial HFS
X-Ray Angiography (XA)	Axial HFS, Coronal HFS

11 Remote Workstations

MultiPlan and MD Suite workstations located externally from the hospital network have additional requirements due to the amount of data it needs to process and move within the network defined by a minimum of 5 MB/s throughput from the device's location to the CyberKnife router. This requirement is necessary for MultiPlan and MD Suites to be able to save plans without running into timeout issues.

12 Customer Support Remote Assistance

Citrix GoToAssist® is an Accuray solution to provide remote assistance for the CyberKnife™. It provides a remote desktop connection via an encrypted connection between the machine and the Accuray Customer Support Representative.

Please go to <http://www.gotoassist.com> to find more detailed information, which includes additional information on GoToAssist, including networking information, and HIPAA compliance.

13 CyberKnife Access™

The CyberKnife Access™ remote service will enable Accuray Customer Support to proactively monitor, diagnose and repair device problems remotely, resulting in an increase in system uptime by decreasing the time required to detect and resolve reported system problems. In addition, remote servicing will enhance the ability to detect root causes of a device failure, providing Accuray Customer Support the ability to anticipate and resolve potential issues before they affect the clinical workflow.

14 MultiPlan® Remote Access

MultiPlan® Remote Access offers remote tools that allow users to remotely run the MultiPlan Treatment Planning System from any location. Remote tools provide enhanced communication capabilities and are giving CyberKnife® centers the ability to collaborate and outreach to remote facilities and physicians. Ultimately these operational improvements are helping to maximize utilization and the bottom-line for our customers.

15 Networking Requirements

The following network requirements are necessary to achieve a fully functional CyberKnife® System.

Accuray requirements:

1. Accuray will abide by all hospital IT policies so as to maintain the CyberKnife® System operation. Accuray will send a statement in case any policy/policies affect any features in any manner.
2. Accuray will provide the hospital IT department with required CyberKnife® System network information.
3. Accuray will assist hospital in DICOM image transfer connectivity issues from the CyberKnife® System LAN to any hospital modality.

Hospital IT Department requirements:

1. Two static IP addresses per CyberKnife® System. One address is for the CyberKnife® System Forwarding IP address, the second address is for CyberKnife® System router management. Both of these IP addresses require one physical port.
2. One physical port with internet access for the Field Service Engineer for remote connectivity.
3. Various remote services require access to specific public IP addresses. These services require the following outbound IP addresses and ports to be opened on the hospital gateway:

Name	Description	IP Address	Ports
FTP (deprecated)	Nonsecure FTP Remote Diagnostics	67.108.13.69	TCP/21
Secure FTP	Secure FTP Remote Diagnostics	67.108.13.71	TCP/990 TCP/2000-2011
Anti-Virus Updates	Symantec anti-virus definition updates	67.108.13.94	TCP/443 TCP/8014
CyberKnife Access™	CyberKnife Access™ Remote Diagnostics	209.202.167.23	TCP/443 TCP/17002
MultiPlan® Remote Access	Treatment Planning Services	66.151.158.177 66.151.158.183	TCP/8200 TCP/443 TCP/80
GoToAssist	GoToAssist Remote Diagnostics	216.115.210.200 216.115.210.202 216.115.208.0 /20 216.219.112.0 /20 66.151.158.0 /24 66.151.150.160 /27 66.151.115.128 /26 64.74.80.0 /24 202.173.24.0 /21 67.217.64.0 /19 78.108.112.0 /20	TCP/443 TCP/80 TCP/8200

4. Provide Accuray with the network configuration information listed in the Network Configuration section, to allow Customer Service to diagnose and troubleshoot issues.
5. Inform Accuray Customer Support (**customersupport@accuray.com**, **1.877.668.8667**) when a network change may cause connectivity between any hospital modalities and the CyberKnife® System LAN to be inoperable.

Appendix - Network Configuration

Accuray Sales – General, Site Planning and Installation in conjunction with Hospital IT:

Please fill out the entries below to document your site configuration. Please submit this document to the appropriate site planner prior to installation.

Contact Information

Equipment Room Number: ()	-	Name: _____
Treatment Room Number: ()	-	Phone: _____
Control Area Number: ()	-	E-Mail: _____

Network Settings

<u>Hospital Connection</u> <i>(circle appropriate connection type)</i>				<u>IP Addresses</u>
LAN	T1	DSL	Cable	Forwarding IP Address: _____
Other	_____			Management IP Address: _____
				Field Service IP Address: _____
				Hospital Subnet Mask: _____
				Hospital Gateway IP: _____

Additional Devices (that will reside on hospital network)

<u>Modality</u> <i>(circle appropriate)</i>			<u>IP Address</u>
MultiPlan	MD Suite	Admin Workstation	Printer _____
MultiPlan	MD Suite	Admin Workstation	Printer _____
MultiPlan	MD Suite	Admin Workstation	Printer _____
MultiPlan	MD Suite	Admin Workstation	Printer _____

Disaster Recovery and Patient Archival Storage

<u>Network Credentials</u>	<u>Network UNC Path</u>
_____	_____
_____	_____
_____	_____

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American Association of Physicists in Medicine

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AAPM's TG-51 protocol for clinical reference dosimetry of high-energy photon and electron beams

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A protocol is prescribed for clinical reference dosimetry of external beam radiation therapy using photon beams with nominal energies between ^{60}Co and 50 MV and electron beams with nominal energies between 4 and 50 MeV. The protocol was written by Task Group 51 (TG-51) of the Radiation Therapy Committee of the American Association of Physicists in Medicine (AAPM) and has been formally approved by the AAPM for clinical use. The protocol uses ion chambers with absorbed-dose-to-water calibration factors, $N_{D,w}^{^{60}\text{Co}}$, which are traceable to national primary standards, and the equation $D_w^Q = M k_Q N_{D,w}^{^{60}\text{Co}}$, where Q is the beam quality of the clinical beam, D_w^Q is the absorbed dose to water at the point of measurement of the ion chamber placed under reference conditions, M is the fully corrected ion chamber reading, and k_Q is the quality conversion factor which converts the calibration factor for a ^{60}Co beam to that for a beam of quality Q . Values of k_Q are presented as a function of Q for many ion chambers. The value of M is given by $M = P_{\text{ion}} P_{\text{TP}} P_{\text{elec}} P_{\text{pol}} M_{\text{raw}}$, where M_{raw} is the raw, uncorrected ion chamber reading and P_{ion} corrects for ion recombination, P_{TP} for temperature and pressure variations, P_{elec} for inaccuracy of the electrometer if calibrated separately, and P_{pol} for chamber polarity effects. Beam quality, Q , is specified (i) for photon beams, by $\%dd(10)_x$, the photon component of the percentage depth dose at 10 cm depth for a field size of $10 \times 10 \text{ cm}^2$ on the surface of a phantom at an SSD of 100 cm and (ii) for electron beams, by R_{50} , the depth at which the absorbed-dose falls to 50% of the maximum dose in a beam with field size $\geq 10 \times 10 \text{ cm}^2$ on the surface of the phantom ($\geq 20 \times 20 \text{ cm}^2$ for $R_{50} > 8.5 \text{ cm}$) at an SSD of 100 cm. R_{50} is determined directly from the measured value of I_{50} , the depth at which the ionization falls to 50% of its maximum value. All clinical reference dosimetry is performed in a water phantom. The reference depth for calibration purposes is 10 cm for photon beams and $0.6R_{50} - 0.1 \text{ cm}$ for electron beams. For photon beams clinical reference dosimetry is performed in either an SSD or SAD setup with a $10 \times 10 \text{ cm}^2$ field size defined on the phantom surface for an SSD setup or at the depth of the detector for an SAD setup. For electron beams clinical reference dosimetry is performed with a field size of $\geq 10 \times 10 \text{ cm}^2$ ($\geq 20 \times 20 \text{ cm}^2$ for $R_{50} > 8.5 \text{ cm}$) at an SSD between 90 and 110 cm. This protocol represents a major simplification compared to the AAPM's TG-21 protocol in the sense that large tables of stopping-power ratios and mass-energy absorption coefficients are not needed and the user does not need to calculate any theoretical dosimetry factors. Worksheets for various situations are presented along with a list of equipment required. © 1999 American Association of Physicists in Medicine.

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I. PREFACE

Advances in radiation dosimetry continue to improve the accuracy of calibrating photon and electron beams for radiation therapy. This document represents the third in a series of protocols adopted by the AAPM and represents a radical departure from the two previous generations. The earlier protocols were based on measurements using ion chambers with dose being derived by applying Bragg–Gray or Spencer–Attix cavity theory. In the first generation protocols, calibration laboratories provided exposure calibration factors for ion chambers in ^{60}Co beams and users needed to look up a simple table of dose conversion factors versus nominal energy for either an x-ray or an electron beam.^{1,2} The procedure was simple because there were no special considerations in these factors for either the type of chamber used or the actual quality of the beam. Omission of some of these considerations led to errors in beam calibrations of up to 5%. In the second generation of protocols, e.g., the AAPM's TG-21 protocol published in 1983,^{3–5} many of these problems were reduced at the expense of added complexity. The accuracy of dose calibration was considerably better, but it required complex calculations, especially for the chamber-dependent factors and their variation with beam quality. These complexities themselves meant an increased potential for errors in the clinic.

The protocol being introduced, TG-51, still uses ion chambers as the basis for measurements, but requires absorbed dose to water calibration factors. As a result, it is conceptually easier to understand and simpler to implement than the earlier protocols. In the last decade, the major em-

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phasis in primary standards laboratories has moved from standards for exposure or air kerma to those for absorbed dose to water since clinical reference dosimetry is directly related to this quantity, and also because primary standards for absorbed dose can be developed in accelerator beams, unlike exposure or air kerma standards. Standards for absorbed dose to water have an uncertainty (1σ) of less than 1% in ^{60}Co and bremsstrahlung beams up to 25 MV (see, e.g., Refs. 6–9). It is appropriate to have a protocol that allows incorporation of this improved accuracy. These improvements are accomplished in this third generation protocol which is based on the use of ion chambers calibrated in terms of absorbed dose to water in a ^{60}Co beam.^{10–13}

Clinical reference dosimetry based on ^{60}Co absorbed-dose calibration factors requires a quality conversion factor, denoted k_Q , and these factors have been calculated using Spencer–Attix cavity theory for the majority of cylindrical ionization chambers currently in clinical use for reference dosimetry. Determination of k_Q factors for electron beams is more complex than for photon beams since there is a change in modality as well as energy, and some dependence on the gradient in the user's beam. The protocol has been written in such a way as to allow future incorporation of measurements with primary standards of absorbed dose in accelerator beams.

An important point in this protocol is that clinical reference dosimetry must be performed in a water phantom. Reference dosimetry measurements in plastics, including water-equivalent plastics, are not allowed. This is to ensure simplicity and accuracy in the protocol since the quantity of

interest is absorbed dose to water. This point does not preclude the use of plastic materials for more frequent quality assurance checks, provided a transfer factor has been established, but does require that in-water calibrations be performed at least annually.

This protocol also differs in one other significant respect from its predecessor. Whereas the TG-21 protocol combined both the theory and practical application in the same document, this protocol serves only as a "how to" document that will lead the medical physicist through all the steps necessary to perform clinical reference dosimetry for a given photon or electron beam. There are separate worksheets for photon and electron beam dosimetry.

Under the assumption that TG-21 correctly predicts the ratio of absorbed-dose to air-kerma calibration factors, it is not expected that implementation of this protocol will change the results of clinical reference dosimetry in photon beams by more than roughly 1% compared to those assigned following TG-21³ for measurements in water. Slightly larger changes can be expected at d_{\max} in electron beams because this protocol uses more accurate procedures regarding stopping-power ratios in realistic clinical electron beams and also takes into account the improvements provided by the TG-39 protocol for plane-parallel chambers.¹⁴

II. NOTATION AND DEFINITIONS

All quantities shall be reported in SI units.

This protocol is based on the use of a set of physical data which is consistent with that used in US and Canadian primary standards laboratories. In particular, electron stopping powers are based on those developed at NIST and recommended in ICRU Report 37.¹⁵

% $dd(10)_x$: the photon component of the photon beam percentage depth-dose at 10 cm depth in a $10 \times 10 \text{ cm}^2$ field on the surface of a water phantom at an SSD of 100 cm (see Sec. VIII B).

% $dd(10)$: the measured photon beam percentage depth-dose at 10 cm depth in a $10 \times 10 \text{ cm}^2$ field on the surface of a water phantom at an SSD of 100 cm. % $dd(10)$ includes the effects of electron contamination in the beam, whereas % $dd(10)_x$ does not. % $dd(10)$ is measured in an open beam.

% $dd(10)_{\text{Pb}}$: same as % $dd(10)$ except that a 1 mm lead foil is in place below the accelerator at about 50 cm from the phantom surface (or 30 cm if 50 cm clearance is not available).

clinical reference dosimetry: determination of absorbed dose to water per MU under reference conditions in the clinic.

D_w^Q : the absorbed dose to water for a given number of monitor units (or minutes for ^{60}Co) from a radiation beam of quality Q . Unit: gray, Gy.

d_{\max} : the depth at which the absorbed dose to water (not ionization) is a maximum for a given beam. In photon beams it may include effects of electron contamination in the incident beam. Unit: cm.

d_{ref} : the reference depth for electron beams given as $d_{\text{ref}} = 0.6R_{50} - 0.1$, where R_{50} is in cm. Unit: cm.

I_{50} : the depth in an electron beam at which the gradient-corrected ionization curve falls to 50% of its maximum (see Sec. VIII C). Unit: cm.

k_Q : the quality conversion factor, which accounts for the change in the absorbed-dose to water calibration factor between the beam quality of interest, Q , and the beam quality for which the absorbed-dose calibration factor applies (usually ^{60}Co) [see Eq. (2)]. k_Q is a function of the beam quality Q [specified by % $dd(10)_x$ or R_{50}] and is chamber dependent. For ^{60}Co beams $k_Q = 1.000$.

$k_{R_{50}}$: the component of k_Q in an electron beam which is independent of the ionization gradient at the point of measurement (i.e., $k_Q = k_{R_{50}} P_{gr}^Q$, see Secs. IV and XB). $k_{R_{50}}$ is a function of the electron beam quality specified by R_{50} .

$k'_{R_{50}}$, k_{ecal} : the electron quality conversion factor and photon-electron conversion factor respectively. For electron beams, $k_{R_{50}} = k'_{R_{50}} k_{\text{ecal}}$ where k_{ecal} is needed to convert $N_{D,w}^{^{60}\text{Co}}$ into an electron beam absorbed-dose calibration factor $N_{D,w}^{Q_{\text{ecal}}}$ for a selected beam quality Q_{ecal} and $k'_{R_{50}}$ is needed to convert $N_{D,w}^{Q_{\text{ecal}}}$ into $N_{D,w}^Q$ for any beam quality Q (see Secs. IV and XB). k_{ecal} is fixed for a given chamber model and $k'_{R_{50}}$ is a function of the electron beam quality specified by R_{50} .

$M_{\text{raw}}(d)$: uncorrected ion chamber reading with the point of measurement of the ion chamber at a depth d in water, for a given number of monitor units (or minutes for ^{60}Co). If no sign is indicated, the measurement is made collecting the same charge as during calibration (see Sec. VII A). If a sign is indicated (+ or -), it is the sign of the charge collected (see Sec. VII A). Unit: C (coulomb) or rdg (meter reading).

M : fully corrected ion chamber reading (see Sec. VII): corrected to the standard environmental conditions of temperature and pressure for which the ion chamber calibration factor applies; and also corrected for polarity effects, lack of complete ion collection efficiency, and electrometer accuracy. Unit: C or rdg.

MU : the number of monitor units (or minutes for ^{60}Co) for which a given irradiation is performed.

$N_{D,w}$: the absorbed-dose to water calibration factor for an ion chamber located under reference conditions in a radiation beam. The absorbed dose measured is that at the chamber's point of measurement in the absence of the chamber. For a vented ion chamber the calibration factors from US and Canadian calibration laboratories apply for standard environmental conditions of temperature, pressure, and relative humidity. Calibration factors apply assuming the chamber reading corresponds to 100% charge collection efficiency [see Eq. (7)]. In contrast, calibration factors are usually for a stated polarity and corrections are needed if there is a significant polarity effect in the calibration beam (see Sec. VII A for how to handle this unusual case). Unit: Gy/C or Gy/rdg.

$N_{D,w}^Q$: the value of $N_{D,w}$ in a photon or electron beam of quality specified by Q .

P : air pressure inside ion chamber. In a vented chamber it is assumed to be the same as the local air pressure (see Sec.

VII C). Unit: kPa (kilopascals, 1 atmosphere = 760 mm of mercury = 101.33 kPa).

P_{elec} : the electrometer correction factor. If the electrometer is calibrated separately from the ion chamber, then P_{elec} is the electrometer calibration factor which corrects the electrometer reading to true coulombs. P_{elec} is considered 1.00 if the electrometer and ion chamber are calibrated as a unit. Unit: C/rdg or C/C.

P_{gr}^Q : the gradient correction factor is the component of k_Q in an electron beam that is dependent on the ionization gradient at the point of measurement. For cylindrical chambers P_{gr}^Q is a function of the radius of the cavity, r_{cav} and the local gradient. P_{gr}^Q is unity for plane-parallel chambers [see Secs. XB and IV and Eqs. (21) and (4)]. The equivalent factor in photon beams is accounted for within k_Q since it is the same for all beams of a given photon beam quality.

P_{ion} : the recombination correction factor takes into account the incomplete collection of charge from an ion chamber (see Sec. VII D). Unlike the TG-21 protocol, this factor does not appear explicitly in the dose equation but it is now taken into account when determining the corrected charge reading M .

P_{pol} : the polarity correction factor which takes into account any polarity effect in the response of the ion chamber (see Sec. VII A).

P_{TP} : the temperature-pressure correction factor which makes the charge or measured current correspond to the standard environmental conditions for which the calibration factor applies (see Sec. VII C).

point of measurement: the point at which the absorbed dose is measured. For cylindrical ion chambers used for clinical reference dosimetry the point of measurement is on the central axis of the cavity at the center of the active volume of the cavity and for plane-parallel chambers the point of measurement is at the front (upstream side) of the air cavity at the center of the collecting region. When used in this specific sense, the phrase "point of measurement" is set out in the text as point of measurement.

Q : The beam quality in the user's photon or electron beam for which clinical reference dosimetry is to be performed. For photon beams it is given in terms of %dd(10)_x (see Sec. VIII B) and for electron beams, in terms of R_{50} (see Sec. VIII C).

Q_{ecal} : an arbitrary electron beam quality taken as $R_{50} = 7.5$ cm. It is introduced to simplify the factors needed in electron beam dosimetry (see Sec. IV).

r_{cav} : radius of the air cavity in a cylindrical ion chamber. Unit, cm. See Secs. VIII A and XB.

R_{50} : the depth in water in a $10 \times 10 \text{ cm}^2$ or larger beam of electrons at an SSD of 100 cm at which the absorbed dose falls to 50% of the dose maximum (see Sec. VIII C). For beams with $R_{50} > 8.5$ cm (i.e., with energy greater than roughly 20 MeV), a $20 \times 20 \text{ cm}^2$ or greater field size is needed. Unit: cm.

rdg: the meter reading of an ion chamber in whatever units are on the scale.

reference conditions: defined conditions of depth, beam

size and SSD/SAD for which clinical reference dosimetry is performed (see Secs. IX A and X A).

reference depth: the depth at which the point of measurement of the ion chamber is placed to measure the absorbed dose.

SSD/SAD: source-to-surface distance for electron or photon beams and source-to-axis distance for photon beams. This is usually a nominal distance since the position of the source is not well defined in many cases (see Sec. IX A). Unit: cm.

standard environmental conditions: conditions of temperature, pressure, and relative humidity for which ion chamber calibration factors apply. In the US and Canada these are temperature, $T_0 = 22^\circ\text{C}$, pressure, $P_0 = 101.33 \text{ kPa}$, and relative humidity of the air in the ion chamber between 20% and 80% (see Sec. VII C).

T : temperature of the air inside an ion chamber, taken as the temperature of the surrounding water when in thermal equilibrium. Unit: $^\circ\text{C}$ (degree Celsius).

The new notation in this protocol may at first seem daunting. The following general observations may be helpful.

Beam quality is denoted by a Q in the general case for both electron and photon beams. Two specific beam qualities that are referred to often are ^{60}Co and Q_{ecal} . The beam quality specifiers used are %dd(10)_x for photon beams and R_{50} for electron beams.

The various k quality conversion factors all transform an absorbed-dose calibration factor from one quality to another as follows (these relationships are formally introduced below and this summary is here only as an *aide-memoire*). Note that the quality conversion factor, k_Q , is used to transform the ^{60}Co absorbed-dose calibration factor to the corresponding factor in any beam quality Q for electrons or photons. In contrast, the $k_{R_{50}}$ factors apply only to electron beams and in the general case require an additional gradient correction factor, hence the different notation.

$$\begin{array}{ccc} N_{D,w}^{^{60}\text{Co}} & \xrightarrow{k_Q} & N_{D,w}^Q \quad (\text{photons or electrons}) \\ N_{D,w}^{^{60}\text{Co}} & \xrightarrow{k_{R_{50}}} & N_{D,w}^Q \quad (\text{electrons}^a) \\ N_{D,w}^{^{60}\text{Co}} & \xrightarrow{k_{\text{ecal}}} & N_{D,w}^{Q_{\text{ecal}}} \xrightarrow{k'_{R_{50}}} N_{D,w}^Q \quad (\text{electrons}^{a,b}) \end{array}$$

^aalso need P_{gr}^Q for cylindrical chambers.

^balso need $P_{\text{gr}}^{Q_{\text{ecal}}}$ for cylindrical chambers.

Note that for electron beams $k_Q = P_{\text{gr}}^Q k_{R_{50}}$ and $k_{R_{50}} = k'_{R_{50}} k_{\text{ecal}}$.

III. INTRODUCTION

This protocol prescribes a methodology for clinical reference dosimetry. It applies to photon beams with nominal energies between ^{60}Co and 50 MV and electron beams with nominal energies between 4 and 50 MeV.

The protocol uses ion chambers calibrated in terms of absorbed dose to water in a ^{60}Co beam.

The primary purpose of this dosimetry protocol is to ensure uniformity of reference dosimetry in external beam ra-

diation therapy with high-energy photons and electrons. To achieve this goal requires a common starting point and this is accomplished by starting with an ion chamber calibration factor which is directly traceable to national standards of absorbed dose to water maintained by Primary Standards Laboratories (National Institute of Standards and Technology, NIST, in the US, the National Research Council of Canada, NRCC, in Canada). Direct traceability is also achieved via calibration factors obtained from an Accredited Dosimetry Calibration Laboratory (ADCL).

IV. GENERAL FORMALISM

Many of the data used in this protocol apply only under certain well-defined reference conditions. These conditions are specified below for photon and electron beams, and include such factors as the depth of measurement, field size, and source-to-surface distance, SSD. Also, throughout this protocol doses and charges are "for a given number of monitor units (or minutes for ^{60}Co)," although this cumbersome phrase will not usually be included.

Given $N_{D,w}^Q$ (in Gy/C or Gy/rdg), the absorbed-dose to water calibration factor for an ion chamber located in a beam of quality Q , then, under reference conditions:

$$D_w^Q = MN_{D,w}^Q \quad (\text{Gy}), \quad (1)$$

where D_w^Q is the absorbed dose to water (in Gy) at the point of measurement of the ion chamber when it is absent (i.e., at the reference depth); M is the fully corrected electrometer reading in coulombs (C) or meter units (rdg) which has been corrected for ion recombination, polarity and electrometer calibration effects and corrected to standard environmental conditions of temperature and pressure (see Sec. VII); and the same or equivalent waterproofing sleeve is used as was used during the calibration (if needed). If an absorbed-dose calibration factor has been obtained for the beam quality of interest, this equation can be used directly and the next step in this protocol, to determine k_Q (see below), can be bypassed.

More usually, it is expected that absorbed-dose calibration factors will be obtained for reference conditions in a ^{60}Co beam, viz. $N_{D,w}^{^{60}\text{Co}}$. In this case, define the quality conversion factor, k_Q , such that

$$N_{D,w}^Q = k_Q N_{D,w}^{^{60}\text{Co}} \quad (\text{Gy/C or Gy/rdg}), \quad (2)$$

i.e., k_Q converts the absorbed-dose to water calibration factor for a ^{60}Co beam into the calibration factor for an arbitrary beam of quality Q which can be for photon or electron beams in general. The quality conversion factor k_Q is chamber specific. Using k_Q , gives^{10,12,13}

$$D_w^Q = M k_Q N_{D,w}^{^{60}\text{Co}} \quad (\text{Gy}). \quad (3)$$

For photon beams, this protocol provides values of k_Q for most chambers used for reference dosimetry (Sec. IX B). Note that plane-parallel chambers are not included because there is insufficient information about wall correction factors in photon beams other than ^{60}Co beams.

In general, for electron beams the quality conversion factor k_Q contains two components, i.e.,

$$k_Q = P_{\text{gr}}^Q k_{R_{50}}, \quad (4)$$

where $k_{R_{50}}$ is a chamber-specific factor which depends on the quality for which the absorbed-dose calibration factor was obtained and the user's beam quality, Q , as specified by R_{50} (see Sec. VIII C), and P_{gr}^Q is necessary only for cylindrical chambers, to correct for gradient effects at the reference depth. The value of P_{gr}^Q depends on the radius of the chamber cavity and the ionization gradient at the point of measurement in the user's beam and must be measured by the user. This protocol provides a procedure for measuring P_{gr}^Q in the user's electron beam (as described in Sec. X B).

The factor $k_{R_{50}}$ is written as the product of two factors, viz.

$$k_{R_{50}} = k'_{R_{50}} k_{\text{ecal}}. \quad (5)$$

The photon-electron conversion factor, k_{ecal} , is fixed for a given chamber model and is just $k_{R_{50}}$ for an electron beam of quality Q_{ecal} , i.e., the value needed to convert $N_{D,w}^{^{60}\text{Co}}$ into $N_{D,w}^{Q_{\text{ecal}}}$, the absorbed-dose calibration factor in an electron beam of quality Q_{ecal} . The electron beam quality conversion factor, $k'_{R_{50}}$, is beam quality dependent and converts $N_{D,w}^{Q_{\text{ecal}}}$ into $N_{D,w}^Q$. Thus, in an electron beam, the dose is given by

$$D_w^Q = M P_{\text{gr}}^Q k'_{R_{50}} k_{\text{ecal}} N_{D,w}^{^{60}\text{Co}} \quad (\text{Gy}). \quad (6)$$

The introduction of the photon-electron conversion factor, k_{ecal} , appears quite arbitrary, but it is very useful since (i) it means the chamber-to-chamber variation of $k'_{R_{50}}$ is much less than that of $k_{R_{50}}$; (ii) it is a directly measurable quantity once primary standards for absorbed dose in electron beams are available; and (iii) it plays a very natural role when cross-calibrating plane-parallel chambers against calibrated cylindrical chambers (see Sec. X C).

Although the protocol allows and provides data to carry through the above approach using plane-parallel chambers, there is evidence that minor construction details significantly affect the response of these detectors in ^{60}Co beams¹⁶ and this makes measurements or calculations of k_{ecal} more uncertain. Therefore, the preferred choice is to cross calibrate them in high-energy electron beams against calibrated cylindrical chambers as recommended by TG-39¹⁴ (see Sec. X C).

The reference depth for electron-beam dosimetry is at $d_{\text{ref}} = 0.6R_{50} - 0.1$ cm, which is essentially at the depth of dose maximum for beams with energies below 10 MeV but is deeper for higher-energy beams.¹⁷ By going to this depth the protocol can make use of stopping-power ratios which account for the realistic nature of electron beams rather than assume they are mono-energetic and at the same time no longer requires stopping-power ratios tabulated as a function of depth and R_{50} (or mean energy at the phantom surface).

To utilize this formalism one starts by obtaining an absorbed-dose to water calibration factor for an ion chamber in a ^{60}Co beam as described in the next section and then

determines the quality conversion factor, k_Q , for the chamber being used. This first requires that one determine the beam quality, Q .

V. OBTAINING AN ABSORBED-DOSE TO WATER CALIBRATION FACTOR

The first step in applying this protocol is to obtain an absorbed-dose to water calibration factor for the user's ion chamber when placed in a ^{60}Co beam under reference conditions (specified in Sec. IX A). The absorbed-dose calibration factor is defined such that

$$N_{D,w}^{^{60}\text{Co}} = \frac{D_w^{^{60}\text{Co}}}{M} \quad (\text{Gy/C or Gy/rdg}), \quad (7)$$

where $D_w^{^{60}\text{Co}}$ is the absorbed dose to water (in Gy) in the calibration laboratory's ^{60}Co beam at the point of measurement of the ion chamber in the absence of the chamber. The calibration factor applies under standard environmental conditions of temperature, pressure, and relative humidity of the air in the ion chamber, viz. 22°C , 101.33 kPa, and relative humidity between 20% and 80%, respectively (in the US and Canada). This calibration factor must be traceable to the user's national primary standard for absorbed dose to water. In practice, for most members of the AAPM, this means the calibration factor must be obtained from an ADCL in the US (traceable to NIST) or NRCC in Canada.

It is the responsibility of the clinical physicist to ensure that there are adequate, independent, and redundant checks in place to ensure that any problems with the ion chamber will be detected prior to the routine calibration.¹⁸ Checks are achieved by use of check sources, by regular measurements in a ^{60}Co beam, or by use of multiple independent dosimetry systems. With adequate and redundant checks in place, it is necessary to have the ion chamber calibrated when first purchased, when repaired, when the redundant checks suggest a need, or once every two years. The clinical physicist must perform at least two independent checks prior to sending a chamber for calibration and repeat the same checks when the chamber is returned to ensure that the chamber characteristics have not changed during transit and the calibration factor obtained applies to the chamber.

The ion chamber and the electrometer with which it is to be used should both be calibrated, possibly as a single unit. All ranges of the electrometer that are routinely used for clinical reference dosimetry should be calibrated.

A. Chamber waterproofing

To follow this protocol a chamber is calibrated in water as well as used clinically in water. As a result, ^{60}Co buildup caps are not needed. However, equivalent waterproofing techniques must be used for measurements in the user's beam and in the calibration laboratory. An inherently waterproof chamber avoids the complications of extra waterproofing sleeves and possible air gaps.

Chambers that are inherently waterproof will be calibrated in water without any extra waterproofing. It is the user's responsibility to ensure the integrity of inherent wa-

terproofing by using the chamber in a water tank immediately prior to sending it for calibration. For nonwaterproof chambers the calibration laboratories will use their own thin-walled waterproofing sleeves to calibrate Farmer-like cylindrical chambers or they will use the clients waterproofing sleeve if it meets the criteria below. It is the responsibility of the clinical physicist to use a waterproofing sleeve which minimizes air gaps near the chamber wall (≤ 0.2 mm) and it should be made of polymethylmethacrylate (PMMA) ≤ 1 mm thick. Another allowed option is to use a latex condom but users are urged to make sure talcum powder is not used in this case since the talcum can lead to problems with the ion chamber. Other materials are not recommended since discrepancies have been observed.^{19–21} For other chamber types, the user should communicate with the calibration laboratory to ensure that the waterproofing sleeves used in the calibration laboratory, and in the user's beam, are similar and meet the criteria above. If the user's waterproofing sleeve meets the above criteria, then the effect of the sleeves in both the calibration lab and the clinic are negligible, as are any differences between them.

VI. MEASUREMENT PHANTOMS

Clinical reference dosimetry must be performed in a water phantom with dimensions of at least $30 \times 30 \times 30$ cm³. If the beam enters through the plastic wall of the water phantom and the wall is greater than 0.2 cm thick, all depths should be scaled to water-equivalent depths by measuring from the outside face of the wall with the phantom full of water and accounting for the wall density. For a PMMA wall, in photon or electron beams the effective wall thickness is given by the measured thickness in cm times 1.12.^{3,22}

VII. CHARGE MEASUREMENT

The fully corrected charge reading from an ion chamber, M , is given by

$$M = P_{\text{ion}} P_{\text{TP}} P_{\text{elec}} P_{\text{pol}} M_{\text{raw}} \quad (\text{C or rdg}), \quad (8)$$

where M_{raw} is the raw ion chamber reading in coulombs, C, or the instrument's reading units (rdg); P_{TP} is the temperature–pressure correction which corrects the reading to the standard environmental conditions for which the ion chamber's calibration factor applies; P_{ion} corrects for incomplete ion collection efficiency; P_{pol} corrects for any polarity effects; and P_{elec} takes into account the electrometer's calibration factor if the electrometer and ion chamber are calibrated separately. In addition, any shutter timing error must be accounted for if needed (see, e.g., Ref. 23, p. 358, or TG-61²⁴).

A. Polarity corrections

Polarity effects^{25–27} vary with beam quality and other conditions such as cable position. Therefore, it is necessary to correct for these effects by making measurements each time clinical reference dosimetry is performed.

To correct an ion chamber's raw reading for polarity effects one takes readings with both polarities applied and deduces P_{pol} from

$$P_{\text{pol}} = \left| \frac{(M_{\text{raw}}^+ - M_{\text{raw}}^-)}{2M_{\text{raw}}} \right|, \quad (9)$$

where M_{raw}^+ is the reading when positive charge is collected, M_{raw}^- is the reading when negative charge is collected, and M_{raw} (one of M_{raw}^+ or M_{raw}^-) is the reading corresponding to the charge collected for the reference dosimetry measurements in the clinic and which should be the same as for the chamber calibration. In both cases, the sign of M_{raw} must be used and usually M_{raw}^+ and M_{raw}^- have opposite signs unless the background is large. Adequate time must be left after changing the sign of the voltage so that the ion chamber's reading has reached equilibrium.

In the unlikely event that the polarity correction is more than 0.3% different from unity in a photon beam of 6 MV or lower energy, then one must establish what the value of P_{pol} is in the calibration laboratory's beam. This can be requested from the calibration laboratory or established by the clinical physicist using a ^{60}Co source. Since calibration laboratories traditionally report the calibration factor for one polarity, if there is a significant polarity correction in the calibration beam, the user must use $N_{D,w}^{^{60}\text{Co}}/P_{\text{pol}}^{^{60}\text{Co}}$ everywhere in this protocol instead of $N_{D,w}^{^{60}\text{Co}}$.

B. Electrometer correction factor

It is common practice in the US to calibrate ion chambers and electrometers separately. This is not essential and it is common practice in Canada to calibrate them as a unit. If the electrometer is calibrated separately from the ion chamber, the electrometer correction factor, P_{elec} , is just the electrometer calibration factor which corrects the electrometer reading to true coulombs. The electrometer calibration factor is obtained from an Accredited Dosimetry Calibration Laboratory. P_{elec} is the electrometer correction factor which is applicable to the range being used on the electrometer. P_{elec} is considered 1.00 if the electrometer and ion chamber are calibrated as a unit. It is also taken as 1.00 for cross-calibrated plane-parallel chambers since it cancels out of the final equations (see Sec. XC).

C. Standard environmental conditions: Temperature, pressure, and relative humidity

Since calibration factors are given for standard environmental conditions of temperature at $T_0 = 22^\circ\text{C}$ and pressure at $P_0 = 101.33 \text{ kPa}$ (1 atmosphere), one corrects charge or meter readings to standard environmental conditions using

$$P_{\text{TP}} = \frac{273.2 + T}{273.2 + 22.0} \times \frac{101.33}{P}, \quad (10)$$

where T is the temperature in degrees Celsius in the water near the ion chamber and P is the pressure in kilopascals (not corrected to sea level and including temperature and latitude corrections for a mercury barometer). Standard environmental conditions are different in some countries outside the US and Canada and the corresponding changes in Eq. (10) are necessary.

Chambers require time to reach thermal equilibrium with their surroundings. After inserting the ion chamber into the water tank it is necessary to ensure that this equilibrium is reached by waiting for changes in chamber output to become negligible. At this point, usually after 5 to 10 min,²⁸ one can assume that the temperature inside the ion chamber has reached the temperature of the water near the chamber in the phantom.

It is assumed that the relative humidity is always in the range of 20% to 80%. In this range, the error introduced by ignoring variations in relative humidity is $\pm 0.15\%$.²⁹

Humid air may cause condensation inside the ion chamber volume and this can affect chamber response, especially for nylon-wall chambers³⁰ which therefore should not be used.

D. Corrections for ion-chamber collection inefficiency

1. General comments on P_{ion}

In this protocol, ion chamber readings in the user's beam must be corrected for lack of complete collection efficiency. This recombination correction factor is denoted P_{ion} and the experimental methods for measuring it are discussed below. It must be emphasized that P_{ion} is a function of the dose per pulse in accelerator beams and thus will change if either the pulse rate for a fixed dose rate, or the dose rate is changed. The correction must be measured in each set of experimental conditions for which clinical reference dosimetry is being performed.

This protocol is based on the definition of the calibration factor given in Eq. (7), which means that it applies when 100% of the ions created are collected. The correction to 100% ion collection at the time of chamber calibration is done at the calibration laboratory. The user must, however, explicitly include in Eq. (8), the recombination correction, P_{ion} , which applies in each of the user's beams.

The recombination corrections are well enough understood³¹ that for small corrections they can be made accurately. However, if an ion chamber exhibits a correction factor, P_{ion} , greater than 1.05, the uncertainty in this correction becomes unacceptably large and another ion chamber with a smaller recombination effect should be used. Voltages should not be increased above normal operating voltages just to reduce P_{ion} since there are indications in the literature that the assumptions in the standard theories break down at higher voltages.^{32–36} In fact, the evidence suggests that lower voltages should be used as long as P_{ion} values are acceptable. Despite these issues, the procedure recommended below is very similar to the TG-21 procedure since the above effects are believed to cause less than 0.5% errors at normal operating voltages of 300 V or less.

2. Measuring P_{ion}

The standard two-voltage techniques for determining the P_{ion} correction should be used. This involves measuring the charge produced by the ion chamber in the beam of interest when two different bias voltages are applied to the detector.

After changing the voltage it is necessary to wait for the chamber readings to come to equilibrium (usually several minutes, at least).

Let V_H be the normal operating voltage for the detector (always the higher of the two voltages in these measurements) and M_{raw}^H be the raw chamber reading with bias V_H . After measuring M_{raw}^H reduce the bias voltage by at least a factor of 2 to V_L and measure M_{raw}^L once the chamber readings have reached equilibrium.

For continuous (i.e., ^{60}Co) beams, the two voltage formula gives^{37,38}

$$P_{\text{ion}}(V_H) = \frac{1 - (V_H/V_L)^2}{M_{\text{raw}}^H/M_{\text{raw}}^L - (V_H/V_L)^2}. \quad (11)$$

Equation (11) extracts an estimate of the general recombination in the continuous beam although initial recombination may dominate.

For pulsed or pulsed-swept beams with $P_{\text{ion}} < 1.05$, i.e., where the linear form of the saturation curve holds,

$$P_{\text{ion}}(V_H) = \frac{1 - V_H/V_L}{M_{\text{raw}}^H/M_{\text{raw}}^L - V_H/V_L}. \quad (12)$$

Although the exact equations for pulsed or pulsed-swept beams are nonlinear,³⁸ Eq. (12) gives the same result as solving the nonlinear equations to within 0.2% and 0.4%, respectively, for a voltage ratio of 2 and 0.3% and 0.6% for a voltage ratio of 3 and is most inaccurate at the limiting value of $P_{\text{ion}} = 1.05$. For larger values of the voltage ratio or values of P_{ion} near 1.05 one may use the published programs or fits for the nonlinear equations.^{5,38}

VIII. BEAM QUALITY SPECIFICATION

For both photon and electron beams from accelerators, the beam quality must be specified in order to determine the correct value of the quality conversion factor, k_Q or the electron quality conversion factor, $k'_{R_{50}}$. For a ^{60}Co beam the factor $k_Q = 1.000$ by definition and hence there is no need for further beam quality specification. Beam quality must be measured each time clinical reference dosimetry is performed for accelerator beams. To do this, one needs to measure a parameter related to the central-axis depth-dose curves for the beam in question. Careful measurement of depth-dose curves is quite complex because various factors needed for converting depth-ionization curves to depth-dose curves change as a function of depth. Although this protocol is quite flexible about the SSD used when establishing the absorbed dose at the reference depth, nonetheless it is essential to use $\text{SSD} = 100 \text{ cm}$ when establishing the beam quality for photon and electron beams. This is because $\%dd(10)$ and R_{50} are functions of SSD whereas absorbed-dose calibration factors are not (for $10 \times 10 \text{ cm}^2$ fields).

A. Accounting for gradient and depth of measurement effects

The point of measurement for a cylindrical chamber is on the central axis of the chamber and this is always placed

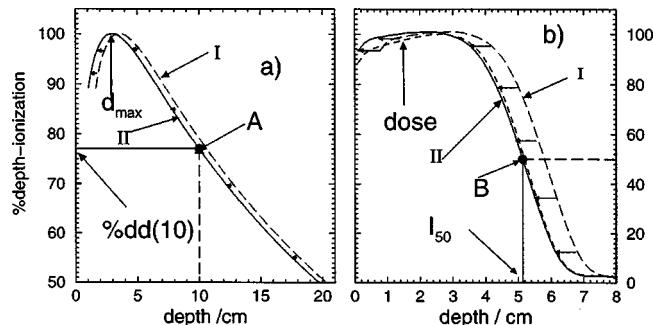


FIG. 1. Effect of shifting depth-ionization data measured with cylindrical chambers upstream by $0.6 r_{\text{cav}}$ for photon beams [panel (a)] and $0.5 r_{\text{cav}}$ for electron beams [panel (b)] (with $r_{\text{cav}} = 1.0 \text{ cm}$). The raw data are shown by curve I (long dashes) in both cases and the shifted data, which are taken as the depth-ionization curve, are shown by curve II (solid line). The value of the % ionization at point A (10 cm depth) in the photon beam gives $\%dd(10)$ and the depth at point B (50% ionization) in the electron beam gives I_{50} from which R_{50} can be determined (see Sec. VIII C). For the photon beams, curve II is effectively the percentage depth-dose curve. For the electron beams, curve II must be further corrected (see Sec. X D) to obtain the percentage depth-dose curve shown (short dashes—but this is not needed for application of the protocol).

at the reference depth when measuring dose at an individual point (as opposed to a depth-dose curve). Nonetheless, the effective point of measurement is upstream of the point of measurement (i.e., closer to the radiation source) due to the predominantly forward direction of the secondary electrons (since the primary beam enters the chamber at various distances upstream). This has an impact on the measurement of depth-ionization (and therefore depth-dose) curves and on the calculation of absolute dose from ionization measurements at the reference depth.

When measuring central-axis depth-dose data with a cylindrical chamber, the effective point of measurement is made use of as follows. First, depth-ionization data are measured with the point of measurement identified as the assumed depth, as shown by curve I in Figs. 1(a) and 1(b). The entire curve is then shifted to shallower depths by a distance proportional to r_{cav} , the radius of the ionization chamber cavity, as shown by curves II in Figs. 1(a) and 1(b). For cylindrical and spherical chambers the shift is taken as $0.6r_{\text{cav}}$ for photon beams³⁵ and $0.5r_{\text{cav}}$ for electron beams.^{22,39,40} The shifted curves are taken as the depth-ionization curves for cylindrical chambers. It is these depth-ionization curves that are used to determine the beam quality for both photons and electrons. Using these measurements as depth-ionization curves ignores any variations in P_{ion} and P_{pol} with depth⁴¹ and for electron beams it also ignores variations in the electron fluence correction factor. Since well-guarded plane-parallel chambers minimize these variations with depth, they are preferred for measuring electron beam depth-ionization curves.

For photon beams the variation in stopping-power ratio is negligible past d_{max} ($< 0.1\%$ ⁴²) and thus the depth-ionization curve is treated as a depth-dose curve (these same techniques should be used to determine any clinical photon beam depth-dose curve). In order to determine depth-dose curves for electron beams, the depth-ionization curve must be further

corrected for the significant change in the stopping-power ratio with depth. This conversion is not needed in this protocol except to transfer the dose from d_{ref} to d_{max} if necessary (Sec. XD).

For plane-parallel chambers, the center of the front (upstream) face of the chamber air cavity is the point of measurement. This is traditionally taken as the effective point of measurement.^{3,39} Therefore there is no shift in the depth-ionization curves for plane-parallel chambers and curves I and II are coincident and give the depth-ionization curve for the purposes of beam quality specification.

In contrast to the above, for measurements of absolute dose at the reference depth in both electron and photon beams, a cylindrical chamber's point of measurement (center of the chamber, Sec. II) is placed at the reference depth (10 cm for photons and d_{ref} for electrons). The gradient effects are included implicitly in the beam quality conversion factor k_Q for photons and explicitly by the term P_{gr}^Q for electrons. That is, the formalism of this protocol yields absorbed dose to water at the point occupied by the point of measurement after the chamber has been removed from the water.

B. Beam-quality specification for photon beams

For the purposes of reference beam dosimetry, beam quality in accelerator photon beams is specified by $\%dd(10)_x$, the percentage depth dose at 10 cm depth in a water phantom due to photons only (i.e., excluding electron contamination). The value of $\%dd(10)_x$ is defined for a field size of $10 \times 10 \text{ cm}^2$ at the phantom surface at an SSD of 100 cm. For ^{60}Co beams $\%dd(10)_x$ is not required since $k_Q = 1.000$ by definition.

At higher energies (about 10 MV and above), the electrons from the accelerator head may significantly affect the dose at d_{max} and hence reduce the measured value of $\%dd(10)$. This electron contamination varies with machine type. However, it has been shown that placing a 1 mm thick lead foil just below the accelerator head reduces the effects of the electrons from the accelerator to a negligible level and calculations have been done which take into account the effect of the known electron contamination from the lead foil.^{43,44} Thus the first step in specifying the photon beam quality for beams with energies of 10 MV or above is to measure the value of $\%dd(10)_{\text{Pb}}$ with a 1 mm lead foil positioned to intercept the beam completely (but remove it for the measurement of absorbed dose at the reference position). For beam energies below 10 MV the lead foil is not needed and one measures $\%dd(10)$ in the open beam.

If a 1 mm lead foil is being used, it should be placed about 50 cm from the phantom surface (± 5 cm) in an otherwise open beam. Only if the accelerator construction does not permit a position near 50 cm (e.g., because of tertiary collimators), then the lead foil may be placed 30 ± 1 cm from the phantom surface. The exact thickness of the lead foil is not critical and a tolerance of $\pm 20\%$ is acceptable.⁴³

To measure $\%dd(10)_{\text{Pb}}$, with the lead foil in place (for 10 MV and above), or $\%dd(10)$ for lower-energy beams

when the foil is not needed, an ion chamber should be used to generate the central-axis percentage depth-ionization curve measured in water [i.e., curve I in Fig. 1(a)] using a field size of $10 \times 10 \text{ cm}^2$ at the phantom surface and an SSD of 100 cm. For cylindrical or spherical chambers, the measured depth-ionization data should be shifted upstream by $0.6r_{\text{cav}}$ to give curve II, the depth-ionization curve. For plane-parallel chambers no shift is needed, i.e., curves I and II are coincident. The percentage depth-ionization curve can be treated as the percentage depth-dose curve.

Next, locate point A at 10 cm depth on the percentage depth-dose curve [i.e., curve II in Fig. 1(a)]. This value is $\%dd(10)$ or $\%dd(10)_{\text{Pb}}$, the measured percentage depth-dose at 10 cm depth.

For beams with energies less than 10 MV, this value of $\%dd(10)$ measured in the open beam is the beam quality, $\%dd(10)_x$. For beam energies of 10 MV and above, the value of $\%dd(10)_x$ for the open beam is obtained from the value of $\%dd(10)_{\text{Pb}}$ measured with the foil in the beam at 50 ± 5 cm from the phantom surface by⁴³

$$\%dd(10)_x = [0.8905 + 0.00150\%dd(10)_{\text{Pb}}]\%dd(10)_{\text{Pb}} \\ [\text{foil at } 50 \text{ cm}, \%dd(10)_{\text{Pb}} \geq 73\%], \quad (13)$$

and, if the foil is placed at 30 ± 1 cm from the phantom surface, by

$$\%dd(10)_x = [0.8116 + 0.00264\%dd(10)_{\text{Pb}}]\%dd(10)_{\text{Pb}} \\ [\text{foil at } 30 \text{ cm}, \%dd(10)_{\text{Pb}} \geq 71\%]. \quad (14)$$

If $\%dd(10)_{\text{Pb}}$ is less than the respective thresholds given above in the equations, then $\%dd(10)_x = \%dd(10)_{\text{Pb}}$.

The foil is only used when determining the beam quality specifier, $\%dd(10)_x$ and must be removed after the beam quality is determined.

There is also a general formula available to correct for electron contamination which can be used as an interim measure for machines with 45 cm or more clearance between the jaws and the phantom surface. For low-energy beams, i.e., for energies below 10 MV with $\%dd(10) \leq 75\%$, $\%dd(10)_x = \%dd(10)$. For higher-energy beams the following applies up to $\%dd(10) = 89\%$:

$$\%dd(10)_x = 1.267\%dd(10) - 20.0 \\ [\text{for } 75\% < \%dd(10) \leq 89\%], \quad (15)$$

where $\%dd(10)$ is measured as described above for an open beam. This formula is based on a global fit⁴⁵ to data in Fig. 7 of Ref. 46. For high-energy beams this global fit may cause errors in assigning $\%dd(10)_x$ of up to 2% in extreme cases,⁴⁶ which would lead to an error in k_Q , and hence the absorbed dose, of 0.4%.

C. Beam quality specification for electron beams

For the purposes of reference beam dosimetry, beam quality in electron beams is specified by R_{50} , the depth in water (in cm) at which the absorbed dose falls to 50% of the maximum dose for a beam, which has a field size on the phantom surface $\geq 10 \times 10 \text{ cm}^2$ ($\geq 20 \times 20 \text{ cm}^2$ for $R_{50} > 8.5 \text{ cm}$, i.e.,

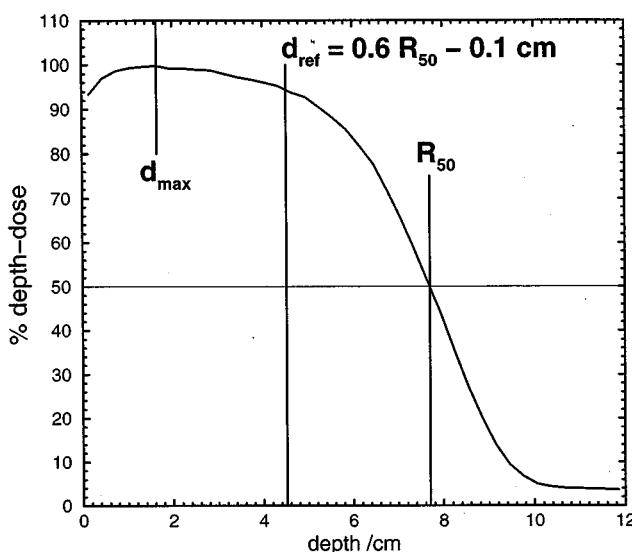


FIG. 2. Here R_{50} is defined as the depth, in cm, at which the absorbed dose falls to 50% of its maximum value in a $\geq 10 \times 10 \text{ cm}^2$ ($\geq 20 \times 20 \text{ cm}^2$ for $R_{50} > 8.5 \text{ cm}$) electron beam at an SSD of 100 cm. The depth for clinical reference dosimetry is $d_{\text{ref}} = 0.6R_{50} - 0.1 \text{ cm}$, in the same sized beam at an SSD between 90 and 110 cm. Note that for low-energy beams, d_{ref} is usually at d_{max} .

$E > 20 \text{ MeV}$) at an SSD of 100 cm. Figure 2 shows R_{50} on a typical electron beam percentage depth-dose curve.

To determine R_{50} one must first measure a central-axis depth-ionization curve in a water phantom at an SSD of 100 cm [curve I in Fig. 1(b)]. For cylindrical chambers, correct for gradient effects by shifting the curve upstream by $0.5 r_{\text{cav}}$ to give curve II.^{22,39,40} For plane-parallel chambers no shift is needed. Curve II is taken as the depth-ionization curve.

Next, locate point B at the level of 50% of the maximum ionization on the depth-ionization curve corrected for gradient effects [i.e., curve II in Fig. 1(b)]. The depth of point B gives I_{50} . The beam quality specifier for the electron beam, R_{50} , is determined from the measured value of I_{50} using^{47,48}

$$R_{50} = 1.029I_{50} - 0.06 \quad (\text{cm}) \quad (\text{for } 2 \leq I_{50} \leq 10 \text{ cm}) \quad (16)$$

or

$$R_{50} = 1.059I_{50} - 0.37 \quad (\text{cm}) \quad (\text{for } I_{50} > 10 \text{ cm}). \quad (17)$$

A second alternative is to determine the percentage depth-dose curve using a good-quality diode detector which responds as a dose-detector in an electron beam,^{22,49} although one must establish that this condition is fulfilled.⁵⁰ A third alternative is to convert the depth-ionization curve for an ion chamber to a percentage depth-dose curve (see Sec. X D).

IX. PHOTON BEAM DOSIMETRY

In photon beams Eq. (3) gives the absorbed dose to water under reference conditions, for the same number of monitor units as used to measure the charge M , at the point of measurement of the ion chamber in the user's photon beam of quality Q , specified by $\% dd(10)_x$, i.e.,

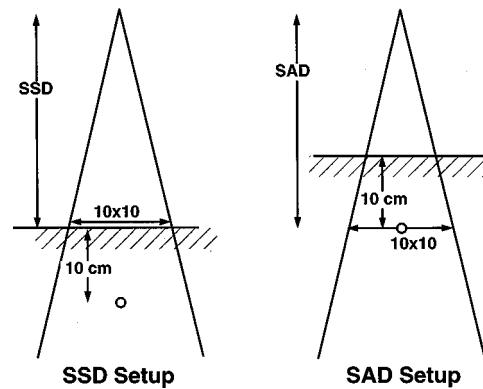


FIG. 3. Schematic of the SSD or SAD setups which may be used for photon beam reference dosimetry. In both cases the ion chamber is at a water equivalent depth of 10 cm in the water phantom. The actual value of SSD or SAD is that most useful in the clinic (expected to be about 100 cm).

$$D_w^Q = M k_Q N_{D,w}^{^{60}\text{Co}} \quad (\text{Gy}).$$

A. Reference conditions of depth, beam size, and source-surface/axis distance

Clinical reference dosimetry for photon beams is performed in an open beam (i.e., without trays, wedges, lead filters, or blocks) with the point of measurement of the cylindrical ion chamber placed at the reference depth which is at a water-equivalent depth of 10 cm in a water phantom (see Sec. VI for corrections if there is a wall in the path of the beam). Either an SSD or an SAD setup can be used (at the normal clinical distance, see Fig. 3). The field size is $10 \times 10 \text{ cm}^2$. When using an SSD setup, the field size is defined at the surface of the phantom. When an SAD setup is being used, the field size is defined at the detector position which is placed at 10 cm depth at the isocenter of the machine.

In calibration laboratories, the traditional reference depth for ^{60}Co beams is 5 g/cm^2 . The difference between an ion chamber's calibration factor determined at this depth versus one determined at a depth of 10 g/cm^2 is negligible,⁴² and hence the calibration factor for a depth of 5 g/cm^2 can be used.

Note that although the reference conditions for measurement of the dose are quite flexible, those for the specification of beam quality are not and must be at $\text{SSD}=100 \text{ cm}$ (see Sec. VIII).

B. Absorbed dose to water in clinical photon beams

To use Eq. (3) one needs a value of k_Q . For ^{60}Co beams $k_Q = 1.000$. Figure 4 presents calculated values of k_Q in accelerator beams as a function of $\% dd(10)_x$ for cylindrical ion chambers commonly used for reference dosimetry. Alternatively, values for specific chambers can be selected from Table I which contains values for the same cylindrical chambers, calculated as described by Rogers⁴⁵ with a minor update.⁵¹ Note that plane-parallel chambers are not included because there is insufficient information about wall correction factors in photon beams other than ^{60}Co .

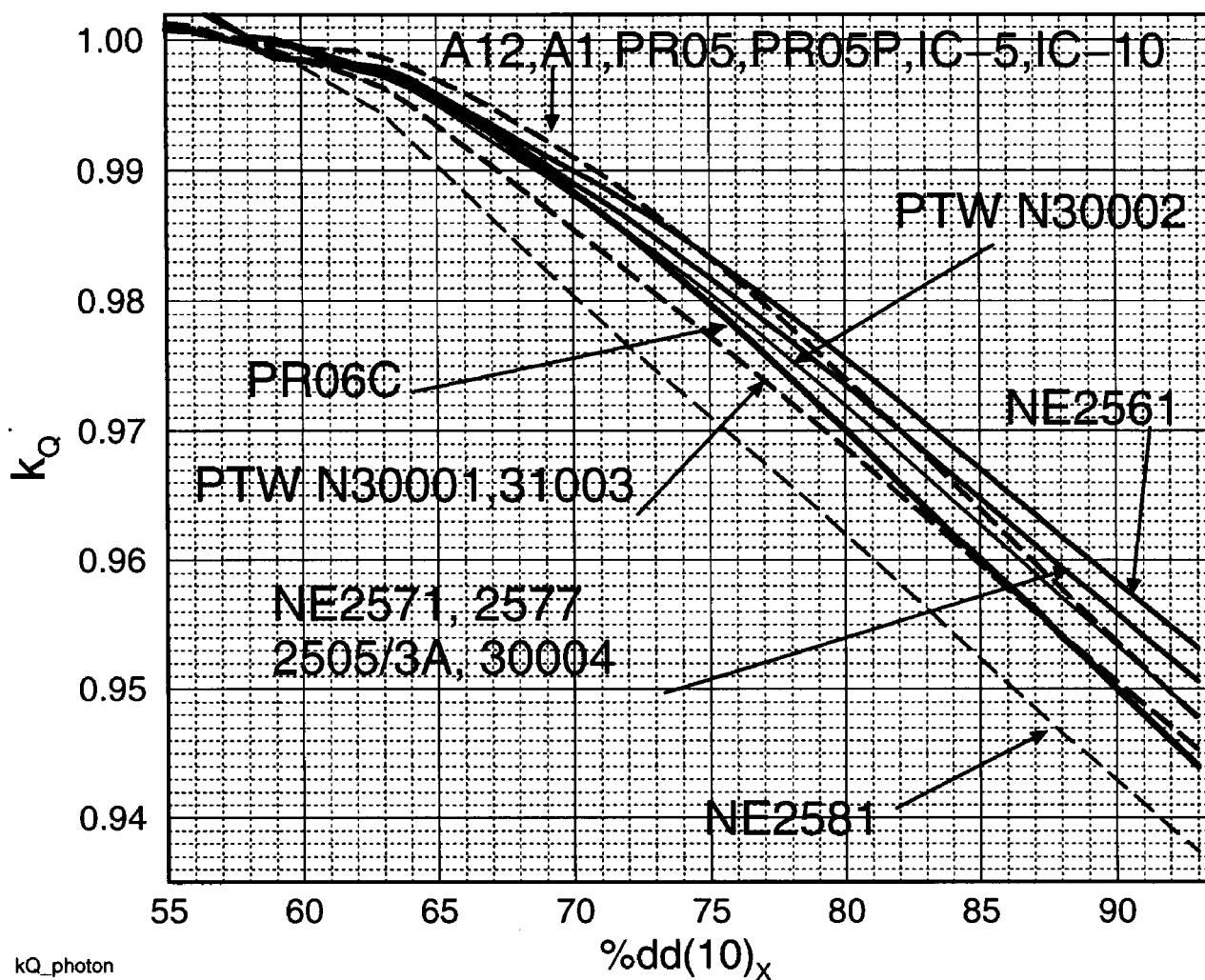


FIG. 4. Values of k_Q at 10 cm depth in accelerator photon beams as a function of $\%dd(10)_x$ for cylindrical ion chambers commonly used for clinical reference dosimetry. When values were the same within 0.1%, only one curve is shown. Explicit values are given in Table I, as is a list of equivalent chambers. For ^{60}Co beams, $k_Q = 1.00$.

TABLE I. Values of k_Q for accelerator photon beams as a function of $\%dd(10)_x$ for cylindrical ion chambers commonly used for clinical reference dosimetry. Values calculated as described in Refs. 45 and 51. The tabulated values can be interpolated linearly in $\%dd(10)_x$. The ion chamber specifications used in these calculations are found in Table III. Figure 4 presents the same data within 0.1%. For ^{60}Co beams, $k_Q = 1.00$ by definition.

Ion chamber	k_Q						
	58.0	63.0	66.0	$\%dd(10)_x$	71.0	81.0	93.0
Capintec PR-05/PR-05P	0.999	0.997	0.995	0.990	0.972	0.948	
Capintec PR-06C/G 0.6cc Farmer	1.000	0.998	0.994	0.987	0.968	0.944	
Exradin A1 Shonka ^a	0.999	0.998	0.996	0.990	0.972	0.948	
Exradin A12 Farmer	1.000	0.999	0.996	0.990	0.972	0.948	
NE2505/3,3A 0.6cc Farmer	1.000	0.998	0.995	0.988	0.972	0.951	
NE2561 0.3cc NPL Sec. Std ^b	1.000	0.998	0.995	0.989	0.974	0.953	
NE2571 0.6cc Farmer	1.000	0.998	0.995	0.988	0.972	0.951	
NE2577 0.2cc	1.000	0.998	0.995	0.988	0.972	0.951	
NE2581 0.6cc robust Farmer	1.000	0.994	0.988	0.979	0.960	0.937	
PTW N30001 0.6cc Farmer ^c	1.000	0.996	0.992	0.984	0.967	0.945	
PTW N30002 0.6cc all Graphite	1.000	0.997	0.994	0.987	0.970	0.948	
PTW N30004 0.6cc Graphite	1.000	0.998	0.995	0.988	0.973	0.952	
PTW 31003 0.3cc waterproof ^d	1.000	0.996	0.992	0.984	0.967	0.946	
Wellhofer IC-10/IC-5	1.000	0.999	0.996	0.989	0.971	0.946	

^aThe cavity radius of the A1 here is 2 mm although in the past Exradin has designated chambers with another radius as A1.

^bThe NE2611 has replaced the equivalent NE2561.

^cPTW N30001 is equivalent to the PTW N2333 it replaced.

^dPTW N31003 is equivalent to the PTW N233641 it replaced.

TABLE II. Values of the photon-electron conversion factor, k_{ecal} , for plane-parallel chambers, calculated as described in Ref. 52 and adopting a beam quality Q_{ecal} of $R_{50}=7.5$ cm. Section X C recommends using a cross calibration technique, if possible, to obtain $k_{\text{ecal}}N_{D,w}^{60\text{Co}}$. However, if not possible, these values of k_{ecal} may be used in Eq. (6) along with a ^{60}Co calibration factor, $N_{D,w}^{60\text{Co}}$.

Chamber	k_{ecal}
Attix	0.883
Capintec	0.921
PTB/Roos	0.901
Exradin	0.888
Holt	0.900
Markus	0.905
NACP	0.888

C. Absorbed dose at other depths in clinical photon beams

Clinical reference dosimetry determines the absorbed dose to water at 10 cm depth. If this is not the reference depth used for clinical dosimetry calculations, one determines the corresponding dose at the appropriate depth using one of two methods. For SSD setups the clinical percentage depth-dose curves are used. For SAD setups the clinical tissue-phantom ratio (TPR) curves are used unless one wants the dose at d_{max} . In such situations the clinical tissue-maximum ratio (TMR) curves are used.

TABLE III. Values of the photon-electron conversion factor, k_{ecal} , for commercial cylindrical chambers, calculated as described in Ref. 52 and adopting a beam quality Q_{ecal} of $R_{50}=7.5$ cm.

Chamber	k_{ecal}	Material	Wall		
			Thickness g/cm ²	Cavity radius r_{cav} (cm)	Al electrode diameter (mm)
Farmer-like					
Exradin A12	0.906	C-552	0.088	0.305	
NE2505/3,3A	0.903	Graphite	0.065	0.315	1.0
NE2561 ^a	0.904	Graphite	0.090	0.370 ^e	1.0
NE2571	0.903	Graphite	0.065	0.315	1.0
NE2577	0.903	Graphite	0.065	0.315	1.0
NE2581	0.885	A-150	0.041	0.315	
Capintec PR-06C/G	0.900	C-552	0.050	0.320	
PTW N23331	0.896	Graphite	0.012	0.395 ^e	1.0
		PMMA	0.048		
PTW N30001 ^b	0.897	Graphite	0.012	0.305	1.0
		PMMA	0.033		
PTW N30002	0.900	Graphite	0.079	0.305	
PTW N30004	0.905	Graphite	0.079	0.305	1.0
PTW N31003 ^c	0.898	Graphite	0.012	0.275	1.0 ^f
		PMMA	0.066		
Other cylindrical					
Exradin A1 ^d	0.915	C-552	0.176	0.200	
Capintec PR-05/PR-05P	0.916	C-552	0.210	0.200	
Wellhofer IC-10/IC-5	0.904	C-552	0.070	0.300	

^aThe NE2611 has replaced the equivalent NE2561.

^bPTW N30001 is equivalent to the PTW N23333 it replaced.

^cPTW N31003 is equivalent to the PTW N233641 it replaced.

^dThe cavity radius of the A1 here is 2 mm although in the past Exradin has designated chambers with another radius as A1.

^eIn electron beams there is only data for cavity radii up to 0.35 cm and so 0.35 cm is used rather than the real cavity radius shown here.

^fElectrode diameter is actually 1.5 mm, but only data for 1.0 mm is available.

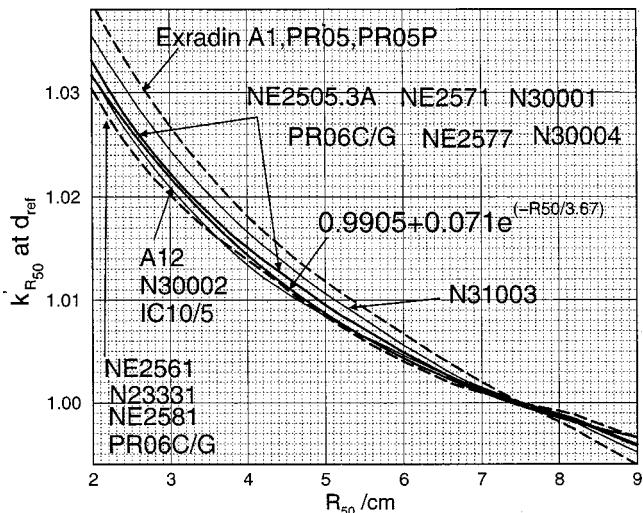


FIG. 5. Calculated values of $k'_{R_{50}}$ at d_{ref} as a function of R_{50} for several common cylindrical ion chambers. These values can be used with Eq. (6) (with a measured value of P_{gr}^Q and a k_{ecal} value from Table III) to determine the absorbed dose to water at the reference depth of $d_{\text{ref}}=0.6R_{50}-0.1$ cm.

X. ELECTRON BEAM DOSIMETRY

Equation (6) gives the absorbed dose to water under reference conditions for the same number of monitor units as

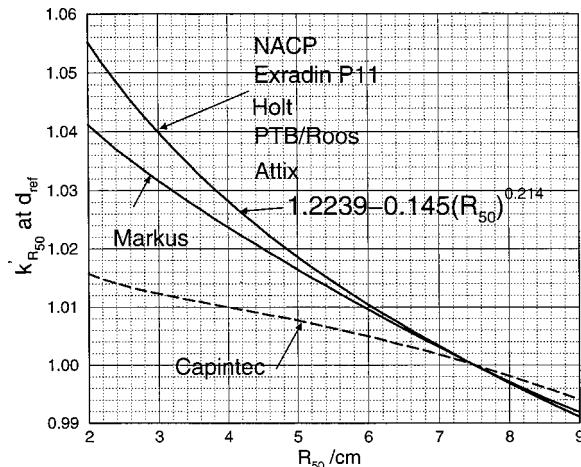


FIG. 6. Calculated values of $k'_{R_{50}}$ at d_{ref} as a function of R_{50} for several common plane-parallel chambers. Note that the values for the five well-guarded chambers lie on the same line in the figure. These values can be used with Eq. (6) (with $P_{\text{gr}}^Q=1.0$) to determine the absorbed dose to water at the reference depth of $d_{\text{ref}}=0.6R_{50}-0.1$ cm.

used to measure the charge M , at the point of measurement of the ion chamber, in an electron beam of quality Q , specified by R_{50} , i.e.,

$$D_w^Q = M P_{\text{gr}}^Q k'_{R_{50}} k_{\text{ecal}} N_{D,w}^{^{60}\text{Co}} \text{ (Gy).}$$

For electron beams with $R_{50} \leq 4.3$ cm (incident energies of 10 MeV or less), well-guarded plane-parallel chambers are preferred and they may be used at higher energies. Plane-parallel chambers must be used for beams with $R_{50} \leq 2.6$ cm (incident energies of 6 MeV or less).

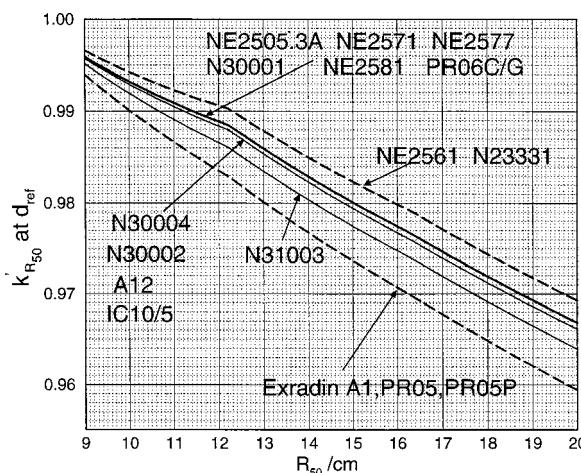


FIG. 7. Calculated values of $k'_{R_{50}}$ at d_{ref} for high-energy electron beams, as a function of R_{50} for cylindrical ion chambers. These values can be used with Eq. (6) (with a measured value of P_{gr}^Q and a k_{ecal} value from Table III) to determine the absorbed dose to water at the reference depth of $d_{\text{ref}}=0.6R_{50}-0.1$ cm.

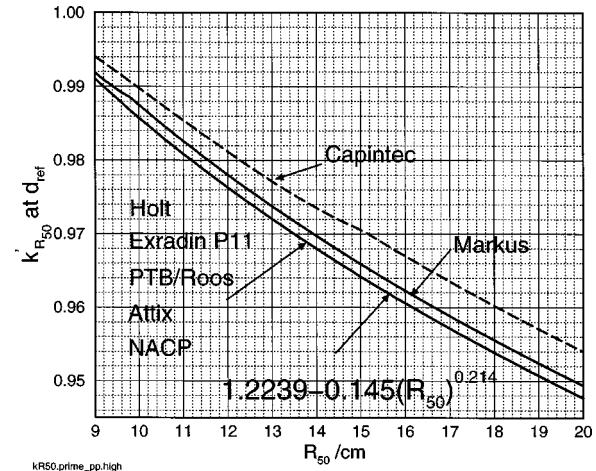


FIG. 8. Calculated values of $k'_{R_{50}}$ at d_{ref} for high-energy electron beams, as a function of R_{50} for plane-parallel chambers. Note that the values for the five well-guarded chambers lie on the same line in the figure. These values can be used with Eq. (6) (with $P_{\text{gr}}^Q=1.0$ and a k_{ecal} value from Table II) to determine the absorbed dose to water at the reference depth of $d_{\text{ref}}=0.6R_{50}-0.1$ cm.

A. Reference conditions of depth, beam size, and source-surface distance

Clinical reference dosimetry for electron beams is performed in an open beam at the reference depth which is at a water-equivalent depth of¹⁷

$$d_{\text{ref}}=0.6R_{50}-0.1 \text{ (cm).} \quad (18)$$

See Sec. VI for corrections to the depth to take into account tank walls which may be in the path of the beam. The point of measurement of the ion chamber is placed at d_{ref} (i.e., the central axis of cylindrical chambers or the front face of the air cavity for plane-parallel chambers). For beams with $R_{50} \leq 8.5$ cm ($E \leq 20$ MeV), the field size is $\geq 10 \times 10 \text{ cm}^2$ at the phantom surface and for higher-energy beams it is $\geq 20 \times 20 \text{ cm}^2$.

Clinical reference dosimetry may be performed with an SSD from 90 to 110 cm. The underlying Monte Carlo calculations of stopping-power ratios were done for SSD=100 cm, but changes of up to 10 cm from this SSD do not affect the parameters used in the protocol.

B. Absorbed dose to water in clinical electron beams

In electron beams, Eq. (6) is used to establish the absorbed dose to water. To use this equation one needs the values of the factors P_{gr}^Q , $k'_{R_{50}}$, and k_{ecal} . The values of k_{ecal} for a number of ion chambers are given in Tables II and III.⁵² The selection of the beam quality Q_{ecal} are arbitrary and has been taken as $R_{50}=7.5$ cm for the purposes of this protocol.

Figure 5 presents calculated values for $k'_{R_{50}}$ for cylindrical ion chambers used for clinical reference dosimetry in electron beams with energies up to about 21 MeV and Fig. 6 presents $k'_{R_{50}}$ values for plane-parallel chambers.⁵² For higher-energy electron beams, the corresponding data are presented in Figs. 7 and 8. For Farmer-like cylindrical cham-

bers the following expression can be used for $2 \leq R_{50} \leq 9$ cm with a maximum error of 0.2%:⁵²

$$k'_{R_{50}}(\text{cyl}) = 0.9905 + 0.0710e^{(-R_{50}/3.67)}. \quad (19)$$

For well-guarded plane-parallel chambers, the following expression is an analytic representation of the curve shown in Figs. 6 and 8, i.e., for $2 \leq R_{50} \leq 20$ cm:

$$k'_{R_{50}}(\text{pp}) = 1.2239 - 0.145(R_{50})^{0.214}. \quad (20)$$

The correction for gradient effects (i.e., P_{gr}^Q) is not necessary for plane-parallel chambers and is close to unity for cylindrical chambers when the reference depth is at d_{\max} , which is usually the case for electron beams below about 10 MeV. For cylindrical chambers P_{gr}^Q is determined as^{22,39}

$$P_{\text{gr}}^Q = \frac{M_{\text{raw}}(d_{\text{ref}} + 0.5r_{\text{cav}})}{M_{\text{raw}}(d_{\text{ref}})} \quad (\text{for cylindrical chambers}), \quad (21)$$

where r_{cav} is the radius of the chamber's cavity in cm and $M_{\text{raw}}(d_{\text{ref}} + 0.5r_{\text{cav}})/M_{\text{raw}}(d_{\text{ref}})$ is the ratio of the integrated charges or ionization currents with the central axis of the chamber at $d_{\text{ref}} + 0.5r_{\text{cav}}$ and d_{ref} . This procedure is equivalent to making the measurement at the "effective point of measurement,"^{22,39} but the present formalism is adopted to facilitate future utilization of primary standards of absorbed dose to water in electron beams. Note that P_{gr}^Q is less than 1 for $d_{\text{ref}} > (d_{\max} + 0.5r_{\text{cav}})$.

C. Use of plane-parallel chambers

For electron beam dosimetry this protocol allows for the use of plane-parallel chambers which have been calibrated in a ${}^{60}\text{Co}$ beam. However, since the ${}^{60}\text{Co}$ calibration factors of at least some plane-parallel chambers appear to be very sensitive to small features of their construction,¹⁶ it is recommended that, when possible, plane-parallel chambers be calibrated against calibrated cylindrical chambers in a high-energy electron beam, as recommended in TG-21³ and TG-39.¹⁴

After determining the beam quality and the reference depth in the high-energy electron beam to be used, measurements are made, in sequence, with the point of measurement of both the calibrated cylindrical chamber and the plane-parallel chamber at d_{ref} . While measuring with the cylindrical chamber, P_{gr}^Q is measured as described above [see Eq. (21)]. From these measurements the product of $k_{\text{ecal}}N_{D,w}^{{}^{60}\text{Co}}$ is determined for the plane-parallel chamber as

$$(k_{\text{ecal}}N_{D,w}^{{}^{60}\text{Co}})^{\text{pp}} = \frac{(D_w)^{\text{cyl}}}{(Mk'_{R_{50}})^{\text{pp}}} \\ = \frac{(MP_{\text{gr}}^Q k'_{R_{50}} k_{\text{ecal}} N_{D,w}^{{}^{60}\text{Co}})^{\text{cyl}}}{(Mk'_{R_{50}})^{\text{pp}}} \quad (\text{Gy/C}). \quad (22)$$

This product is then used in Eq. (6), thereby avoiding the need for obtaining the ${}^{60}\text{Co}$ absorbed-dose calibration factor for the plane-parallel chamber.

D. Absorbed dose at d_{\max} in clinical electron beams

This protocol provides the reference dose at a depth of d_{ref} which, for higher-energy beams, will not be at d_{\max} where clinical normalization most often takes place. To establish the dose at d_{\max} one should use the clinical percentage depth-dose data for a given beam and determine the dose at d_{\max} from that at d_{ref} . Methods for measuring electron-beam percentage depth-dose curves are given in TG-25.²² These procedures require stopping-power ratios when ion chambers are used and in TG-25 these are presented for mono-energetic electron beams. In TG-51, stopping-power ratios for realistic electron beams have been used and these differ from the mono-energetic stopping-power ratios. To extract the dose maximum in a completely consistent manner, the expression presented by Burns *et al.*¹⁷ for stopping-power ratios in realistic electron beams as a function of R_{50} and depth should be used to determine the clinical depth-dose data since they are consistent with the values used here (a FORTRAN routine is available at <http://www.irs.inms.nrc.ca/inms/irs/papers/SPRR50/node12.html>). Measuring depth-dose curves for electron beams also requires corrections for variations in P_{repl} according to TG-25.²² This variation can be significant for cylindrical chambers although there is no variation for well-guarded plane-parallel chambers.

XI. USING OTHER ION CHAMBERS

This protocol provides k_Q data for the vast majority of chambers used in clinical reference dosimetry in North America as evidenced by the data on ADCL calibrations. However, other cylindrical chambers can be used by finding the closest matching chamber for which data are given. The critical features are, in order, the wall material, the radius of the air cavity, the presence of an aluminum electrode, and the wall thickness. As long as the wall material is matched and the chamber is "normal," these matching data should be accurate to within 0.5%. It is the responsibility of the user to confirm this by comparing the results to those of a calibrated cylindrical chamber for which data are given in the protocol.

ACKNOWLEDGMENTS

The members of the task group would like to thank the members of the RTC over the years in which this protocol was developed for their helpful comments and suggestions and, in particular, the 1998 members for their very helpful reviews. We also thank Alan Nahum of the Royal Marsden Hospital in Sutton, UK, and David Burns of the BIPM in Paris for detailed external reviews on behalf of the RTC and Jan Seuntjens of NRC Canada for helpful comments on many versions of the protocol. We also wish to acknowledge the contributions of Herb Attix who was involved with the early development of this protocol and the anonymous journal referee who provided thoughtful comments. Finally, we thank the members of the ADCL Subcommittee of the RTC for their substantial efforts to put in place a system for absorbed-dose calibrations and their helpful inputs to the protocol.

TG-51 Worksheet A: Photon Beams

1. Site data

Institution:

Physicist:

Date:

Accel or ^{60}Co Mfr:

Model & serial number:

Nominal photon energy/beam identifier:

MV

2. Instrumentation

a. Chamber model:

Serial number:

cavity inner radius (r_{cav} , Table III):

cm

Waterproof:

If no, is waterproofing \leq 1 mm PMMA or thin latex?: yes no

b. Electrometer model:

Serial number:

i. $P_{\text{elec, electrom. corr factor}}$ (Sec.VII.B):

C/C or C/rdg.c. Calibration Factor $N_{D,w}^{^{60}\text{Co}}$ (Sec.V):

Gy/C (or Gy/rdg)

Date of report (not to exceed 2 years):

3. Measurement Conditions ($10 \times 10 \text{ cm}^2$, point of measurement at 10 cm depth (water equivalent))

a. Distance (SSD or SAD):

cm SAD or SSD

b. Field size:

 cm^2

on surface(SSD setup):

at detector(SAD setup):

c. Number of monitor units:

MU (min for ^{60}Co)

4. Beam Quality (Sec.VIII.B –not needed for ^{60}Co)

If energy $< 10 \text{ MV}$, use no lead foil.Measure $\%dd(10)$ [% depth-dose at 10 cm depth for curve shifted upstream by 0.6 r_{cav}]Field size $10 \times 10 \text{ cm}^2$ on surface, SSD=100 cm: yes no a. $\%dd(10)_x = \%dd(10)$

If energy $\geq 10 \text{ MV}$ Distance of 1 mm lead foil from phantom surface $50 \pm 5 \text{ cm}$ $30 \pm 1 \text{ cm}$ Measure $\%dd(10)_{\text{Pb}}$ [% depth-dose at 10 cm depth for curve shifted upstream by 0.6 r_{cav}]Field size $10 \times 10 \text{ cm}^2$ on surface, SSD=100 cm: yes no $\%dd(10)_{\text{Pb}}$ (includes e^- contamination):

50 cm: $\%dd(10)_x = [0.8905 + 0.00150 \%dd(10)_{\text{Pb}}] \%dd(10)_{\text{Pb}}$ $[\%dd(10)_{\text{Pb}} \geq 73\%]$ Eq.(13)30 cm: $\%dd(10)_x = [0.8116 + 0.00264 \%dd(10)_{\text{Pb}}] \%dd(10)_{\text{Pb}}$ $[\%dd(10)_{\text{Pb}} \geq 71\%]$ Eq.(14)If $\%dd(10)_{\text{Pb}} < 71\%$ (30cm) or 73% (50cm): $\%dd(10)_x = \%dd(10)_{\text{Pb}}$ b. $\%dd(10)_x$ (for open beam):

Has lead foil been removed?

yes no

Worksheet A: Photon Beams (cont)

- 4.(cont): Interim alternative for energy > 10 MV & with ≥ 45 cm clearance: using no lead foil
 Measure %dd(10) [% depth-dose at 10 cm depth for curve shifted upstream by $0.6 r_{\text{cav}}$]
 %dd(10): _____

$$\%dd(10)_x = 1.267 (\%dd(10)) - 20.0 \quad [\text{for } 75\% < \%dd(10) \leq 89\%]$$

c. %dd(10)_x = _____

5. Determination of k_Q (Sec.IX.B)

Chamber model used to get k_Q : _____

a. %dd(10)_x (from 4, above): _____

b. k_Q [Table I or Fig 4]: _____

6. Temperature/Pressure Correction (Sec.VII.C)

a. Temperature: _____ $^{\circ}\text{C}$

b. Pressure: _____ kPa [=mmHg $\cdot \frac{101.33}{760}$]

c. P_{TP} : _____ $[Eq.(10) = \left(\frac{273.2+6a}{295.2} \right) \left(\frac{101.33}{6b} \right)]$

7. Polarity Correction (Sec.VII.A)

M_{raw}^+ : _____ C or rdg

M_{raw}^- : _____ C or rdg

a. M_{raw} (for polarity of calibration): _____ C or rdg

b. P_{pol} : _____ $[Eq.(9) = \left| \frac{(M_{\text{raw}}^+ - M_{\text{raw}}^-)}{2M_{\text{raw}}} \right|]$

8. P_{ion} measurements (Sec.VII.D.2)

Operating voltage = V_H : _____ V

Lower voltage V_L : _____ V

M_{raw}^H : _____ C or rdg

M_{raw}^L : _____ C or rdg

^{60}Co treated as general recombination

a. $P_{\text{ion}}(V_H)$ (Eq.(11)): _____ $\left[\left(1 - \left(\frac{V_H}{V_L} \right)^2 \right) / \left(\frac{M_{\text{raw}}^H}{M_{\text{raw}}^L} - \left(\frac{V_H}{V_L} \right)^2 \right) \right]$

Pulsed/swept beams

b. $P_{\text{ion}}(V_H)$ (Eq.(12)): _____ $\left[\left(1 - \frac{V_H}{V_L} \right) / \left(\frac{M_{\text{raw}}^H}{M_{\text{raw}}^L} - \frac{V_H}{V_L} \right) \right]$

If $P_{\text{ion}} > 1.05$, another ion chamber should be used.

9. Corrected ion. ch. rdg. M (Sec.VII) at 10 cm depth, water equivalent

$$M = P_{\text{ion}} P_{TP} P_{\text{elec}} P_{\text{pol}} M_{\text{raw}} = [8(a \text{ or } b) \cdot 6c \cdot 2bi \cdot 7b \cdot 7a]$$

Fully corrected M (Eq.(8)): _____ C or rdg

10. Dose to water at 10 cm depth: $D_w^Q = M k_Q N_{D,w}^{^{60}\text{Co}} = [9 \cdot 5b \cdot 2c]$ Eq.(3)

a. Dose to water at 10 cm depth= _____ Gy

b. Dose / MU(or min, ^{60}Co) at 10 cm depth _____ Gy/MU(or min) [10a/3c]

11. Dose to water/MU(or min, ^{60}Co) at d_{max} (if relevant locally)

a. Clinical %dd(10) for SSD setup / 100.: _____

or Clinical TMR(10,10×10) for SAD setup: _____

b. Dose / MU(or min, ^{60}Co) at d_{max} : _____ Gy/MU(or min) [10b/(11a)]

TG-51 Worksheet B: Electron Beams – Cylindrical Chambers

For electrons with $R_{50} \geq 2.6$ cm (energies > 6 MeV) only and preferably ≥ 4.3 cm (10 MeV).

1. Site data

Institution:

Physicist:

Date:

Accel Mfr:

Model & serial number:

Nominal electron energy/beam identifier:

MeV

2. Instrumentation

a. Chamber model:

Serial number:

cm

cavity inner radius (r_{cav} , Table III):

Waterproof:

yes no

If no, is waterproofing ≤ 1 mm PMMA or thin latex?: yes no

b. Electrometer model:

Serial number:

C/C or C/rdg.

i. $P_{elec,electrom.}$ corr factor (Sec.VII.B):

c. Calibration Factor $N_{D,w}^{60Co}$ (Sec.V):

Gy/C (or Gy/rdg)

Date of report (not to exceed 2 years):

3. Measurement Conditions (central axis of chamber at d_{ref} , Sec.X.A)

a. Distance SSD:

cm

b. Field Size on surface:

cm²

c. Number of monitor units:

MU

4. Beam Quality (Sec.VIII.C)

Measure I_{50} by measuring depth-ionization curve and, for cylindrical chambers only, shifting curve upstream by 0.5 r_{cav}

I_{50} :

cm

a.i. If $2 \leq I_{50} \leq 10$ cm:

$$R_{50} = 1.029I_{50} - 0.06$$

cm

ii. If $I_{50} > 10$ cm:

$$R_{50} = 1.059I_{50} - 0.37$$

cm

b. Reference depth $d_{ref} = 0.6R_{50} - 0.1$

cm (water equivalent)

Worksheet B: Electron Beams - Cylindrical Chambers (cont)**5. Determination of k_{ecal} and $k'_{R_{50}}$** Chamber model used to get k_{ecal} :a. k_{ecal} _____ [Table III]b. i. $k'_{R_{50}}$ from figures: _____ [Fig 5 or 7]or: ii. $k'_{R_{50}}$ from analytic expression for Farmer-like cylindrical chambers

$$\therefore k'_{R_{50}} = 0.9905 + 0.071e^{(-R_{50}/3.67)} \quad \text{[Eq.(19) } 2 \leq R_{50} \leq 9\text{cm}]$$

6. Temperature/Pressure Correction (Sec.VII.C)a. Temperature: _____ $^{\circ}\text{C}$ b. Pressure: _____ $\text{kPa} [= \text{mmHg} \cdot \frac{101.33}{760}]$ c. P_{TP} : _____ $[Eq.(10) = \left(\frac{273.2+6a}{295.2} \right) \left(\frac{101.33}{6b} \right)]$ **7. Polarity Correction (Sec.VII.A)** M_{raw}^+ : M_{raw}^- :a. M_{raw} (for polarity of calibration): _____ C or rdgb. P_{pol} : _____ C or rdg

$$\left[Eq.(9) = \left| \frac{(M_{\text{raw}}^+ - M_{\text{raw}}^-)}{2M_{\text{raw}}} \right| \right]$$

8. P_{ion} measurements (Sec.VII.D.2)Operating voltage = V_H : _____ VLower voltage V_L : _____ V M_{raw}^H : M_{raw}^L : $P_{\text{ion}}(V_H)$ (pulsed/swept beam, Eq.(12)): _____ $\left[\left(1 - \frac{V_H}{V_L} \right) / \left(\frac{M_{\text{raw}}^H}{M_{\text{raw}}^L} - \frac{V_H}{V_L} \right) \right]$ If $P_{\text{ion}} > 1.05$, another ion chamber should be used.**9. Corrected ion. ch. rdg. M (Sec.VII) at d_{ref}**

$$M = P_{\text{ion}} P_{TP} P_{\text{elec}} P_{\text{pol}} M_{\text{raw}} = [8 \cdot 6c \cdot 2bi \cdot 7b \cdot 7a]$$

Fully corrected M (Eq.(8)): _____ C or rdg**10. Dose to water at reference depth, d_{ref} : $D_w^Q = MP_{gr}^Q k'_{R_{50}} k_{\text{ecal}} N_{D,w}^{60Co} = [9 \cdot 10a \cdot 5b \cdot 5a \cdot 2c]$**

$$\text{a. } P_{gr}^Q(\text{cyl}) = \frac{M_{\text{raw}}(d_{\text{ref}} + 0.5r_{\text{cav}})}{M_{\text{raw}}(d_{\text{ref}})}$$

b. Dose to water at $d_{\text{ref}} =$ _____ Gyc. Dose / MU at $d_{\text{ref}} =$ _____ Gy/MU [10b/3c]**11. Dose to water / MU at d_{max} (if relevant locally)**a. $\%dd(d_{\text{ref}})$ as used clinically: _____b. Dose / MU at $d_{\text{max}} =$ _____ Gy/MU [10c/(11a/100)]

TG-51 Worksheet C: $k_{\text{ecal}}N_{D,w}^{^{60}\text{Co}}$ for plane-parallel chambers

There are two methods for determining $k_{\text{ecal}}N_{D,w}^{^{60}\text{Co}}$ for a plane-parallel chamber. Method A uses cross-calibration against a calibrated cylindrical chamber and is the preferred method. Method B uses a ^{60}Co absorbed-dose calibration factor.

Method A: Cross-Calibration

1. Site data

Institution: _____
 Physicist: _____
 Date: _____
 Accel Mfr: _____
 Model & serial number: _____
 Nominal e^- energy/beam identifier: _____ MeV

2. Dose using cylindrical chamber

Do reference dosimetry for this beam using Worksheet B.

Transfer the following information from that worksheet:

- a. Date: _____ [B:1]
- b. Beam quality R_{50} : _____ [B:4a]
- c. Reference depth, d_{ref} : _____ [B:4b]
- d. Dose / MU at d_{ref} : _____ [B:10c]
- e. Number of MU[same used here]: _____ [B:3c]

Now place the point of measurement of the plane-parallel chamber at d_{ref}

3. Temperature/Pressure Correction (Sec.VII.C)

- a. Temperature: _____ $^{\circ}\text{C}$
- b. Pressure: _____ kPa [=mmHg $\cdot \frac{101.33}{760}$]

$$\left[\text{Eq.(10)} = \left(\frac{273.2 + 3a}{295.2} \right) \left(\frac{101.33}{3b} \right) \right]$$
- c. P_{TP} : _____

4. Polarity Correction (Sec.VII.A)

- M_{raw}^+ : _____ C or rdg
- M_{raw}^- : _____ C or rdg
- a. M_{raw} (for polarity used clinically): _____ C or rdg

$$\left[\text{Eq.(9)} = \left| \frac{(M_{\text{raw}}^+ - M_{\text{raw}}^-)}{2M_{\text{raw}}} \right| \right]$$
- b. P_{pol} : _____

Worksheet C: $k_{\text{ecal}}N_{D,w}^{^{60}\text{Co}}$ for plane-parallel chambers (cont)**5. P_{ion} measurements (Sec.VII.D.2)**Operating voltage = V_H :

V

Lower voltage V_L :

V

 M_{raw}^H :

C or rdg

 M_{raw}^L :

C or rdg

 $P_{\text{ion}}(V_H)$ (pulsed/swept beam, Eq.(12)): $\left[\left(1 - \frac{V_H}{V_L} \right) / \left(\frac{M_{\text{raw}}^H}{M_{\text{raw}}^L} - \frac{V_H}{V_L} \right) \right]$ If $P_{\text{ion}} > 1.05$, another ion chamber should be used.**6. Corrected ion. ch. rdg. M (Sec.VII)**

$$M = P_{\text{ion}} P_{TP} P_{\text{elec}} (= 1.0) P_{\text{pol}} M_{\text{raw}} = [5 \cdot 3c \cdot 1.0 \cdot 4b \cdot 4a]$$

Fully corrected M (Eq.(8)):

C or rdg

7. Determination of $k'_{R_{50}}$ for plane-parallel chamber, beam quality R_{50} (2b)i. $k'_{R_{50}}$ from figures _____ [Fig 6 or 8]or ii. $k'_{R_{50}}$ from analytic expression for well-guarded plane-parallel chambers

$$k'_{R_{50}} = 1.2239 - 0.145(R_{50})^{0.214} \quad [\text{Eq.(20)} \quad 2 \leq R_{50} \leq 20\text{cm}]$$

8. Cross-calibration value

$$(k_{\text{ecal}}N_{D,w}^{^{60}\text{Co}})^{\text{pp}} = \frac{(D_w/MU)^{\text{cyt}} MU}{\left(M k'_{R_{50}} \right)^{\text{pp}}} = \left[\frac{2d \cdot 2e}{6 \cdot 7(i \text{ or } ii)} \right]$$

Gy/C(or Gy/rdg)

Method B: ^{60}Co Calibration**1. Instrumentation**

a. Chamber model:

Serial number:

Waterproof:

yes no If no, is waterproofing ≤ 1 mm PMMA or thin latex?: yes no

b. Electrometer model:

Serial number:

i. $P_{\text{elec,electrom. corr factor}}$ (Sec.VII.B):

C/C or C/rdg.

c. Calibration Factor $N_{D,w}^{^{60}\text{Co}}$ (Sec.V):

Gy/C (or Gy/rdg)

Date of report (not to exceed 2 years):

2. Determination of k_{ecal} Chamber model used to get k_{ecal} :

[Table II]

a. k_{ecal} :

3. $k_{\text{ecal}}N_{D,w}^{^{60}\text{Co}}$:

Gy/C(or Gy/rdg)

TG-51 Worksheet D: Electron Beams using Plane-Parallel Chambers

1. Site data

Institution:

Physicist:

Date:

Accel Mfr:

Model & serial number:

Nominal electron energy/beam identifier:

MeV

2. Instrumentation

a. Chamber model:

Serial number:

Waterproof:

yes no If no, is waterproofing \leq 1 mm PMMA or thin latex?: yes no

b. Electrometer model:

Serial number:

i. P_{elec} , electrom. corr factor (Sec.VII.B): take as 1.0 if using cross-calibration. P_{elec} :

 C/C or C/rdg

3. Measurement Conditions (point of measurement at d_{ref})

a. Distance SSD:

 cm

b. Field Size on surface:

 cm²

c. Number of monitor units:

 MU

4. Beam Quality (Sec.VIII.C)

Measure I_{50} by measuring depth-ionization curve and, for cylindrical chambers only, shifting curve upstream by $0.5 r_{cav}$

 I_{50}

 cma.i. If $2 \leq I_{50} \leq 10$ cm:

$$R_{50} = 1.029I_{50} - 0.06$$

 cmii. If $I_{50} > 10$ cm:

$$R_{50} = 1.059I_{50} - 0.37$$

 cmb. Reference depth $d_{ref} = 0.6R_{50} - 0.1$

 cm

Worksheet D: Electron Beams - Plane-Parallel Chambers (cont)**5. Determination of $k_{\text{ecal}} N_{D,w}^{60\text{Co}}$ and $k'_{R_{50}}$ (Sec.X.C)**

- a. $k_{\text{ecal}} N_{D,w}^{60\text{Co}}$ (Worksheet C - A:8 or B:3): _____ Gy/C (or Gy/rdg)
 b. i. $k'_{R_{50}}$ from figures _____ [Fig 6 or 8]

or ii. $k'_{R_{50}}$ from analytic expression for well-guarded plane-parallel chamber

$$k'_{R_{50}} = 1.2239 - 0.145(R_{50})^{0.214} \quad \boxed{\text{Eq.(20) } 2 \leq R_{50} \leq 20\text{cm}}$$

6. Temperature/Pressure Correction (Sec.VII.C)

- a. Temperature: _____ °C
 b. Pressure: _____ kPa [=mmHg $\frac{101.33}{760}$]
 c. P_{TP} : _____ [Eq.(10) = $\left(\frac{273.2+6a}{295.2} \right) \left(\frac{101.33}{6b} \right)$]

7. Polarity Correction (Sec.VII.A)

- M_{raw}^+ : _____ C or rdg
 M_{raw}^- : _____ C or rdg
 a. M_{raw} (for polarity of calibration): _____ C or rdg
 b. P_{pol} : _____ [Eq.(9) = $\left| \frac{(M_{\text{raw}}^+ - M_{\text{raw}}^-)}{2M_{\text{raw}}} \right|$]

8. P_{ion} measurements (Sec.VII.D.2)

Operating voltage = V_H : _____ V

Lower voltage V_L : _____ V

- M_{raw}^H : _____ C or rdg
 M_{raw}^L : _____ C or rdg

$$P_{\text{ion}}(V_H) \text{ (pulsed/swept beam, Eq.(12))}: \quad \boxed{\left(1 - \frac{V_H}{V_L} \right) / \left(\frac{M_{\text{raw}}^H}{M_{\text{raw}}^L} - \frac{V_H}{V_L} \right)}$$

If $P_{\text{ion}} > 1.05$, another ion chamber should be used.

9. Corrected ion. ch. rdg. M (Sec.VII)

$$M = P_{\text{ion}} P_{TP} P_{\text{elec}} P_{\text{pol}} M_{\text{raw}} = [8 \cdot 6c \cdot 2bi \cdot 7b \cdot 7a]$$

Fully corrected M (Eq.(8)): _____ C or rdg

10. Dose to water at reference depth, d_{ref}

$$D_w^Q = M k'_{R_{50}} k_{\text{ecal}} N_{D,w}^{60\text{Co}} = [9 \cdot 5b \cdot 5a] \quad \boxed{\text{Eq.(6)}}$$

a. Dose to water at $d_{\text{ref}} =$ _____ Gy

b. Dose / MU at $d_{\text{ref}} =$ _____ Gy/MU [10a/3c]

11. Dose to water / MU at d_{max} (if relevant locally)

a. %dd(d_{ref}) as used clinically: _____

b. Dose / MU at $d_{\text{max}} =$ _____ Gy/MU [10b/(11a/100)]

APPENDIX: EQUIPMENT NEEDED

To implement this protocol the following minimal set of dosimetric equipment is needed.

- (i) A secondary-standard ion chamber, associated electrometer (and cables), all of high-quality. These are calibrated when first purchased, after repairs, whenever internal checks suggest problems and at least every two years. Calibrations must be traceable to the appropriate national primary standard for absorbed dose to water (Sec. V). For photon beams the chamber must be cylindrical (Secs. IV and IX B). For electron beams with energies of 6 MeV or less, plane-parallel chambers are mandatory, preferred for beams of 10 MeV or less and can be used for any energy (Sec. X).
- (ii) Equipment to allow for two independent checks of the secondary-standard ion chamber (check sources, independent dosimetry systems, a ^{60}Co unit, Sec. V).
- (iii) A system which allows the voltage applied to the ion chamber to be set to at least two different voltages differing by a factor of 2 or more and which allows for reversing the applied polarity (Sec. VII).
- (iv) If the ion chamber is not inherently waterproof, a PMMA waterproofing sleeve of <1 mm thickness or other approved waterproofing methods (Sec. V A).
- (v) A water phantom (dimensions at least 30 cm on each side) which allows for the measurement of depth-dose curves (preferably with a scanning system) and allows for accurate placement of the ion chamber at a specified depth (Sec. VI).
- (vi) If calibrating a beam of 10 MV or greater, a lead foil with area adequate to intercept the entire beam, with a thickness within 20% of 1 mm (Sec. VIII B).
- (vii) A high-quality system for measuring the local air pressure in the room where the measurements are being made (Sec. VII C).
- (viii) A high-quality system for measuring the temperature of the water near the ion chamber when doing reference dosimetry (Sec. VII C).

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Report of AAPM TG 135: Quality assurance for robotic radiosurgery

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The task group (TG) for quality assurance for robotic radiosurgery was formed by the American Association of Physicists in Medicine's Science Council under the direction of the Radiation Therapy Committee and the Quality Assurance (QA) Subcommittee. The task group (TG-135) had three main charges: (1) To make recommendations on a code of practice for Robotic Radiosurgery QA; (2) To make recommendations on quality assurance and dosimetric verification techniques, especially in regard to real-time respiratory motion tracking software; (3) To make recommendations on issues which require further research and development. This report provides a general functional overview of the only clinically implemented robotic radiosurgery device, the CyberKnife®. This report includes sections on device components and their individual component QA recommendations, followed by a section on the QA requirements for integrated systems. Examples of checklists for daily, monthly, annual, and upgrade QA are given as guidance for medical physicists. Areas in which QA procedures are still under development are discussed. © 2011 American Association of Physicists in Medicine. [DOI: 10.1118/1.3579139]

Key words: quality assurance, stereotactic radiosurgery, radiation therapy, robotic radiosurgery

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I. INTRODUCTION

Fundamental to stereotactic radiosurgery (SRS) is the accurate placement of the intended radiation dose. Small errors in the placement of radiation dose from individual beams or beamlets can result in inaccurate estimates of accumulated dose as well as inaccurate estimates of the steepness and location of the high dose gradient regions that may be designed to protect adjacent critical structures and organs at risk.

The Accuray CyberKnife® Robotic Radiosurgery system^{1–3} is at the time of publication the only robotic radiosurgery device in clinical use. It consists of a compact x-band linear accelerator mounted on an industrial robotic manipulator arm. The manipulator arm is configured to direct the radiation beams to the region of beam intersection of two orthogonal x-ray imaging systems integrated to provide image guidance for the treatment process. The patient under treatment is positioned on an automated robotic couch such that the target to be treated is located within this radiation beam accessible region. The movements of the robotic manipulator arm and the robotic patient support assembly are under the direct control of a computer system that is in turn controlled by the radiation therapist (during patient treatments) or the medical physicist (for quality assurance measurement purposes).

The treatment planning system for the CyberKnife® is device-specific. It is an inverse planning system which uses linear optimization to optimize the beam angle and beam monitor units (MU). The user selects the preconfigured treatment path, collimator size, dose calculation algorithm (ray-tracing or Monte Carlo), and sets the dose constraints.

While most CyberKnife® treatments are nonisocentric, there is a reference point in the room which serves as the origin for several coordinate systems used within the

CyberKnife® application, and to which the robot and imaging calibration is defined. This point in space is defined by an “isocrystal” which is mechanically mounted on the “isopost.” In this report, this point in space is defined as the “geometric isocenter.” It must not be confused with the “treatment isocenter,” which refers to an isocentric treatment to a target which may be located at a distance from the geometric isocenter. While a small fraction of CyberKnife® treatments are either isocentric or an overlay of isocentric shots of different collimator sizes, the majority of treatments are “nonisocentric.” This means that beams are pointing away from the geometric isocenter to create highly irregular target shapes that can contain surface concavities.

This document will cover the aspects of the CyberKnife® system that were well established at the time this report went to review, and therefore excludes devices or software which had a very limited user base (e.g., IRIS™ collimator, Monte-Carlo dose calculation, InTempo®, and external physician workstations).

This report aims to define standards for an institutional quality assurance (QA) protocol for robotic radiosurgery. Efficacy and efficiency are key considerations in our process of developing the QA methodology. This report intends to give guidelines on setting up a comprehensive quality assurance (QA) program for robotic radiosurgery systems to complement the vendor guidelines. Acceptance testing and commissioning are outside the scope of this report; this report focuses on routine QA after commissioning and serves as a supplement to TG 142.⁴

Each institution should develop a comprehensive QA program for their robotic radiosurgery program that is customized to the unique nature of this treatment delivery system. It is incumbent upon the physicist to develop and implement such a program, based on how the equipment is to be used. In this task, he/she should refer to professional guidelines such as this document, manufacturer’s recommendations, and the experience of other users. Any program must minimally meet state and federal regulatory requirements.

In the following sections of this report, the words *shall* and *must* are italicized to emphasize that they are being used in the special sense conveyed by the definition given below.

- “Shall” and “must” are used when the activity is required by various regulatory agencies, or may be essential to meet currently accepted standards.
- “Recommend” and “should” are used when the task group expects that the procedure should normally be followed as described. However, equivalent processes, criteria or methodologies may exist which can produce the same result.

I.A. Structure of report

This report is structured in five parts: an introduction, two major parts discussing QA, a summary section including QA checklists, and references. Section II is titled “QA for Individual System Components.” Each of the subsystems (robot and room, accelerator, imaging subsystem, and software)

will be described and QA recommendations developed. Section III is titled “QA for Integrated Systems.” In this section we will discuss how the individual components are linked and describe the QA to check the various links between subsystems, leading to overall system QA. Section IV contains tabulated checklists for daily, monthly, and annual QA, as well as recommendations for special situations.

I.B. Record-keeping

In the current environment, technology is rapidly evolving. Hence, thorough quality assurance (QA) and quality control (QC) become an essential component in treating patients safely. With the arrival of new treatment techniques and modalities it is very important that the new procedures for QA tests and QC are well documented. Good record-keeping⁵ can increase work efficiency and reduce the risk of making errors for newly implemented QA tests. It will also make it easier to compare the test results to previous test results and ensures easy repeatability by multiple individuals, thus limiting the potential for errors.

For every QA test, there should be a written guideline which clearly defines the objective, lists the action levels for the test, and corrective action(s) to be taken when these levels are exceeded. The QA guideline should include all tests necessary to evaluate equipment safety, patient safety, and overall treatment accuracy. In addition, the guideline must also meet state, federal, and/or any other regulatory agency requirements. It is essential to keep either a handwritten record or electronic record in a well-organized file. This file will provide documentation for a site visit or a department audit, as well as educate new personnel to the status and service history of the equipment.

A good record allows another physicist to come into a clinic and completely understand what has been done previously and to recreate the tests performed.^{6,7} There should be a clear and concise description of each test. The results should be legible (if one is keeping paper copies) and should be compared to data which is clinically relevant. The comparison should clearly state if the result is or is not within the required criteria level. If it is outside the criteria level then it should clearly state what corrective action was taken, when, and by whom. Also, if the procedure has several different action levels (i.e., morning checks) it should clearly define each step and who should be notified at each of the different action levels. All documents should be dated and have a legible (if applicable, digital) signature of the person who completed the test. If a second check is made by another physicist then it should be clearly signed and dated by that physicist.

I.C. Glossary

- AQA “Auto QA,” a Robot pointing test: The centering of a radiographic shadow of a 2 cm diameter tungsten ball hidden in a cubic phantom is measured on a pair of orthogonal films.
- CNR Contrast-to-noise ratio.

Code of Practice:	A systematic collection of rules, standards, and other information relating to the practices and procedures followed in an area.
DQA	Delivery Quality Assurance: The DQA plan is an overlay of a patient plan on a phantom. The plan is delivered and the measured dose in the phantom can be compared with the calculated dose for quality assurance, typically by using a gamma-index pass/fail criteria. The DQA assesses both spatial and dosimetric accuracy of delivery, and is the most comprehensive, overall assessment of the system.
DRR	Digitally reconstructed radiograph.
E2E	End-to-End test. A phantom containing a hidden target and orthogonal films is taken from simulation through treatment delivery. The spatial distribution of delivered dose is compared to the plan dose for the 70% isodose line. The E2E test is performed using an isocentric treatment plan. Its purpose is to be a more sophisticated Winston–Lutz test, ⁸ checking spatial delivery accuracy together with tracking modality accuracy. Unlike the DQA test, the E2E does not have a patient-specific dosimetry component.
EMO	Emergency Motion Off.
EPO	Emergency Power Off.
IGRT	Image-Guided Radiation Therapy.
Geometric Isocenter	A point in space defined by the position of the isocrystal.
Treatment Isocenter	The common crossing point of the CyberKnife® beams in an isocentric (single center) treatment plan. This point is not required to be coincident with the Geometric Isocenter.
Isocrystal	A light-sensitive detector of about 1.5 mm diameter mounted at the tip of a rigid post whose position of peak internal sensitivity marks the alignment center for the ideal pointing direction of the center of all CyberKnife® radiation beams as defined by the position of the centerline laser.
MC	Monte Carlo.
MTF	Modulation transfer function.
MU	Monitor unit.
OCR	Off-center ratio.
PDD	Percent depth dose.
QA	Quality assurance.
QC	Quality control.
SAD	Source-to-axis distance.
SNR	Signal-to-noise ratio.
SRS	Stereotactic radiosurgery (including stereotactic radiotherapy, SRT).
TG	Task group.
TPR	Tissue-phantom ratio.
TPS	Treatment planning system.

II. QA FOR INDIVIDUAL SYSTEM COMPONENTS

II.A. Robot and room safety

Any robotic system that causes the motion of either the patient couch or treatment apparatus in the immediate vicinity of a patient must have collision safeguards to prevent a potential collision with the patient. The details of how collision safeguards are implemented vary with the component and the overall system configuration. In general, collision safety precautions are dealt with in three stages in the use of a robotic radiosurgery system:

- (1) Design specification: Adequate space for all system components such that clearance issues for both the equipment and patient are verified prior to and during facility design and construction.
- (2) System installation, acceptance, commissioning, and upgrades: Items that are fixed by system design are verified as functional and adequate. In this category are elements of electrical safety (emergency offs, system motion disable, etc.), patient and robot movement restrictions, patient safety zones where robotic motion is excluded for patient safety, etc.
- (3) On-going system accuracy and safety testing: The periodic testing of safety systems to document the on-going function of system components.

II.A.1. Mechanical safety and collision avoidance

The CyberKnife® uses a minimally modified industrial robot to support and position a linear accelerator weighing approximately 160 kg. In the clinical implementation, the robot range of motion is restricted to a hemisphere around the patient. There are no inherent mechanical restrictions placed on the robot's movement, with the exception of the collimator assembly collision detector. We recommend checking the collimator assembly collision detector as part of the daily QA.

The definition of any motion-restricted space is completely executed in the controlling computer software. It is very important to note that robot-patient collision control software is only functional while the system control software is running. If the robot is operated under manual control, software defined safety zones are not functional and cannot stop a violation of the robot exclusion zone and a subsequent collision.

The CyberKnife® maintains separate zones of motion restriction. One zone is fixed with respect to the robot and includes system components that do not move, such as imaging system components, floor, walls, and ceiling. The second zone, the patient safety zone, is defined relative to the patient couch, and thus must be tested at various couch locations within the range of couch motions. Both fixed and patient safety zones *shall* be tested prior to the first clinical use of the system, and after any major software upgrade. A testing procedure is provided by the manufacturer during installation, but requires the assistance of a field service engineer.

If an unusual patient position is required to access a particular treatment location such that a portion of the patient

may extend beyond the patient safety zone, there will be no collision protection for this part of the patient. In this case, the setup should be evaluated for potential collisions by running the patient plan in simulation/demonstration mode with the couch and a phantom positioned similar to the realistic patient setup. The "simulation/demonstration mode" provides a mock treatment with the robot moving, but the accelerator switched off so the motion can be studied with observers in the treatment room. Alternatively, the patient position might be modified with the robot exclusion zone in mind to make better use of the patient safety zone. For instance, for a mid-pelvis treatment, a patient might be positioned feet first supine on the treatment table in order to have the feet extend out of the robot exclusion zone instead of the head.

II.A.2. Ancillary safety systems

All safety systems incorporated into the facility design *must* be verified initially and periodically as part of daily and monthly QA. These systems include emergency interruption for robot movement, emergency power off, audio and visual monitors, and door interlocks. In addition to the routine checks outlined below, these systems *must* be checked at installation and each time they may have been disabled or disconnected during maintenance work. Interlocks *must* occur immediately upon activation and remain engaged until the generating condition is reversed and acknowledged by the operator.

Emergency power off (EPO) and emergency motion off (EMO) switches are required on robotic systems with components which could collide with a patient. The EPO will shut off power to the complete system, while the EMO only engages the robot mechanical brakes while leaving the accelerator and robot powered up. If a collision occurs and the EPO button is pressed instead of an EMO button, responders could lose precious minutes waiting for the robot system to be powered on before the robot could be moved away from the collision site. In addition, the EPO could potentially cause loss of robot mastering (see Sec. III B 1) due to the unclean shutdown of the robot controller PC. Therefore, the EMO button should be pressed in an emergency situation unless the electrical power is the cause of the unsafe condition, in which case the EPO should be used. All EMO and EPO wall switches *shall* be tested annually. The EMO switch on the console should be tested on a daily basis, because it is the switch most likely to be used should an emergency situation arise during treatment.

Audio and visual patient monitoring: As with all radiation therapy installations, state regulations requiring the presence of audio and visual patient monitoring also apply to a robotic system. Because the linear accelerator of a robotic treatment system is so flexible in its ability to be positioned around the patient, the likelihood of the robot and/or linac obscuring the view of the patient is high if there are only one or two observation sources. It is therefore recommended that at least three (preferably four) closed circuit television cameras (CCTV) be positioned in the treatment room such that any

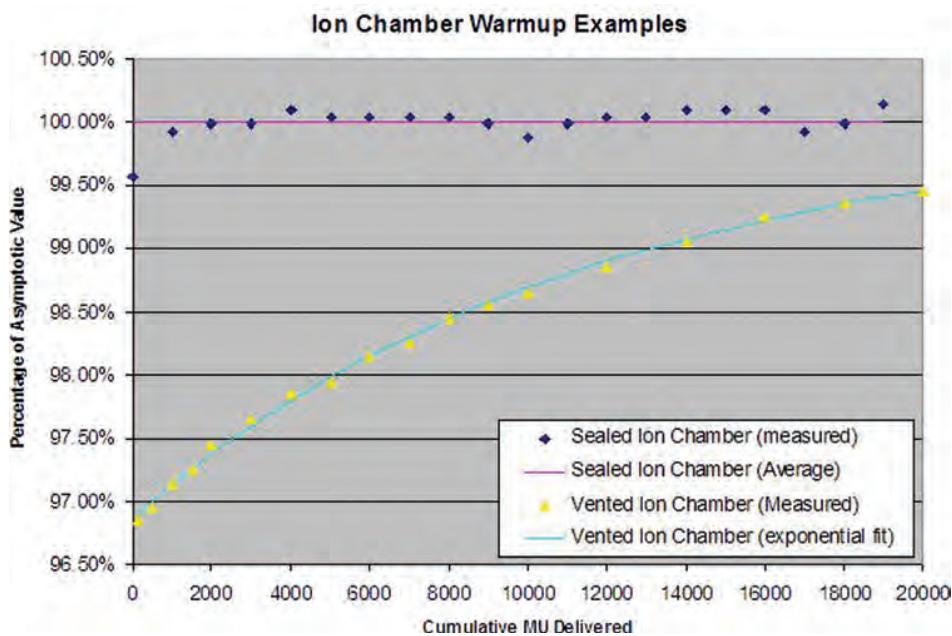


FIG. 1. Output of a closed (sealed) vs. open (vented) chamber as a function of warm-up MU. Data courtesy of Accuray, Inc.

possible patient contact points can be seen by at least two of the monitoring CCTV cameras. Equally important as the presence of adequate CCTV cameras is the staffing requirement that at least one person in charge of treatment delivery must watch the video monitors during robot movement.

II.A.3. Room shielding and radiation safety

An example of room shielding design is given in NCRP Report No. 151,⁹ including a thorough treatment of the special assumptions and calculations required to execute an adequate shielding specification for this type of therapy machine.

II.B. Accelerator QA

Radiation for robotic radiosurgery devices is produced by compact linear accelerators that differ in some aspects from their isocentric gantry-mounted counterparts. The robotic nature of treatment delivery necessitates smaller weight and dimensions than conventional radiotherapy accelerators. The CyberKnife® beam source is a 9.5 GHz X-band accelerator producing 6 MV X-rays using a fixed tungsten alloy target with primary and removable secondary collimators. The secondary collimators have circular apertures with diameters ranging from 5 to 60 mm [defined at a source-to-axis distance (SAD) of 800 mm]. In addition, there is an in-line dual ion chamber for dose monitoring. Other collimator configurations with moving leaves similar to a camera aperture have become available (IRIS™) and will require additions to the QA procedures described in this report.

Despite the differences between a robotic radiosurgery linear accelerator and the S-band accelerators used in conventional radiotherapy applications, most QA concerns and questions remain the same for both types of devices. With

this approach in mind, it is straightforward to develop a quality assurance schedule for a robotic radiosurgery accelerator based on existing AAPM Reports.^{4,7,10–14}

II.B.1. Daily accelerator QA

It is important that the linear accelerator is sufficiently warmed up prior to obtaining any quality assurance measurements. It is recommended that each site establish a fixed number of monitor units (MU) for warm-up consistency. The number of MUs needed may depend on accelerator generation and chamber type (open vs closed).

Older CyberKnife® accelerators have monitor ion chambers that are open to ambient temperature and pressure changes, while newer systems have “closed” chambers. Figure 1 shows the output of a closed and an open ion chamber as a function of warm-up MU. Running a warm-up should be considered after a machine downtime of more than 4 h. For accelerators with closed chambers, a warm-up of 2000 MU is sufficient.

An open chamber will continue to warm up and cool down during a normal treatment day. A warm-up of about 6000 MU will put the chamber at a temperature which reflects the average chamber temperature status during a typical treatment. The actual fluctuation of the chamber during a treatment day is smaller than the full range of 2.5% graphed in the plot.

The output of the linear accelerator in general should be measured once per treatment day, e.g., using a Farmer chamber with buildup cap. More frequent measurements for open-chamber systems may be justified if significant changes in temperature or atmospheric pressure occur within the course of a treatment day. In order to minimize the possibility of manual entry errors leading to incorrect output, it is strongly recommended that each CyberKnife® site determine an

acceptable tolerance level, e.g., 2%, within which no adjustment to the calibration factor is made. This daily variation is less than the 3% recommended in TG-40 (Ref. 7) and TG-142,⁴ but the large fractional doses delivered in radiosurgery and hypo-fractionated radiotherapy justify a more stringent guideline. It is also strongly recommended that if the variation exceeds 2%, a Qualified Medical Physicist corrects the calibration.

On a daily basis, we also recommend inserting an incorrect secondary collimator in treatment mode to verify the collimator interlock. Similarly, the interlock for a missing collimator should be checked daily.

II.B.2. Monthly accelerator QA

The dose output, energy constancy, and the consistency of the beam shape and beam symmetry should be checked monthly and compared to values obtained during commissioning. Typically, the largest collimator (60 mm) is used for this check.

Symmetry measurements are similar to those performed on radiotherapy linear accelerators.¹⁰ Film irradiation and analysis may use point or area methods to evaluate beam symmetry, but following TG 45 and TG 142 (Ref. 4) are encouraged. Symmetry should be measured at a depth of 50 mm in two orthogonal planes (nominal in-plane and cross-plane). The measurements should pass the criterion established at the institution, which should be the same or more stringent than the acceptance testing criteria.

Because the CyberKnife[®] linear accelerator does not have a flattening filter, beam profiles are curved in the central portion of the beam. Therefore, the concept of “flatness” normally measured for radiotherapy beams is not applicable. While any number of point or area measurements for the beam profile may be used to establish constancy, it is recommended to use at least three radial locations within the central portion of the beam. The relative values should not differ from beam data in the treatment planning system by more than 1%. For example, irradiate radiochromic film using the 60 mm collimator and compare the ratios of intensity values at 10, 15, and 25 mm radii to the treatment planning system (TPS) beam data.

II.B.3. Annual accelerator QA

Though recommendations on commissioning^{15,16} are beyond the scope of this report, it is recognized that commissioning is a critical aspect from the point of view of patient safety. In small beam dosimetry, the choice of an inadequate detector can result in severe dosimetric errors. AAPM TG 106 (Ref. 14) on “Accelerator Beam Data Commissioning and Equipment” contains guidance on appropriate equipment for use in the commissioning and annual QA process, including guidance on which detectors may or may not be appropriate for measuring data for small beam sizes.

TG 51 (Ref. 13) or IAEA TRS-398 (Ref. 11) will be the assumed method for performing annual dose calibrations until new standards for small beam dosimetry are developed. The key difficulty with employing either method for

CyberKnife[®] calibration is the assumption of a 10 cm × 10 cm radiation field for determining the value for k_Q .^{13,17} Instead, a machine-specific reference field,¹⁷ i.e., the 60 mm collimator, is used for CyberKnife[®]. Equivalent field size corrections can be estimated for either %dd(10)_x or TPR(20/10) using, for example, the BJR Supplement 25 tables.¹⁸ Only a 0.3% error is made if the k_Q from a 6MV linac with TPR(20/10) of 0.68 is used.¹⁹ For consistency, the PDD at SSD = 100 cm for the 60 mm collimator should be measured with the same (small) chamber that is used for the TG-51 calibration. Converting the round field size of the 60 mm collimator and adjusting the collimator size for the extended SSD, an equivalent square field size of 6.75 mm × 6.75 mm results. An interpolation leads to the PDD at 10 cm depth. The PDD at 10 cm depth can be compared with a standard reference such as the British Journal of Radiology (BJR) Supplement 25 (Ref. 18 for the 6.75 cm square field size. From this value, the equivalent associated PDD value for a 10 cm × 10 cm field can be inferred.

The active length of the detector used for absolute dose calibration has been shown to systematically change the calibration results.¹⁹ Detectors for absolute dose calibration of the CyberKnife[®] should not have an active length of more than 25 mm, and ideally have an active length of no longer than 10 mm. As with any clinical accelerator, the calibration shall be traceable to NIST. The recommendation is to perform an independent verification as well, e.g., by participating in a TLD program through an accredited dosimetry calibration lab (ADCL). A secondary check using independent equipment by another qualified physicist similar to the annual peer review as recommended in Ref. 6 is also an option.

The annual QA of the accelerator should repeat selected water phantom measurements performed during commissioning. It is important to verify that the accelerator central axis laser and radiation field centroid match to better than 1 mm at 800 and 1000 mm DAD before performing water phantom measurements. (The Task Group recognizes that measuring and adjusting the CyberKnife[®] centerline laser to a tolerance less than 1 mm using the laser mirror assembly available on the CyberKnife[®] prior to June 2008 is a difficult undertaking. CyberKnife[®] machines delivered after this date use a gimbal mounted laser adjusting system that makes it possible to reduce this tolerance to better than 0.5 mm). Reducing the coincidence tolerance to this level will require measurement techniques more exacting than those used for conventional linear accelerators. One technique which has been successfully used it to adjust the laser/beam alignment to 1 mm at 160 cm SAD, which translates to a 0.5 mm alignment accuracy at 80 cm SAD. Refer to Sec. III B 1 for a more complete discussion of the influence of laser position on the overall dose placement accuracy of the Cyberknife[®] system). Checking a minimum of three (clinically most used) collimators including the 60 mm collimator is highly recommended. Beam data checks for the selected collimators should include TPRs at several depths, or alternatively a check of PDD if a PDD curve was obtained at the same time as the TPR during commissioning. The off-center ratio (OCR) measurements for the selected collimators should be done at five tabulated

depths. Output factors should be checked for the 60 and 5 mm collimator as well as the collimators selected for TPR checks.

Currently, the gold standard detector for TPR, OCR, and output factor measurements for small beam dosimetry is a diode, but other detectors have been studied as well.^{20,21} Several diode models are available commercially. The diodes should be evaluated for potential dose perturbation based on their respective construction.²² It is not recommended to use chambers, even microchambers, for output factor measurements below collimator sizes of 20 mm.¹⁴ For the OCR measurements, film is a good alternative to diodes, as it has a higher resolution. Other detectors such as diamond detectors may be suitable for small field dosimetry, but have not been widely used because of limited availability and cost.

Dose output linearity measurements should be performed during the annual QA. Linearity should be measured through the range of clinically used MU/beam values down to the level of the minimum monitor units delivered per beam in any given fraction. Linearity should be measured as a ratio of detector reading per monitor unit delivered, based on the final reading for the primary monitor chamber. The monitor units of clinical beams should be maintained within the 1% linearity range. The physicist should use caution when unusual circumstances require treating with beams below this range.

II.C. Imaging subsystem

The primary goals of imaging QA for the CyberKnife® are to ensure accurate image guidance for patients undergoing SRS, and to minimize the radiation exposure to patient and staff. QA tests should detect changes in function of the imaging subsystem from its original level of performance that may result in a clinically significant degradation in image quality, which in turn may contribute to a loss of targeting accuracy and/or a significant increase in radiation exposure. The objective of such tests, when carried out routinely, allows for prompt corrective action to maintain targeting accuracy at levels suitable for SRS.

With the increased utilization of image guidance in radiation therapy it has become increasingly common for the Qualified Medical Physicist to be responsible for managing and evaluating an x-ray imaging system. This requires knowledge of QA procedures, specialized diagnostic measurement equipment, and imaging fundamentals that have been the purview of diagnostic medical physicists in the past. The difficult issue of having to accomplish effective QA in complex systems which incorporate technologies that cross traditional professional discipline boundaries will have to be addressed in depth elsewhere. Our goal in this section is to present what we believe are the fundamentals of adequate QA for this important subsystem. We recommend that institutions make appropriate resources available to perform the necessary QA for the imaging subsystem.

At the time of publication, Accuray Inc. makes no recommendations for QA procedures for the imaging subsystem of the CyberKnife® beyond those identified for periodic preventative maintenance conducted by field service personnel (see Secs. II.C.1 and II.C.2). Also, the current Accuray ac-

ceptance test procedure (ATP) does not contain any tests that could form the baseline for x-ray imager performance. Consequently we recommend that the following measurements be performed or verified at the time of original CyberKnife® acceptance and thereafter as deemed appropriate by the clinic's Qualified Medical Physicist commensurate with the scope of clinical services provided.

II.C.1. Imaging geometry

The principle imaging elements (sources and detectors) of the CyberKnife® image guidance system are rigidly attached to the treatment room. The imaging geometry is schematically shown in Table 1 below for the two detector configurations currently in existence (G3 and G4). The centerline of the imaging field of view from the location of each x-ray tube focal spot to the center of its respective image receptor makes a 45-deg angle with the plane of the floor. The CyberKnife® targeting and imaging alignment center is defined by the isopost, a rigid fixture that reproducibly mounts to the imager base frame Table 1. A small isocrystal is mounted at the tip of the isopost and represents the coordinate system reference of the CyberKnife® system. The isocrystal is a small light sensitive bead whose supporting circuitry detects the light from the central axis laser.

All targeting processes rely on both a good knowledge and the continuing stability of the imaging geometry. Once the site-specific imaging geometry is established and measured, it is important to verify on an ongoing basis that this rigid geometry has not shifted from events such as building settling, equipment collisions, earthquakes, etc. The upright detectors of the G3 configuration have mounting camera stands that allow both rotation around the normal to the detector axis and translation in the mounting plane of the detector. The G4 configuration allows only translation along the long axis of the detector. The evaluation of the rotational aspect of G3 imagers is beyond the scope of these recommendations; concerns should be directed to the manufacturer.

One of the routine checks is to verify that the radiographic shadow of the tip of the isopost falls at a consistent imager pixel location. This imaging alignment check is carried out by attaching the isopost to the camera stand and acquiring an image of the tip of the isopost. The image of the isocrystal should be within 1 mm of the center of the diagonals of the image, and at the center pixel ± 2 pixels. Measurements should be made as often as monthly if there is concern for movement due to special local conditions such as frequent earthquakes, elastic soil conditions not mitigated by building design, the x-ray tube or an amorphous silicon detector replacement or servicing, or when a potential imager shift is suspected for any reason. This imaging iso-center test covers the alignment of the imaging subsystem with the geometric isocenter.

II.C.2. X-ray generator and sources

The x-ray sources are conventional rotating anode tube and housing assemblies equipped with at least 2.5 mm aluminum added filtration. A fixed collimator shapes the beam

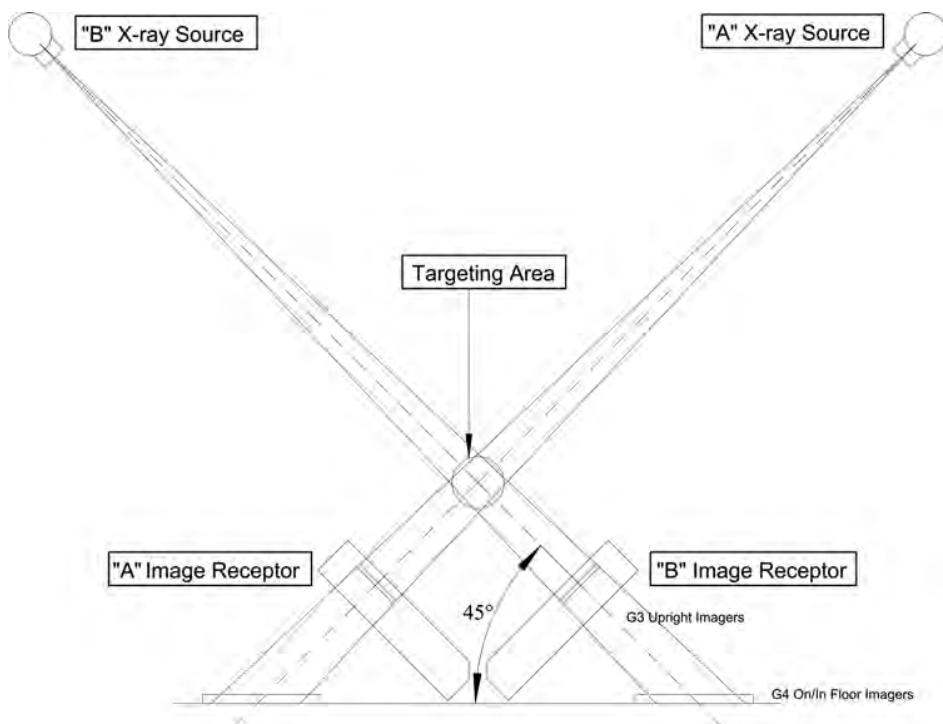


FIG. 2. Image Geometry of image-guidance x-ray system. This view has the observer standing at the head of the couch looking toward the patient.

of useful radiation. The x-ray generators supplying high-voltage power operate at 37.5 kW at peak power output and can deliver x-rays with technique factors of 40–125 kV, 25–300 mA, and 1–500 ms.

Because the x-ray machines used for targeting in the CyberKnife® system are essentially unmodified conventional x-ray generators and x-ray tube configurations, the QA principles and procedures described in AAPM Reports No. 14, Part 3 (Ref. 23), and No. 74 of Task Group 12 (Ref. 24) can be applied. The details of these procedures will have to be modified to accommodate the imaging geometry and the resulting testing setups required, e.g., recommendations on the focal spot

size affecting the image resolution. The rule of thumb suggested in AAPM TG 12 (Ref. 24) for general purpose imaging situations, that the nominal focal spot size should be approximately 0.1% of the source–image distance (SID), cannot be realized in the very long SID geometry of the CyberKnife® targeting system. This long SID geometry reduces the contribution of focal spot size on image sharpness. Therefore, image sharpness in the CyberKnife® targeting system is more likely to be detector limited and depend on the inherent resolution of the image receptor (1024×1024 pixels covering 41×41 centimeters for the G4 implementation).

Because the x-ray machines have no light localizers, special care must be exercised to verify that the sensitive region of conventional test equipment is properly centered in the imaging field. A small inexpensive diode tool laser placed on a small tripod and directed back across the tip of the isopost to the center of the x-ray tube collimator aperture has been found to greatly facilitate positioning the test equipment that must be placed far above the floor to a position suitable for its sensitivity. Once positioned, the image of the detector on the system imager verifies that the full sensitive area of the detector is radiated.

A list of the suggested quality assurance measurements, suggested frequencies, and references for a description of the procedures is summarized in Table 1.

II.C.3. Amorphous silicon detectors

There are currently two types of imager configurations as shown schematically in Fig. 2: (1) two $41 \text{ cm} \times 41 \text{ cm}$ amorphous silicon detectors with a resolution of 1024×1024 pixels mounted flush or 15.2 cm above the treatment room floor



FIG. 3. The black isopost is mechanically mounted on the base frame of the imager system. The isocrystal at the tip of the post defines the coordinate system reference of the CyberKnife® system. The robot is going through the path calibration process (Sec. III B 1), with the beam laser scanning the isocrystal.

TABLE I. Imaging system related quality assurance.

Parameter	Method	Tolerance	Suggested frequency	Reference
Filtration	First half value layer	> 21 CFR, 1020.30	Annually	AAPM Report 14, Part 3, p. 85; AAPM Report 74, Sec. 5.2.1
kVp Accuracy	Noninvasive kVp meter	+/- 5%; = or better than manufacturers specifications	Annually	AAPM Report 74, Sec. 5.3.1
mA Station exposure linearity	Diagnostic ion chamber	Adjacent mA stations within +/- 20%	Annually	AAPM Report 74, Sec. 5.3.3, AAPM Report 14, Part 3, p. 84
Exposure reproducibility	Diagnostic ion chamber	Coefficient of variation < 0.10	Annually	AAPM Report 74, Sec. 5.3.3, AAPM Report 14, Part 3, p. 84
Focal spot size	Slit camera or star pattern	NEMA Standard XR 5-1992 (R1999)	At ATP then as required	NEMA Standard, AAPM Report 74, Sec. 5.2.6
Imager position reproducibility	Isopost tip	+/- 2 pixels	Quarterly	Accuracy test procedures in conjunction with field service
Bad pixel statistics	Accuracy field service	Bad pixels less than maximum limit, number, and position	Quarterly	Accuracy test procedures in conjunction with field service
Other predictive imager tests, SNR, CNR, gain stability	Under development, more research needed			

(G4); (2) two 20 cm × 20 cm amorphous silicon detectors with a resolution of 512 × 512 pixels mounted in 61.0 cm high stands (G3) perpendicular to the x-ray generator beam axis.

The underlying principles described in AAPM Report 75 (Ref. 25) should transfer very well to the evaluation of the amorphous silicon imagers used in the CyberKnife® system, particularly the discussion and evaluation of signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR). There are several spatial resolution and contrast detail phantoms available on the market today that are beginning to be used on the imaging subsystem of the CyberKnife®.

The effect on the 45-deg incidence of x-rays to the plane of the imager presents an interesting problem when trying to interpret the effect of pixel size on modulation transfer function (MTF) or relative MTF measurements. Similarly, the image conversion calculations to reformat the 1024 × 1024 raw pixel images to an equivalent 512 × 512 pixel image orthogonal to the x-ray image central ray may have consequences for QA measurements.

There is currently no published data on tracking algorithm accuracy as a function of imager parameters. Imager parameters that are expected to have a direct relationship to functional adequacy in x-ray target imaging are signal-to-noise ratio, contrast-to-noise ratio, relative modulation transfer function, imager sensitivity stability, bad pixel count and pattern, uniformity corrected images, detector centering, and imager gain statistics. More work is required to establish reliable QA threshold recommendations for these tests. Specific recommendations for the type of imager testing and expected results are thus still premature. Until then, baselining imager parameters at install, and repeat measurement of the baselined parameters on an annual basis, will provide a database for evaluation.

II.C.4. Patient dose due to image guidance

The magnitude of radiation dose estimates due to the image guidance process using the methodology of AAPM

TG 75 (Ref. 25) has been reviewed for the CyberKnife® G4 geometry. The assessment of TG-75 was done for the original G3 imager configuration. For the G4 geometry, the default source-to-isocenter separation is 225 cm; the isocenter-to-detector separation is 120 cm for the “on-floor” detectors and 141.8 cm for the “in-floor” detectors; the detector active area is now 41 cm × 41 cm. The source/patient entrance distance is nominally 210 cm for cranial radiosurgery and 200 cm for body radiosurgery using the same isocenter to entrance surface offsets as AAPM TG 75. The imaging radiation field for the in-floor geometry is collimated to a trapezoid shape whose maximum full dimension, including penumbra, is approximately 33 cm × 26 cm, W × L. The sentence in AAPM TG 75 stating, “The source collimator is telescopic, which allows the field size to be adjusted.” is incorrect: The collimation of the imaging fields is a fixed aperture. Measurements made in the default geometry described above produce dose per image results that still fall in the range of 0.10–0.70 mGy as presented in Table 1 of AAPM TG 75. We recommend that the methods of AAPM TG 75 continue to be used to estimate the entrance dose levels due to image guidance for the CyberKnife® system.

II.D. Treatment planning software—QA and safety

Treatment planning software has become increasingly complex. Versions are updated frequently with new features and tools, as well as changes to the underlying optimization and dose calculation algorithms. It is essential that each software upgrade be considered as a new installation because it is not safe to assume that previously tested features be carried over into the new version without changes. Because changes in one part of the software can have unexpected impact on other functions, basic software testing of the whole application should be performed. The exception to this rule is software patches to fix known bugs. In this case the functions in the part of the software code being changed have to be validated, and a less extensive overall software check is sufficient.

The AAPM TG 53 has published an extensive document on software testing.²⁶ TG 53 lists a series of tests for photon dose calculation commissioning. This task group recommends that all verification checks listed in Appendix 3, if applicable, should be performed before a patient is treated. The following discussion is limited to software QA issues which have not been discussed in TG 53.

Secondary MU checks for plan validation are part of the software QA. AAPM TG-114 (verification of monitor unit calculations) will cover the general concepts of secondary MU calculations. The specific challenges of a secondary MU check for robotic radiosurgery lie in the high number of beams and the high sensitivity to inhomogeneities as well as steep dose gradients. In addition, multiple targets may be treated in one plan, which means it is not possible to choose one dose calculation point to verify the accuracy of all beams. Nevertheless, a secondary MU check *shall* be done for all plans for the ray-tracing calculation, using either commercial software, self-developed independent MU check software, or by hand-calculating all beams. The tolerance should be within 2% to the reference point for the composite of all beams in which the point is within the penumbra or in-field region, but excluding beams in which the point is outside the penumbra region.

In the case where the dose calculation was performed using the Monte-Carlo code (e.g., in lung, T-spine, nasopharynx), a hand calculation will result in differences much larger than a normal secondary calculation check tolerance. For small fields in highly inhomogeneous areas, for example, lung tumors, mean differences of 20% have been observed for individual beam dose calculation for ray-tracing vs Monte Carlo^{27,28} (Fig. 4). When a second MU check of a MC plan is performed, a mean deviation of about 20% lower dose in the MC dose vs ray-tracing dose calculation algorithms is to be expected. The actual value can, of course, vary based on tumor size and location within the lung, i.e., proximity to denser areas. It is worth noting that the beam list for MC plans contains ray-tracing dose calculation results as well, which could be used as first-order approximation in a second MU check.

Doing an actual DQA measurement for MC-based plans is not feasible with currently available phantoms. The large variances in mean dose variation between MC and ray-tracing based on tumor size and position would require a customizable, anthropomorphic lung phantom with the option of placing different size tumor models, including spacing for a detector such as film, at a variety of locations in the lung. Nevertheless, it is feasible to verify the accuracy of the MC dose calculation for at least one or two sample anatomies by performing DQA in an inhomogeneous lung phantom (see Sec. III C 3) at a frequency determined by the individual user.

Data security: At commissioning, we recommend checking if the essential beam data entered in the treatment planning software could be changed, either on purpose or inadvertently. If potential security issues are discovered, the user should report the findings immediately to the vendor to expeditiously identify a method to secure the data. Until the data are secured, appropriate safeguards should be implemented.

The software should also be evaluated for Health Insurance Portability and Accountability Act (HIPAA) compliance; specifically, procedures need to be put in place to prevent accidental disclosure of Protected Health Information (PHI). Special attention should be placed on situations when the workstations are unattended or potentially unsecured during and after work hours.

Custom CT model: Most treatment planning systems (TPS) allow entering a custom CT density model for calculating heterogeneity corrections, and the CyberKnife® planning system is no exception. This model may be based on electron and/or mass density. It is important to understand which data is needed to correctly commission the CT density model: electron density, mass density, or both. The user is cautioned to know which density type their system uses for each dose calculation algorithm and follow the recommendations for CT QA given by AAPM TG 66 (Ref. 29) and NCRP Report 99 (Ref. 30). The physicist should be able to verify the change in calculated dose from the TPS for different CT density models by using beams with the same orientation and MU, and only changing the CT density model.

If multiple CT scanners are used for patient simulations, the physicist may choose to either create a separate model for each scanner, or create a multiple-scanner average. It is recommended that if separate models are used for each CT scanner that a QA program be implemented which ensures the correct CT density model is selected for a patient's plan. Alternatively, if a composite CT density model from all scanners is developed, the task group recommends that the uncertainty in the dose calculation based on the composite CT density model be evaluated to be less than 2%.

Tissue inhomogeneity correction (without Monte Carlo): Accurately correcting for tissue inhomogeneity has become increasingly important when a SRS treatment of the lung or in the head and neck area is planned. AAPM TG 65 (Ref. 31) discusses the topic extensively, including factors influencing the required level of accuracy for inhomogeneity correction in planning. All inhomogeneity correction options available in the software *should* be evaluated for their respective accuracy by doing absolute dose measurements with a suitable chamber in a phantom. A slab phantom using different density slabs for bone and lung³² is the minimum standard; a more anthropomorphic phantom, e.g., with a dense tumor inside a low-density lung, should be used if available. The most accurate inhomogeneity model for an anatomic location should be chosen. An example for a situation in which the ray-tracing calculation is more accurate than the MC calculation is spine plans for 3.x version of the planning software. The lower resolution of the MC dose calculation causes a difference in dose interpolation, which may cause a decrease in the dose gradient toward the spinal cord, leading to higher reported than actual cord dose. We discourage using the ray-tracing dose calculation algorithm for targets in the lung; instead, the Monte-Carlo dose calculation algorithm described below should be used for treatment planning in the lung.

Tissue inhomogeneity corrections with Monte-Carlo dose calculation: MC dose calculation algorithm commissioning is

done in two stages. In the first stage, after creating the accelerator-specific source model, the source model is evaluated as to how well its calculation can match the measured beam data in water. The MC source model, when calculating with 1% uncertainty, should be able to generate TPR data with maximum deviation of no more than 2% from the measured data at d_{max} and beyond. The off-axis ratios should not deviate from measured values more than 2% at the point from the field center to 50% of the field center dose (FWHM). The output factors should be modeled to within 0.5% uncertainty. Because the MC calculation is a statistical model, current computing speeds will not realistically allow plan calculations to better than 2% uncertainty within a reasonable calculation time. As a general rule, the uncertainty of TPR and OAR match should be similar but no worse than the lowest uncertainty used for MC.

The second stage of commissioning applies the MC calculation delivering beams to an inhomogeneous phantom to measure the difference between plan dose and delivered dose at selected points. Ideally, the experimental setup would include a DQA plan to an anthropomorphic phantom (e.g., Quasar with lung insert, Modus Medical, Ontario, Canada) including dosimeters in the target as well as in low-dose regions. As an alternative, we recommend using a dose verification method as described by Wilcox³² or in TG 105 (Ref. 33) as a minimum standard. In this test, a dose is delivered to a Farmer chamber embedded in a simple slab phantom, using different density slabs (e.g., cork, Styrofoam, or commercial lung density slab).

For small cones with a diameter ≤ 10 mm, MC models of older software releases may not fit the beam data to the tolerance levels described above, but are more on the order of 5% accuracy. In this case, the advantages gained by using a small collimator and correcting for tissue inhomogeneities by using MC have to be weighed against the level of accuracy of the MC model. The ultimate judgment on dose accuracy is a dose measurement in an inhomogeneous phantom which is modeled closely on the patient anatomy. An example is a small lung tumor, which could be modeled by a piece of dense plastic inserted in cork or Styrofoam, with space for either TLD detectors or, ideally, small film. Simulating the complex, inhomogeneous anatomy of a small tumor in the nasopharynx, however, will go beyond what a typical clinic can provide in regard to phantom. Packing the air cavities is an option which should be considered. The reasoning for either decision in a clinical case should be

TABLE II. Peripheral dose values as a percentage of the MU ($100 \times$ dose in cGy/MU) delivered in each treatment. Data taken from Ref. 36; the preshielding CyberKnife® data was omitted because all machines were retrofitted in 2006.

Distance from the target (cm)	Peripheral dose values as a percentage of MUs ($100 \times$ dose in cGy/MUs)				
	LINAC-mMLC (%)	LINAC-cone (%)	CK postshielding (%)	TomoTherapy (%)	Gamma knife (%)
30.5	0.110	0.092	0.036	0.003	0.030
43	0.049	0.045	0.030	0.002	0.010
53	0.032	0.030	0.033	0.002	0.010
75.7	0.014	0.013	0.023	0.002	0.002
80	0.012	0.011	0.023	0.002	0.002

documented in a special physics report by a Qualified Medical Physicist.

DQA plan: A series of DQA tests should be performed for several diverse treatment plan types (e.g., trigeminal, spine, multiple brain metastases in one plan) before patient treatments are started on a newly installed machine. We also recommend doing DQA for every patient on a newly installed machine until the treatment team gets a good assessment of what level of accuracy, for example, 90% pass rate of a 2 mm/2% gamma index for an area encompassing the 20% isodose line, can be achieved in their clinic. Because SRS is by definition performed with high doses delivered in 1–5 fractions,³⁴ the physicist should perform DQA, selecting a sufficiently complex patient plan, on a regular basis as discussed in Sec. III C 3. Examples of complex plans are a retreatment of a spinal lesion in immediate proximity of the spinal cord, or a pediatric case where the tumor is close to the optic apparatus or other critical structure.

Whole-body dose: Two phantom studies have been published regarding the whole-body dose for CyberKnife® treatments.^{35,36} During the treatment process, the ALARA principle should be considered, i.e., the treatment planning should be designed to achieve the clinically optimal results with as few beams and monitor units as feasible. The use of multiple collimators has been demonstrated³⁷ to reduce the number of MU needed for a treatment plan. In addition, using the sequential optimization³⁸ treatment planning tool with MU optimization, and utilizing the MU limit function, will reduce the peripheral dose considerably compared to the older system configuration reported on in Ref. 35 (Tables II and III).

III. QA FOR INTEGRATED SYSTEMS

III.A. Tracking system (software and imaging)

The image guidance process of the CyberKnife® system is the core technology that produces dose placement accuracy adequate for SRS without the aid of mechanical fixation of the patient. The ultimate accuracy of the image guidance process depends on a number of specific parameters, namely design, installation, and usage, which all have their own QA issues.

A targeting system testing process where a phantom (target object) is moved a known and carefully measured amount, forms the basis of all image guidance accuracy testing. There are two specific components to this process: (1) the *image processing component* where a live image is

TABLE III. CK peripheral dose measurements at various points in a Rando phantom for a conformal treatment plan in the thorax and in the brain. Doses are expressed in cGy as a percent of the delivered MU [i.e., each table entry represents $100 \times (\text{dose in cGy})/\text{MU}$]. Standard deviation for the measurement was $\pm 0.002\%$ to 0.003% of MU delivered. Data taken from Ref. 35.

Thorax plan			Brain plan		
Cranio-Caudal distance from the field edge (cm)	Location	With shielding (% of MU delivered)	Cranio-caudal distance from the field edge (cm)	Location	With shielding (% of MU delivered)
15	Neck	0.065	>18	Neck	0.066
18	Thorax	0.050	30	Upper thorax	0.048
			43	Mid thorax	0.046
30	Lower thorax	0.036	53	Lower thorax	0.042
43	Pelvis	0.038	71	Pelvis	0.036

compared to a standard or ideal image in a 2D/3D registration producing typically, both shift and rotation estimates and a figure of merit for the confidence of the process and (2) the conversion of the output of the image processing stage to a *geometric targeting change* that will be acted upon by the radiation delivery system or the machine operator. Changes in image quality may affect parts of this process and is the area where routine, on-going QA efforts will be focused.

Among the imaging conditions that would be expected to reduce the image guidance systems' accuracy are very large, difficult to penetrate patients, operating the imaging system at too low a kVp or mA station setting, trying to image a target region with too little inherent object contrast, such as spine tracking on a patient with severe osteoporosis, or attempting to use x-ray image receptors suffering from degraded sensitivity or high levels of image artifacts.

III.A.1. Targeting methods

The following sections describe issues specific to each of the CyberKnife® targeting modalities that must be considered when attempting to determine accuracy and reproducibility for that targeting method. In this section, the targeting methods will be introduced, while the specific image guidance QA tests and limits applicable to all targeting methods are described in Sec. II A 2.

There are three targeting methods currently in use in the CyberKnife® image guidance system: bony structure tracking,³⁹ fiducial marker tracking,⁴⁰ and soft tissue tracking. The bony structure tracking includes skull tracking (6D Skull) and spine tracking^{41,42} (XSight® Spine). Soft tissue tracking (XSight® Lung) uses density differences between the target and surrounding lung tissues without the need for invasive fiducial placement.

6D Skull tracking: The Skull tracking algorithm uses the entire image region to develop a targeting result. Because of the very high radiographic contrast at the boundary of the skull, steep image gradients are produced that allow the 2D/3D registration algorithm³⁹ to function very reliably. Imaging parameters *should* be adjusted in both imager views so that brightness and gradient gains are close to 1, i.e., most similar to the digitally reconstructed radiograph (DRR).

While the skull tracking algorithm is generally very robust, there are a few scenarios where special attention is

required. In *elderly patients*, Paget's disease of the cranium may cause unusually high vascularization. If contrast is needed for contouring purposes, these patients *should* also have a noncontrast CT at simulation for tracking purposes. A contrast simulation CT causes the vascularization in the cranium to be emphasized in the DRR, which will lead to high tracking uncertainty characterized by large (>1.1) brightness gradient values. When treating lesions in the *cervical spine*, XSight® Spine or fiducial tracking *must* be used. The high flexibility of the cervical spine does not permit accurate targeting if the cranium is used for tracking. For targets in C1 or C2, the merits of cranial vs spine tracking can be debated. However, spine tracking tends to fail not because of the location *per se*, but because the deformation, i.e., movements of bones relative to each other, is outside the spine tracking tolerance.

Fiducial tracking: Tracking by locating radio-opaque markers rigidly associated with a target is one of the most accurate CyberKnife® targeting procedures. Overall accuracy is primarily dependent on the number of fiducials implanted,^{43,44} their spread, and their ability to be uniquely identified on each targeting image. Among the conditions that can influence this accuracy are fiducials that move with respect to each other, fiducials that cannot be resolved on both images, fiducials that are implanted near metallic surgery clips, imagers that have severe uncorrected pixel artifacts, and CT imaging artifacts.

All localization x-rays for patients with the above mentioned conditions, as well as all fiducial patients in general, need to be carefully monitored at all times. The CyberKnife® software displays the fiducial configuration, as marked by the treatment planner on the planning CT, in the DRR window for both camera views. In the live images, the tracked fiducials (or what the system has identified as fiducial) are displayed as well. It is important to monitor the live image for accurate tracking to be able to immediately interrupt the treatment if a mistracking occurs. Image tracking parameters should be tuned during patient setup to achieve as robust tracking as possible. Fiducials which consistently mistrack should be switched off for tracking.

Spine tracking: Spine tracking relies on the feature rich boney structure along the spinal column. To accommodate small interfraction deformations, this algorithm performs small-image registrations at 81 points at the intersections of a rectangular tracking grid. This targeting method is

influenced by initial placement of the targeting grid, inherent bony contrast (e.g., either a large patient or severe osteoporosis), x-ray technique, and initial alignment to the wrong vertebral body.

There are several methods which can be employed to increase tracking robustness. It is essential that the spine segmentation tool is used, if the software version allows, removing DRR artifacts such as the diaphragm, clavicles, ribs, and mandible. In most cases, spinal hardware increases the tracking accuracy, unless the hardware consists of long, unstructured rods, in which case fiducials should be placed. If the bone is severely osteoporotic in the target area, it is recommended to track a vertebral body above or below and adding a PTV margin. Osteoporotic bone is not only found in the elderly, especially women, but also in pediatric patients with bone lesions.

The tracking grid size should be chosen to maximize the amount of spine within the grid. The grid should neither include too much soft tissue (in which case it *should* be made smaller), nor miss part of the bony spine (in which case it *should* be enlarged).

At all times, it is important to verify visually that the correct level is tracked. Special attention should be paid when treating thoracic spine. Due to similarities in the bony structures at that particular region, misalignment to the incorrect vertebral body could occur. This could lead to a spatial misplacement of dose causing treatment of the wrong vertebral body. It is therefore important that after the radiation therapist has aligned the patient, the radiation oncologist and the Qualified Medical Physicist are called to verify that the correct vertebra is being treated. Mistracking is less likely if the “confidence level” in the software is kept at the default value. On the other hand, it is important to have an additional visual safety check for the rare case when the algorithm does go wrong. A good trick for starting to gain experience to visually identify the correct vertebral level is to place a gold fiducial marker, oriented in superior-inferior direction with its position marked by a tattoo, on the skin at the level of the tracking area before simulation. At the time of treatment, the gold marker can be easily placed into the same position again using medical tape or wound dressing, thereby visually verifying the accuracy of the tracking level.

Soft tissue (XSight® Lung) tracking: This tracking modality uses the density difference of the target to the surrounding tissue. Tumors to be treated with this algorithm must have well defined boundaries, not be obscured by radiographically dense structures (spine, heart), and be within a range of sizes that can be accommodated by the algorithm. This tracking algorithm is very susceptible to x-ray technique and targeting parameter range choices (acceptable confidence threshold, image contrast setting, search range, etc.). If the x-ray imaging system is operating near its signal-to-noise ratio limits, targeting techniques utilizing soft tissue discrimination such as XSight Lung® would be expected to be most strongly affected. Anatomical criteria are also essential for accurate tracking. The tumor cannot be obscured by the mediastinum; therefore, it needs to be located in the lateral lung. It also cannot be obscured by the diaphragm,

which means that tumors located too inferiorly in the lung also are not good candidates for tracking.

XSight® lung tracking is the most challenging to verify for tracking accuracy. One way to learn the accurate use of the technology is to have a tracking session with the patient on the CyberKnife® to take setup images, build a Synchrony model, and visually verify stable tracking. Another option is to place fiducials (even though the patient is a potential XSight Lung patient) and compare the tracking results (e.g., motion amplitude in each translational direction) between XSight lung and fiducial-based Synchrony tracking.

III.A.2. Specific image guidance QA tests

Imaging algorithm calculation accuracy will only require verification during initial acceptance testing or major image guidance system upgrades. At installation, Accuray uses a series of automated tests (“TTool”) using anthropomorphic phantoms containing hidden targets⁸ to test the accuracy of the image guided targeting process. These phantoms can be attached directly to the robotic manipulator arm. The robot then moves the phantom such that all 6 deg of positional and angular freedom are tested throughout the range of clinical significance. The translational accuracy should be within 0.2 mm, and the rotational accuracy within 0.2 deg below 2 deg rotation from setup, and 0.5 deg at more than 2 deg rotation. The phantom positioning could be produced independently from the robot by using any number of precision positioning tools available, e.g., independent motorized positioning stages.

Effects of x-ray technique: The imaging parameters should be adjusted with the phantom at a defined offset to determine the effect of x-ray technique factors on targeting result stability. The imaging process can be degraded by choice of technique factors such that the limits of signal to noise ratio are approached to evaluate the targeting system in less than ideal imaging circumstances. The range of targeting results produced by these nonideal test conditions can help identify the variation in dose placement accuracy and consequent dose distribution blurring to be expected under similar circumstances in actual patient treatments.

If the tracking results vary considerably with x-ray technique, e.g., in the range of more than 0.3 deg in rotation, it is usually a strong indicator that the tracking accuracy, and therefore safe and accurate dose delivery, is compromised. Before treatment is started, it is essential for patient safety that the cause of the tracking instability is identified and eliminated. If the tracking instability cannot be eliminated, the treatment *should* be aborted and corrective actions be implemented before a new treatment is attempted.

Targeting accuracy: The CyberKnife® is capable of automatically moving the dose distribution to a new position identified by the targeting system as long as this new position is a translation less than 10 mm from a previous targeting result. The CyberKnife® can also compensate for detected target rotations; the magnitude of the maximum correction depends on the axis, path set, and the tracking modality. This capability should be specifically verified by

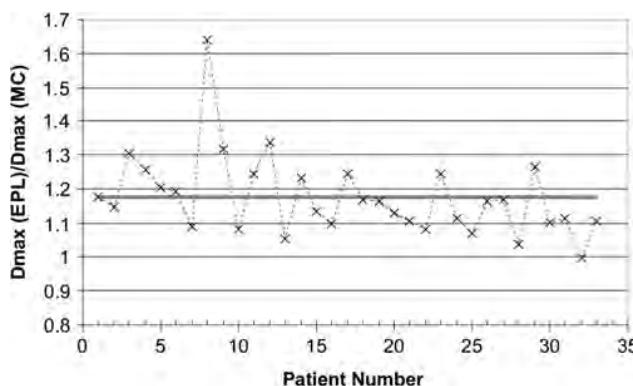


FIG. 4. Expected change in dose for Monte Carlo vs raytracing algorithms. Figure taken with permission from Ref. 27.

offsetting the phantom used for the End-to-End (E2E) test by a known amount within this range, and then delivering the plan radiation in this or several similar offset positions. The expected accuracy and reproducibility of this test *shall* result in an E2E test result within the system specifications of < 0.95 mm.

III.A.3. Practical implementation of image guidance

The use of anthropomorphic phantoms to characterize the targeting accuracy of an IGRT machine has at least two important aspects. The first is to demonstrate an accuracy result whose measurement conditions provide confidence that the measured accuracy value will apply directly to the conditions that exist in real patients. This is most logically the case when the phantom is a very close structural match to the anatomy present in real patients and produces targeting images that match very well with those produced from human anatomy. The concern comes in attempting to judge if there may be a different targeting result by using a targeting phantom that is less than a perfect physical match. Some sense of this can possibly be achieved by demonstrating consistent targeting results using anthropomorphic phantoms of different manufacture and construction (Fig. 5). The second targeting aspect is to use an anthropomorphic phantom to evaluate the limits of a targeting algorithm. This use is an attempt to find out what accuracy penalty might result when all conditions are not perfect. There are two ways to simulate a nonperfect imaging condition: Either the phantom is specifically designed to produce a difficult targeting situation, or the imaging process is degraded to simulate a similar difficult targeting situation using an unmodified phantom.

Routine imaging QA is best served when the testing process is demanding enough that changes in imaging quality can be detected before they have clinical consequences. Phantoms whose design is perfectly adequate for establishing system accuracy, for example, the head phantom used for End-to-End testing, may have features that are too idealized to be suitable for helping to detect a loss of accuracy when the imaging system is degrading or imaging conditions are less than optimal. There is still much work to be done by



FIG. 5. An anthropomorphic target phantom with the top removed to show the placement of the E2E ballcube to verify tracking accuracy. The top of the smaller ballcube used for Xspine tracking verification can be seen at the base of the cervical spine, labeled with an inverted "A". This phantom shown here can be used to verify cranial, fiducial and Xsight® Spine tracking.

both phantom and QA procedure designers before this balance will be better understood and taken advantage of.

There is often not enough feedback from the targeting algorithm to help the operator make intelligent decisions about which input changes will improve the reliability of the targeting process. For instance, the patient positioning function of the CyberKnife® treatment software includes the ability to display various statistics for live images depending on the type of targeting process in use (gain parameters for skull tracking, individual fiducial tracking statistics for fiducial tracking, etc.). This function is available by replacing the large scale "focus" image on the right of the patient-set-up user interface with a streaming log of data from the targeting process. This display location in the treatment-delivery user interface is taken up with dose and current treatment node related information. This sort of targeting system feedback should also be made accessible during the actual treatment process, although obviously in another region of the user interface. In general, this task

group strongly encourages manufacturers of image guidance systems to provide immediate feedback to the operators in the form of figures of merit or confidence estimates that will help guide changes to the imaging factors under the control of the operator.

III.B. Accuracy of radiation delivery (robot and accelerator)

The goal of path calibration and path calibration QA is to set and verify that the central axis (pointing direction) of a symmetrical radiation beam coincides, as close as is practically achievable, with the tip of the isopost for all deliverable beams in all CyberKnife® path sets. If a radiation beam centerline surrogate, such as a centerline laser, is used, then the coincidence of this surrogate to the actual radiation central axis must be established first. The following sections will describe the approach the manufacturer of the CyberKnife® robotic radiosurgery system currently utilizes to calibrate the robot pointing accuracy. Practical approaches to the verification and quality assurance of the results of this calibration process are discussed.

The robot manipulator places the position of the nominal radiation source of the linear accelerator at specific points in space called “nodes,” roughly distributed evenly on the surface of a sphere that is centered at the center of the x-ray targeting system (Fig. 6). Each node can originate a number of treatment beams (currently up to 12, Fig. 7). The location of these nodes is currently fixed in space, with some range over which the node sphere can be moved to accommodate targets that are not located at the center of the targeting and imaging volume. A group of nodes is termed a “path,” with path sets currently consisting of 1–3 subpaths. There are multiple sets of these treatment node “path” sets to accommodate specific treatment targets and situations. Each path set is separately calibrated

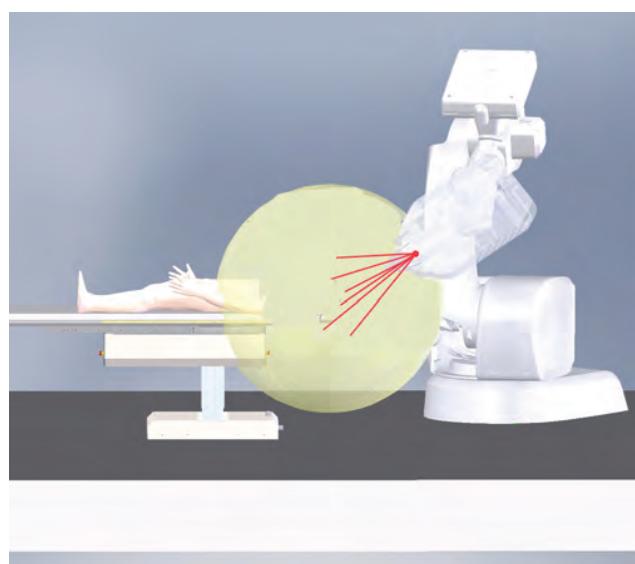


FIG. 7. Schematic of up to 12 beam directions originating from a node. Figure courtesy of Accuray Inc.

and thus must be separately evaluated for accuracy. It should be emphasized that all path calibrations are done isocentrically, i.e., by calibrating the beam pointing to the isocrystal.

III.B.1. Manipulator and path calibration

Several levels of positional calibration are applied to accomplish the submillimeter scale of positioning accuracy for the robot manipulator. These calibrations from coarsest to finest are Robot Mastering, 1st Order Path Calibration, and 2nd Order Path Calibration.

The *Robot Mastering calibration* is performed by the manipulator manufacturer and allows the specific raw joint encoder values for a single known, neutral, manipulator position to be provided to the manipulator controller computer. Once this “mastering” calibration is performed, the native robot coordinate system exists and the robot can move either under program or manual control in coordinate space.

The *1st Order Path Calibration* uses automated optical positioning to determine position data in the robot coordinate system specific to an individual system installation. Accuray installation or service personnel perform this procedure. These data fine-tune the mechanical pointing accuracy of the system based on the mounted position of the linear accelerator and determine the approximate location of the tip of the isopost to ~1 mm. The tip of the isopost (isocrystal) is a mechanical location in space to which the center of both the x-ray targeting system, and the manipulator path sets are nominally set. All primary system calibration procedures depend on the reproducible location of the isopost. Any physical damage to this post causes invalidation of future QA measures.

The *2nd Order Path Calibration* process fine tunes the pointing accuracy of the manipulator system to submillimeter accuracy. The QA process must also be capable of demonstrating reasonable accuracy in evaluating the adequacy of this calibration.

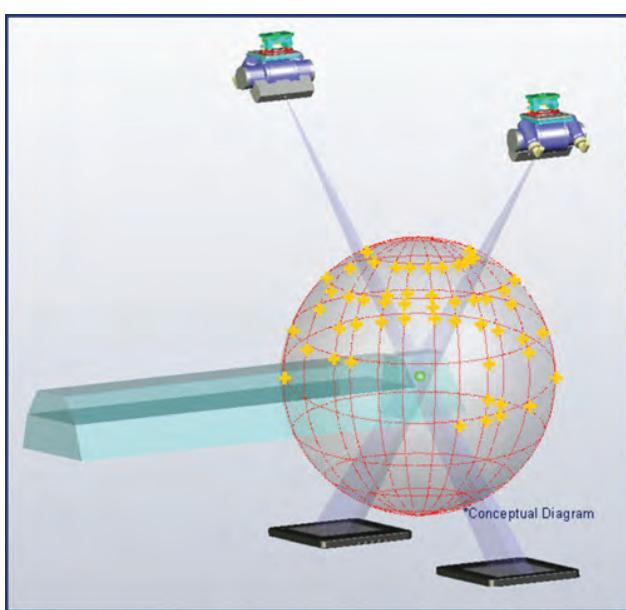


FIG. 6. Conceptual diagram of the node locations around the patient. Figure courtesy of Accuray Inc.

Both 1st and 2nd order path calibrations rely on the laser/beam central axis coincidence (see Sec. II B 3). After verifying that the radiation beam is symmetrical, by measuring the width of the penumbra at various opposing points around the perimeter, the mirror reflecting the laser is adjusted to match the measured location of the radiation central axis. The accuracy of the path 1st and 2nd order calibrations depend on how well the beam centerline surrogate, the laser, is adjusted to the center of the radiation field. The right-to-left averaged beam profile data entered into the CyberKnife® treatment planning system assumes that this relative offset is zero. If the laser marks a location within the field that is offset from the field center by as much as a millimeter as allowed by previous recommendation (Sec. II B 3), then this offset will be included in the calibration for every treatment node. This does not strongly affect the accuracy of the placement of aggregate dose distributions formed by many radiation beams because the overall position of these aggregates are corrected by setting a global offset correction vector as a final step in CyberKnife® system calibration. For large beams and volumes this will have the effect of blurring the steep dose gradient region at the edge of dose distributions in unpredictable ways. While this effect will always exist to some degree for all path calibrations, it is prudent to attempt the best possible laser/radiation position alignment prior to any 1st and 2nd order path calibration or path verification process.

III.B.2. Path calibration QA

Overall, there are three levels of QA evaluations providing a more accurate evaluation of the current state of manipulator-pointing accuracy.

The *first level* is either a (qualitative) laser geometric alignment check on the floor and/or the (quantitative) AQA test. The AQA test observes the co-centricity of a lateral and AP beam with the shadow of a tungsten ball placed inside the AQA phantom. The AQA test suffers from the limitation that actual treatment paths are not used. A detailed description of AQA will be given in Sec. III C 1. Both tests provide a broad, global check of the system alignment that does not have the ability to distinguish the source of a misalignment if either of the tests should fail.

For the laser geometric alignment check, a point on the floor where the linac radiation center is directed is marked after robot calibration during acceptance testing is completed. The daily comparison between the laser spot and the floor mark depends only on the accuracy of robot mastering and how well the laser is adjusted to the centerline of the radiation collimator structure. If this comparison shows a difference larger than $+/-1$ mm, then the physicist should be notified. Subsequent testing must be conducted to determine the specific cause before a patient can be treated. A successful AQA test consistent with previous AQA results can detect or rule out changes in robot calibration of the linac. If a beam/laser centerline check in combination with a passing AQA test determines a laser misalignment as the only cause for the laser geometric alignment check failure, treatments may be resumed. Should the physicist decide to

realign the laser, second and third level checks are invalidated until a full robot recalibration is performed.

The *second level*, running a simulation in “BB-test mode” is suitable for visually evaluating individual beam pointing accuracy to a level of approximately $+/-1.5$ mm. A visual check is performed to verify that on an isocentric plan the centerline laser fully illuminates the isocrystal tip of the iso-post. This test should be done monthly (one path set per month) with dummy nodes being pre-identified to assure their constancy. In addition, the relative location of beam laser to beam central axis should be verified to not have changed since the last path calibration process.

The *third level* is a rigorous repeat of the 2nd Order Path Calibration process. This test is typically performed at acceptance testing and after a 2nd level QA failure. The results are quantitative and produce a detailed list of node-by-node deviations that can be evaluated individually or in combination. Record the node-by-node results and verify that no individual node exceeds 0.5 mm deviation or that the total RMS deviation does not exceed 0.3 mm. If a path fails the above criteria, the position of the beam central axis laser should be rigorously tested to check if the laser position may have shifted. If the laser is either confirmed to be in the same position, and/or the AQA and E2E tests are out of the specification limits, a complete path recalibration is indicated. At this time, 2nd Order Path Calibration can only be done with the assistance of a field service engineer. However, the TG recommends the development of a procedure which could easily and safely be run by a Qualified Medical Physicist on an annual or as needed basis, since there is currently no alternative to quantitatively check individual node pointing accuracy and the E2E test is not sensitive enough.

III.C. Overall accuracy (all subsystems)

The current overall clinical delivery accuracy tests recommended by the vendor and routinely preformed at each site are the E2E test and AQA test. Neither of the tests verifies nonisocentric delivery accuracy nor delivered dose. Therefore, DQA shall be performed on a regular basis.

III.C.1. AQA test

The AQA test is an isocentric targeting accuracy test that can be performed in less than 10 min to verify the delivery accuracy of the CyberKnife® system. This test is similar and analogous to the Winston–Lutz test⁸ commonly used on gantry mounted SRS systems, but has a much narrower application since there is no rigid mechanical coupling between the two tested beam positions.

The initial setup requires obtaining a CT of the AQA phantom, consisting of an approximately 2 cm acrylic sphere that replaces a similar sized metal sphere embedded in a 3.175 cm acrylic target sphere (Fig. 8), importing it into the treatment planning system, and creating a two-beam plan (AP and Lateral). The relative position of the centers of the concentric circles formed by the shadow of the metal ball is used to determine the targeting accuracy for the AP and lateral direction. Targeting errors should deviate less than 1 mm

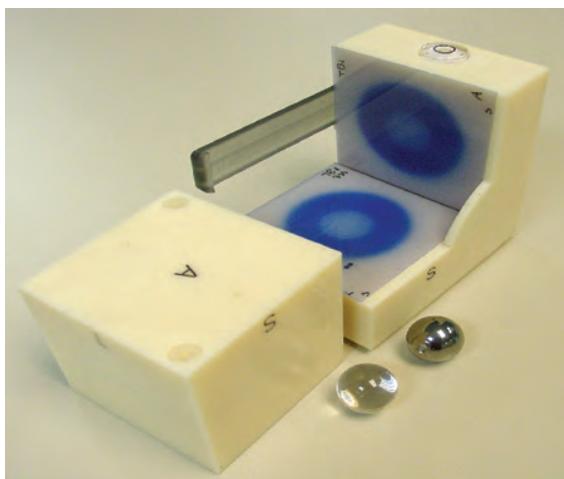


FIG. 8. The AQA phantom showing the orthogonal films after exposure. The clear plastic ball is inserted for the CT scan and replaced by the tungsten ball for the Winston-Lutz test. Figure courtesy of Accuray Inc.

from the baseline value set at time of calibration. Positioning accuracy test with the AQA test should be performed daily.

III.C.2. Isocentric end-to-end (E2E) test

The E2E test phantom consists of a ballcube in which a pair of orthogonal radiochromic films can be placed (Fig. 9). A set of ballcubes in different sizes is provided by the vendor for the various phantoms used to test each of the targeting methods (Sec. III A 1). After a CT scan of the phantom is taken and imported into the TPS, the central sphere is contoured and an isocentric treatment plan covering the sphere with the 70% isodose line is created. This plan is then delivered and a comparison of the position of the 70% isodose line dose distribution with the known centroid position is performed. The maximum difference between the centers of the planned dose and delivered dose *must not* exceed 0.95 mm for static treatments and 1.5 mm for motion-tracking treatments. A well-calibrated CyberKnife® system typically performs static E2E tests on the level of 0.3–0.7 mm.^{41,45,46}

Since it is very time-consuming to perform E2E tests for all tracking modalities and path combinations every month, it is recommended that one intracranial and one extra-cranial E2E be performed at least monthly. These tests need to be cycled through each path and tracking method combination that is in clinical use. All paths used routinely should be tested every time there is an upgrade of the delivery system. If a path or tracking method is rarely used clinically, testing may be reduced to at least once, but preferably multiple times, shortly before use on a patient.

Currently E2E testing is only used for mechanical accuracy, but it is important that dose accuracy should also be determined. Therefore, we recommend using Radiochromic film dosimetry to compare the isodose distribution with planned dose in the central orthogonal planes. This would especially be informative for Synchrony treatments (both Synchrony and XSight Lung Synchrony) and 4D treatment planning.

III.C.3. DQA plan

While the E2E test enables the user to perform an isocentric targeting accuracy test, it does not give the user any information as to the overall accuracy of the dose to complex targets in nonisocentric treatment plans, even though the majority of the cases on the CyberKnife® are nonisocentric deliveries. Currently, the nonisocentric targeting accuracy is assumed to be correct if the isocentric targeting is within specification. One of the main concerns the task group has is that for each patient, the beam directions and placements for the nonisocentric beams are unique. Currently, there is no easy way for the physicists to verify that the robot is targeting the nonisocentric beam directions in the directions produced by the planning system on a beam-by-beam basis. Therefore, it is recommended by this task group to perform DQA tests using film or detectors with equally high resolution on a phantom as part of machine commissioning and monthly QA. The acceptance criteria should be a 90% pass rate of distance-to-agreement⁴⁷ of 2%/2 mm for the tumor, critical structures, and in the high-dose region down to the 50% isodose line. For Synchrony, the 90% pass rate for the distance-to-agreement should be within 3%/3 mm for a region encompassing the 50% isodose line. The recommended phantom for DQA in an inhomogeneous environment such as the lung should contain a low-density region enclosing a higher-density lung “tumor;” the optimum dosimeter for the dose verification measurement is radiochromic film.⁴⁸

This task group recognizes that to perform DQA for every patient with experimentally measured dose distributions would require significant additional physics resources and would be a major change in current practice. The usefulness of this additional physics effort should be validated by a thorough failure-modes and effects (FMEA) analysis. We also recognize that at this time, there is no accepted industry standard across delivery modalities, and sometimes not even within the same delivery modality. For the time being, we recommend that DQA for CyberKnife® be done for the first several patients for every new tracking modality, and should be checked periodically (e.g., monthly) afterward.

III.D. Motion tracking (synchrony) QA

AAPM TG 76 (Ref. 49) discusses the general concepts of managing respiratory motion in Radiation Oncology. At this time, the CyberKnife® system relies on a hybrid tracking model correlating skin motion detected at approximately 30 Hz with the internal target detected radiographically during an interval of 30–60 s.^{50–52} It is conceivable that in the near future, motion modeling systems may be replaced by direct real-time tracking systems.^{53,54}

Fiducials (with the exception of XSight®Lung) are used as surrogates for the tumor location. Depending on the fiducial configuration, accuracy of the tracking model, and fiducial migration, a target localization error can be present.⁴⁴ Each x-ray image taken should be carefully monitored for correct tracking and the treatment should be interrupted if

mistracking occurs. If the fiducial motion is fast, the image quality can be improved by shortening the exposure time to prevent excessive blurring of the fiducial marker. It is essential for patient safety that the radiation therapist(s) operating the CyberKnife® are well trained in monitoring the accuracy of fiducial tracking. It is therefore also recommended that at least two therapists, or a therapist and another medical professional such as a physicist or physician, are watching the monitors at all times during treatment.

Visible-light optical sources (“beacons”) are used to generate a respiratory trace based on abdominal motion. The accuracy of this respiratory trace will directly translate into the accuracy of the skin–tumor correlation model for tumor tracking. At installation and annually, the sensors should be checked for system noise both at rest and during regular motion. The noise should not exceed 0.2 mm at a sensor-to-detector distance of 2 m. It is recommended that the accuracy of the relative sensor motion be checked for the range of distances used in clinical practice. The skin markers should be placed on the patient in an area of maximum excursion to maximize the signal-to-noise ratio.

In general, the effects of target motion should not affect the dose placement with respect to the target but will cause smearing of the dose outside of the target area. A phase shift may be present between the skin motion and the tumor motion.⁵⁴ The origin of this phase shift is the lag time between the diaphragm driving respiration and the motion of the target. If this skin-to-tumor phase shift cannot be modeled correctly by the algorithm, or if there is residual untracked motion of the target, dose blurring will occur. As part of the annual QA, the amount of dose blurring as a function of the phase shift should be measured with a motion phantom. A respiratory motion phantom with adjustable phase shift as provided by the manufacturer, or a phantom with similar functionality, should be used for this test.

The accuracy of adaptive real-time motion tracking techniques depends on the frequency with which the correlation model is updated to reflect the current status of the patient’s respiratory pattern throughout the length of the treatment. The update frequency of the model, therefore, should be chosen high enough such that shifts in patient breathing can be corrected. In addition to patient status changes, the imaging frequency should be high enough to catch changes in patient baseline or correlation pattern early. Respiratory cycle coverage should not fall below 90% to ensure the tumor motion path can be properly fitted by the correlation model.

Before the patient is treated, a maximum permissible range for the correlation model error should be discussed by the physician and physicist, and communicated to the treatment delivery team. The correlation model error is defined as the difference between the expected tumor position based on the existing correlation model to the tumor position at the time the current x-ray is taken. For a subset of the patient population, a good correlation model between skin and tumor motion may not be possible to establish. Several methods have been studied to use breathing training to improve treatment accuracy in the presence of irregular respiratory motion,^{56–58} although none have yet been eval-

uated for the CyberKnife®. If a user decides to use such a system to improve breathing regularity, a QA program *shall* be developed to test non-interference with the functionality of the CyberKnife®.

Synchrony motion tracking puts special stresses on robot joints, especially when treatments are interrupted due to patient interaction and the robot brakes have to engage often. At least one Synchrony treatment, either on a patient or a phantom, should be observed by the Qualified Medical Physicist on a monthly basis to check for any unusual robot noises or vibrations.

III.E General patient safety

Up to this point in the report, the focus has been mainly on the technical aspects of CyberKnife® QA. However, it is also the responsibility of a Qualified Medical Physicist to work with the whole care team to design a safe treatment process. There are many components to a patient’s path through a Radiation Oncology Department—from first consult to end of treatment—which varies considerably from patient to patient, as well as between Radiation Oncology practices. The following recommendations serve as guideline and example of how a safe process, and process control, could be established.

Due to the peculiar aspects of robotic radiosurgery compared to other radiation therapy methods, it is recommended that new personnel, and personnel that might be temporarily employed on a robotic radiosurgery program, receive specific training sessions before being given measurement, planning, treatment, or QA responsibility.

Time-out procedure: Time-out procedures have been firmly established in operating rooms (“surgical” time-out or “universal protocol”), and a modified procedure should be implemented for Stereotactic Radiosurgery procedures as well. A surgical time-out sheet should contain a

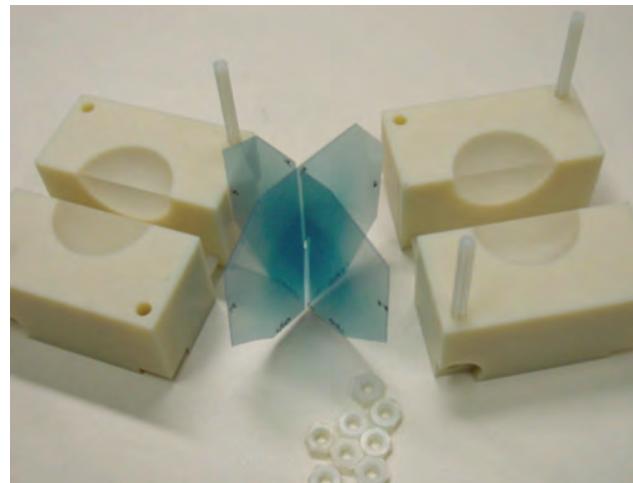


FIG. 9. The E2E ballcube used for fiducial and cranial tracking tests. A hidden target is irradiated. The orthogonal films are analyzed for spatial accuracy of dose delivery and can also be used for film dosimetry as plan verification. Figure courtesy of Accuray Inc.

checklist of items which have to be verified before the patient is being treated, e.g., informed consent, physician prescription, allergies, second physics chart check. For each fraction in each plan the patient is being treated with, there should be a signature line for the treating physician, radiation therapist, and physicist. After the patient is placed on the table, and before the first setup image is taken, these three members of the care team gather in front of the treatment console to confirm the correct patient is treated to the intended plan, and that the treatment plan displayed on the treatment console is identical to the physicians' intent as well as the paper or electronic medical record.

Safety culture: It should be understood that no treatment should proceed if any member of the care team has concerns about the safety of the procedure, or has a question regarding the treatment planning and delivery.

Treatment procedure monitoring: For a typical treatment procedure, the accuracy of image tracking and dose delivery is monitored on one screen, while the patient is monitored via closed circuit television on a second screen. We recommend that in addition to the treating therapist, a second medical professional (therapist, physicist, or physician) should be in the immediate vicinity at all times to assist when necessary. It is essential to avoid distractions such as phone calls or other interruptions of attention while a therapist is treating

Department of Radiation Oncology

Trigeminal Neuralgia Cyberknife Pre-Treatment Check List

Patient Name: Medical Record Number:			
Target Laterality:	Left	-	Right
Protocol Amifostine	Yes	No	
Procedure Guidelines	Responsible Person	Verified by	Date Verified
Pre Simulation			
1 Laterality is indicated on Cyberknife Treatment Consent Form .	Radiation Oncology attending and/or Resident		
2 H&P will be dictated by both Neurosurgery and Radiation Oncology, indicating laterality.	Radiation Oncology attending <u>and</u> Neurosurgery Attending		
Simulation			
3 At simulation, a physician (Radiation oncologist or Neurosurgeon) will verify the treatment site with either the patient or his/her guardian.	MD (Radiation Oncology <u>or</u> Neurosurgery)		
4 Patient Identification: Name and Date of Birth have been verified. Digital ID Photo is in ARIA	Radiation Therapist		
Treatment Planning			
5 The neurosurgeon will verify the treatment site and laterality against Neurosurgery History and Physical at the time the contour is defined.	Neurosurgery Attending		
6 Treatment site and laterality on the isodose plan and radiation prescription have been verified against Radiation Oncology History and Physical and Treatment Consent .	Radiation Oncology Attending		
Treatment Delivery			
7 Radiation Oncologist and/or Neurosurgeon are present at the start of procedure	Radiation Oncologist and Neurosurgeon		
8 This list has to be completed, signed and dated on items #1-7 before treatment is started.	Radiation Therapist		

FIG. 10. Sample process safety sheet for functional treatments.

a patient. If there is any concern about potential patient issues (such as nausea for mask-based treatments), the second medical professional should be present at the treatment console (Fig. 9).

For a Synchrony treatment, a third screen with the respiratory motion tracking data has to be observed. In this case, two therapists *shall* be at the console to monitor the treatment at all times.

Special procedures

Functional treatments: Functional treatments (e.g., trigeminal neuralgia, obsessive-compulsive disorder,^{59,60} etc.) deliver a very high dose in the region of ~60 Gy–80 Gy in a single fraction to a very small target area which is, on imaging, typically indistinguishable from healthy anatomy. Often, the treatment is unilateral as well as very close to a critical structure like the brainstem, such as for trigeminal neuralgia. There are several ways to design additional process safeguards to decrease the added risk. In the example of a trigeminal neuralgia treatment, a patient could be asked to place a metal BB on the immobilization mask (below the treatment level to avoid imaging artifacts) to mark the correct laterality. In addition, a laterality and DQA check sheet (Fig. 10) can be implemented either in paper or on the electronic medical record.

Pediatric patients: Often, pediatric patients are treated under conscious sedation or anesthesia. A third camera and monitor should be available to allow the anesthesiologist to monitor the status of the patient and the equipment without interfering with the monitoring of the treatment delivery. In addition, the pediatric anatomy requires special consideration and attention for the image-guided part of the treatment, which this report discussed in Sec. III A 1.

IV. SUMMARY AND QA CHECKLISTS

IV.A. Summary

Like many of the technologies that are applied to the treatment and cure of malignant and benign diseases, radiation modalities, and the machines that produce and control them, require strict quality assurance to ensure their safe operation. It is only the careful and judicious application of these technologies and measurable safety margins that ensure the desired result. Quality control, the measurements and tools to assess a quality result, and quality assurance, the management plan intended to guarantee the desired quality, are the principles that help keep us from inadvertently introducing errors.

This report provides initial guidelines and suggested methods for ensuring the technical aspects of a quality treatment result using this robotic radiosurgery system. Ultimately it is the responsibility of the local Qualified Medical Physicist to apply these principles using his or her best professional judgment. Major life threatening medical accidents often occur not because an adequate quality assurance program did not exist, but because it was not performed. These omissions can occur because of, among other things, a lack of administrative discipline, or a loss of the culture of safety, or a series of very rare events or QC failures whose predic-

tion and control were unlikely. Some of these circumstances are controllable and some are not. It is our task to identify the points of highest risk in our processes and put quality control measurements and quality assurance procedures in place to minimize adverse results.

Robotic radiosurgery systems are complex radiation delivery systems that require careful, thorough QA. This report aims to provide a Code of Practice for the CyberKnife® robotic radiosurgery system after commissioning has been completed. Individual component QA, with the notable exception of imaging QA, is well advanced at this point. The QA of component integration is a developing field which is also unique to each delivery system, depending on the degree of automation, open or closed feedback loops, and the quality of safeguards implemented in the radiation delivery system. For example, the integration of image quality and its effect on the tracking algorithm is lacking a systematic approach at this time. The authors of this report hope to inspire more research and publications on all aspects of robotic radiosurgery QA, but have given the reader sufficient QA methods to safely treat patients.

Our recommendations will certainly have to be adapted over time. In this regard, we aimed to design a Code of Practice which will serve as a guideline and underlying QA philosophy for future developments. We strongly encourage all clinical medical physicists to closely follow the scientific literature on robotic radiosurgery QA as well as make use of continuing education opportunities during professional meetings as part of their lifelong learning process.

Finally, the QA checklists provided in the following sections constitute suggestions and are meant as starting points to help the clinical medical physicist develop a comprehensive QA program. Local legislation may require additional QA tests while some tests may not be necessary for sites which do not use certain treatment modalities.

IV.B. Daily QA

Section	Item	Tolerance
II.A.2	Safety interlocks (Door, console EMO, Key)	Functional
	CCTV cameras and monitors	Functional
	Audio monitor	Functional
	Collimator assembly collision detector	Functional
II.B.1	Accelerator warm-up: 6000 MU for open chambers, 3000 MU for sealed chambers	N/A
	Accelerator output	<2%: no change needed >2%: adjust calibration
	Detection of incorrect and missing secondary collimator	Functional
III.B.2	Visual check of beam laser and a standard floor mark.	<1 mm
III.C.1	AQA test	< 1 mm from baseline

IV.C. Monthly QA

Section	Item	Tolerance
II.A.2	Safety interlocks.	Functional
II.B.2	Energy constancy.	2%
	Beam symmetry.	>3%
	Beam shape.	>2% Compared to beam data
	Output.	> 2%
II.C.1	Imager alignment.	1 mm or center pixel \pm 2 pixels
II.C.3	Contrast, noise, and spatial resolution of amorphous silicon detector. Homogeneity/bad pixels.	To be decided by user based on available literature
II.D	Custom CT model: CT QA (spatial accuracy, electron density).	See TG 66 (Ref. 29)
III.B.1	Verify relative location of beam laser vs. radiation CAX has not changed.	0.5 mm
III.B.2	Visually check isocentric plan to verify beam laser illuminates isocrystal; rotate through path sets each month	Laser on isocrystal for each node
III.C.2	Intracranial and extracranial E2E; set schedule to cycle through each clinically used tracking method and path.	<0.95 mm or <1.5 mm for motion tracking
III.C.3	Nonisocentric patient QA or DQA; ideally performed quarterly.	DTA 2 mm/2%; Synchrony DTA 3%/3 mm
III.D	Observe Synchrony treatment or simulation; listen for unusual noise and visually check for vibrations.	No significant change

IV.D. Annual QA

Section	Item	Tolerance
II.A.2	EPO button	Functional
II.B.3	TG 51 or IAEA TRS-398, including secondary independent check. Beam data checks on at least three collimators, including largest and smallest collimator (TPR or PDD, OCR, output factors). Dose output linearity to lowest MU/beam used.	Adjust calibration if >1% difference is found To be decided by user
II.C.2	Imager kVp accuracy, mA station exposure linearity, exposure reproducibility, focal spot size.	1%
II.C.3	Signal to noise ratio, contrast-to-noise ratio, relative modulation transfer function, imager sensitivity stability, bad pixel count and pattern, uniformity corrected images, detector centering, and imager gain statistics.	See Table 1 for references Compare to baseline
II.D	TG 53 as applicable. CT QA (in addition to monthly). Data security and verification.	TG 53 (Ref. 26) See TG 66 (Ref. 29) Functional
III.B.2	2nd Order Path Calibration; currently only possible with the help of a service engineer.	Each node < 0.5 mm RMS < 0.3 mm
III.D	Check noise level of optical markers.	<0.2 mm
IV.C	Run Synchrony E2E test with at least 20 deg phase shift; analyze penumbra spread.	To be decided by user
IV.C	Monthly QA.	In addition to tolerances listed above, update all parameters and checklists
IV.B	Daily QA.	Update parameters

IV.E. Special considerations after upgrades

Occasion	Section	Item	Tolerance
Software upgrade	II.A.1	Patient exclusion zone boundaries	Functional
	II.D	Beam data security	Functional
		HIPAA compliance procedures	Up-to-date with regulatory and institutional policies
Imager exchange	II.C.1	Imager alignment, bad pixels, spatial resolution, contrast, noise, E2E	

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QA for helical tomotherapy: Report of the AAPM Task Group 148^{a)}

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Helical tomotherapy is a relatively new modality with integrated treatment planning and delivery hardware for radiation therapy treatments. In view of the uniqueness of the hardware design of the helical tomotherapy unit and its implications in routine quality assurance, the Therapy Physics Committee of the American Association of Physicists in Medicine commissioned Task Group 148 to review this modality and make recommendations for quality assurance related methodologies. The specific objectives of this Task Group are: (a) To discuss quality assurance techniques, frequencies, and tolerances and (b) discuss dosimetric verification techniques applicable to this unit. This report summarizes the findings of the Task Group and aims to provide the practicing clinical medical physicist with the insight into the technology that is necessary to establish an independent and comprehensive quality assurance program for a helical tomotherapy unit. The emphasis of the report is to describe the rationale for the proposed QA program and to provide example tests that can be performed, drawing from the collective experience of the task group members and the published literature. It is expected that as technology continues to evolve, so will the test procedures that may be used in the future to perform comprehensive quality assurance for helical tomotherapy units. © 2010 American Association of Physicists in Medicine. [DOI: 10.1118/1.3462971]

Key words: helical tomotherapy, quality assurance

We dedicate this task group report to the memory of Sam Jeswani. Sam was a great enthusiast of the tomotherapy technology and a tireless customer champion. Sam was the Director of Customer Relations at TomoTherapy, Inc. and a friend to many of us. Sam died during the terrorist attacks in Mumbai in November 2008.

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I. INTRODUCTION

Task Group Report 40 outlines a comprehensive quality assurance (QA) program in radiation oncology that applies to any external beam radiation therapy equipment.¹ A code of practice specific to radiotherapy accelerators is provided by Task Group Report 45.² Both reports are comprehensive in nature and supply fundamental guidelines to the medical physics community.

With the introduction of new technology into the field of radiation oncology, a need arises to provide guidelines that are tailored to these newer treatment modalities. The quality assurance of newer technologies is addressed in Task Group Report 142.³ While TG-142 provides the foundation for QA guidelines of newer technologies, there are several commercially available technologies that are sufficiently different from C-arm type accelerators and require a unique set of QA recommendations. One such technology is helical tomotherapy. It is therefore the intent of this Task Group Report to provide QA guidelines for helical tomotherapy that, while based on TG-142 guidelines, are specifically adapted to this technology.

There are a fair number of the TG-142 QA recommendations that can be directly applied to helical tomotherapy (e.g., output constancy). Whenever possible, guidelines from TG-142 and other relevant task group reports have been adopted in this report. However, several traditional QA recommendations are not applicable (e.g., light field tests) to helical tomotherapy. On the other hand, important aspects of the tomotherapy treatment modality are not tested with traditional QA tests. This Task Group Report provides a comprehensive set of recommendations on all aspects of the helical tomotherapy system that should be tested and the respective recommended test frequencies. References to existing Task Group Reports are made throughout this report where appropriate. General QA guidelines such as the establishment of a departmental comprehensive QA program, as described in TG-40 are not discussed in this report.

Helical tomotherapy is an intensity modulated radiation therapy (IMRT) delivery technique that was developed at the University of Wisconsin-Madison and was later commercialized by TomoTherapy, Inc. of Madison, Wisconsin.⁴ TomoTherapy, Inc. is the only vendor that markets and manufactures treatment units that use this delivery process. Procedures and recommendations discussed in this report are therefore specific to TomoTherapy's treatment units. TomoTherapy units combine IMRT treatment delivery and megavoltage computed tomography (MVCT) imaging capabilities. The units were introduced into clinical routine in 2003. Currently, more than 280 units have been installed worldwide. It is anticipated that additional Tomotherapy-specific treatment techniques will be developed in the future. Static gantry angle and dynamic y-jaw modes are currently under development. These techniques are not considered in this report. Quality assurance procedures specific to these techniques will have to be developed once those techniques become commercially available.

In this Task Group Report, an overview of the Tomo-

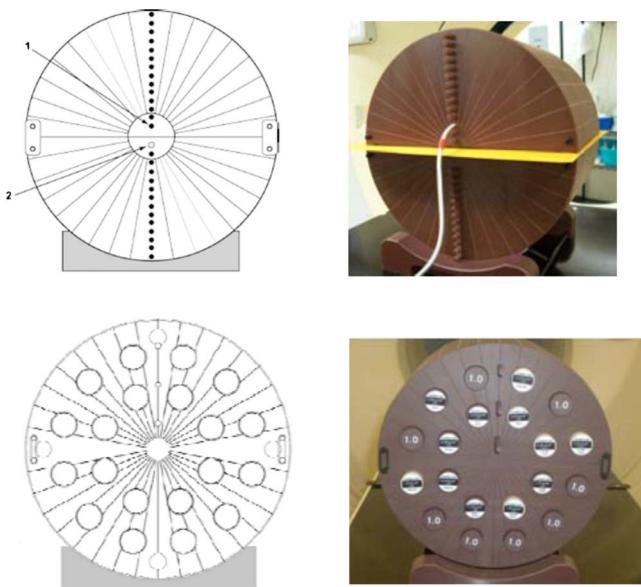


FIG. 1. Top row: Drawing and picture of a front view of the vendor supplied Virtual Water™ phantom. Each of the black circles (e.g., arrow 1) contains a Virtual Water™ plug that can be removed (arrow 2) for ion chamber insertion. The picture of the front view shows the phantom with a film inserted in the coronal plane and an ion chamber located above the film plane. Lower row: Drawing and picture of the back view of the phantom. There are 20 holes for insertion of test plugs. All holes can be filled with Virtual Water™ plugs or with a set of density calibration plugs as shown in the photo. Resolution and ion chamber plugs are also available.

Therapy system and its unique aspects is provided. Delivery, imaging, and treatment planning quality assurance are discussed in three chapters of this report. Quality assurance aspects are summarized according to their recommended frequency in Sec. VIII. The Appendix contains a collection of useful discussions that we hope will be of interest to the practicing medical physicist.

II. GLOSSARY AND ABBREVIATIONS

Virtual Water™ phantom: A cylindrical Virtual Water™ phantom that is supplied by TomoTherapy, Inc. Tomotherapy users commonly refer to this phantom as the “cheese” phantom. This phantom can be used for various quality assurance procedures. The phantom comes apart in two hemicylinders and has holes for placing ion chambers as well as plugs for CT density tests. It has a diameter of 30 cm and a length of 18 cm. Figure 1 shows diagrams and pictures of this phantom.

TomoTherapy coordinate system convention: TomoTherapy uses the following machine coordinate system naming convention: When the patient is positioned head-first-supine on the couch, +x points toward patient’s left side, +y points toward the patient’s head, and +z points toward the patient’s anterior side. This coordinate system is fixed, i.e., it does not rotate with the gantry. Figure 2 shows a picture of the treatment unit with the coordinate system superimposed.

DQA: Delivery quality assurance. This procedure is integrated in the TomoTherapy planning system. The patient plan is recalculated in a new CT anatomy. This new CT

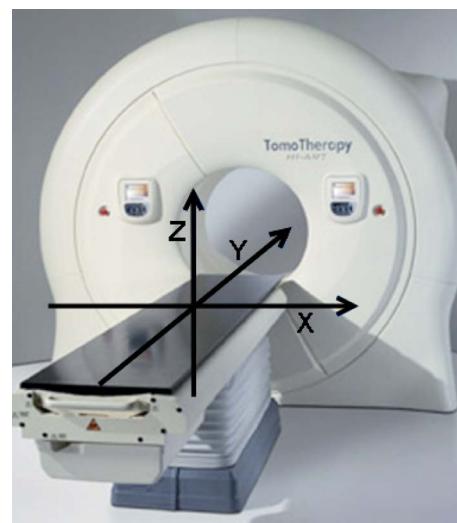


FIG. 2. The coordinate system used by TomoTherapy.

anatomy is typically a phantom. The DQA plan can then be delivered and the measured dose in the phantom can be compared to the calculated dose for quality assurance.

Field width/slice width: The longitudinal extent (i.e., in y-direction) of the fan beam is frequently referred to as field width in the literature. In this document, we follow the normal diagnostic radiology convention and use the term “slice width” to refer to the longitudinal extent of the treatment field.

Helical tomotherapy: The specific delivery technique.

Modulation factor: Longest leaf opening time in a plan divided by the average opening time of all nonzero leaf opening times.

MVCT: Megavoltage computed tomography.

Output: The TomoTherapy plans are based on time rather than on monitor units. The output of the machine is therefore measured in dose per unit time. Throughout this Task Group, the term output is used in this sense.

Pitch: The pitch is defined as the ratio of the couch travel per gantry rotation divided by the treatment slice width.

Sinogram: A binary file that contains data for each projection. There are several types of sinograms, such as imaging sinograms derived from detector data or control sinograms that contain fluence or MLC data for each projection or pulse.

Treatment plane: This plane marks the area that is defined by the center of the radiation field in the longitudinal (y) direction. In the x- and z-directions, this plane is parallel to the rotating fan beam.

TomoTherapy: Company that produces and markets a system that is based on a helical tomotherapy delivery technique.

Virtual isocenter: The treatment plane is located inside the bore and for convenient patient setup a virtual isocenter is defined 70 cm from the treatment isocenter in the negative y-direction. As with CT simulation, the virtual isocenter is located outside the bore and is localized via laser projections.

XML file: An XML file is generated at the end of the

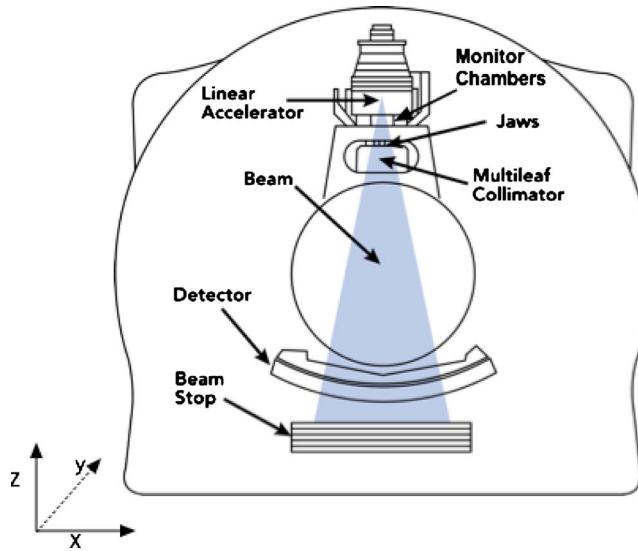


FIG. 3. Diagram of the main components of a TomoTherapy unit.

treatment planning process by the planning software and contains delivery instructions for the various machine components. To generate delivery instructions for QA tests, these files can also be generated independently of the treatment planning system (TPS). Tools to accomplish this are included in the operator station software.

III. SYSTEM OVERVIEW

The TomoTherapy system uses a unique geometry that resembles that of a helical CT scanner. The beam is generated by a 6 MV linear accelerator that is mounted on a slip ring gantry. The beam passes through a primary collimator and is further collimated into a fan-beam shape by an adjustable jaw. For further collimation, a binary multileaf collimator (MLC) is used. During treatment, the ring gantry continuously rotates while the patient is continuously translated through the rotating beam plane. The dose is thus delivered in a helical fashion. The ring gantry also contains a detector system that is mounted opposite the accelerator and is used to collect data for MVCT acquisition. A beam stopper is used to reduce room-shielding requirements. Figure 3 shows the general layout of the tomotherapy unit. The distance from the source to the center of rotation is 85 cm. The distance from the source to the detector is 145 cm. The Tomotherapy machine currently employs a standard detector array from a third generation CT scanner. This detector is not focused on the source but on a point that is proximal to the source. The diameter of the bore is 85 cm.

The fan beam has an extension of 40 cm in the lateral (x) direction at isocenter. In the superior-inferior, or y-direction, the beam is collimated by an adjustable jaw. In principle, this y-jaw can collimate the beam to any size that is smaller or equal to 5 cm but typically, only three distinct treatment slice widths are commissioned in the treatment planning system for clinical use. These fields have an extension of 1.0, 2.5, and 5.0 cm at isocenter in the y-direction. Figure 4 shows a

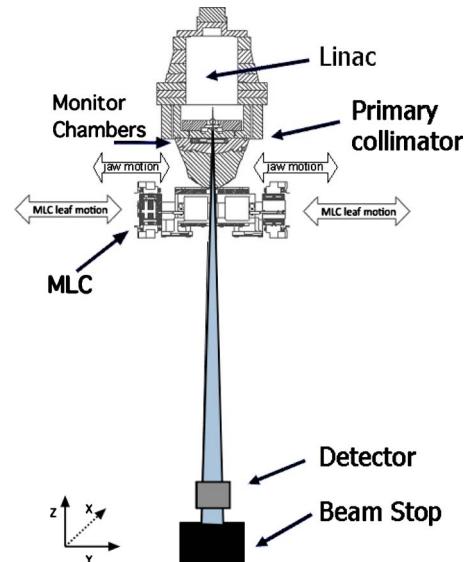


FIG. 4. Lateral view of the beam collimation components. The linac is at the 12 o'clock position in this drawing.

diagram of the lateral view of the linac and collimation system. The TomoTherapy units do not have field flattening filters.

A binary 64 leaf collimator is used to divide the fan beam in the x-direction (with the linac at 12 o'clock). The MLC leaves travel in the y-direction as indicated in Fig. 4. Each MLC leaf is either closed or open and intensity modulation is achieved via leaf specific opening times. The MLC is pneumatically driven. It consists of two separate MLC banks. If the leaves are closed, they move across the entire treatment slice width and stop at a position beyond the treatment field under the opposite jaw. This allows a rapid transitioning (about 20 ms) of the leaf. The leaves are made from 95% tungsten and are 10 cm thick. The MLC is only focused in the lateral direction. Figure 5 shows a diagram and a photo of the MLC. The diagram also shows the MLC leaf numbering convention. All even-numbered leaves belong to the rear (located in +Y direction from isocenter) MLC bank and the odd-numbered leaves belong to the front (located in -y direction from the isocenter) MLC bank.

A beamlet is defined as the part of the treatment beam that one MLC leaf covers. The y-dimension of each beamlet at the isocenter depends on the y-jaw setting; the size of each beamlet in the x-direction is 0.625 cm (40 cm divided by 64 leaves) at the isocenter.

For the purpose of treatment planning each rotation is divided into 51 sections. These are called projections. For each projection, each MLC leaf has a unique opening time. A leaf may be open for most of the duration of the projection (with adjustments for leaf transitioning times), for part of it, or may never open during a given projection. Figure 6 illustrates the use of the MLC system during a gantry rotation for a head and neck treatment. Only every third projection is shown.

The gantry rotates clockwise if viewed from the foot of the patient couch or in the view shown in Fig. 3. The gantry

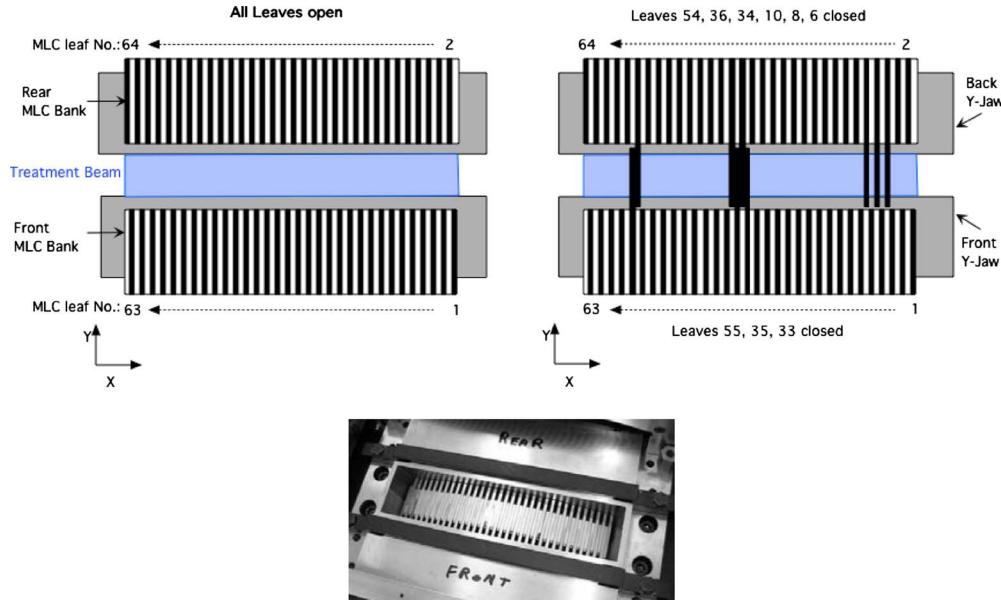


FIG. 5. A schematic drawing of the TomoTherapy MLC. The drawing on the left shows the MLC with all leaves open. The right hand drawing shows the MLC with several leaves closed. A photo of the MLC with all leaves closed is also shown. In the drawings, the MLC is in the 6 o'clock position and the observer looks down from the isocenter.

angle naming conventions conform to the International Electrotechnical Commission standard, i.e., the gantry angle is zero if the beam points downward in the vertical direction. The gantry angle increases from 0° to 359° with a clockwise rotation of the gantry.

Besides the machine hardware, two laser systems are installed in the room whose arrangement is different than what is typically found in a treatment room. The treatment plane is inside the bore and for patient setup purposes a virtual isocenter is defined outside of the bore. The distance from the virtual to the treatment plane isocenter is 70 cm in the

y-direction. A fixed green laser system is used to project laser lines to the virtual isocenter. In addition, a movable red laser system is installed in the room. This laser system is similar to the laser marking systems commonly found in a CT simulator suite. The red lasers are mounted on tracks along which the laser can move. In their “home” position, the red laser lines will project to the virtual isocenter. In total, there are five red laser units in the room (two coronal, two axial, and one sagittal laser). In the treatment planning system, the red lasers can be requested to project lines to the patient setup marks. Hence, the red laser position is plan-specific. The patient may be aligned to the red or green laser system and depending on its use, the green laser system may be turned on or off during patient treatments. However, the green laser system is often used for physics tests. Figure 7 shows a diagram of the laser arrangement in the room. Only lateral and sagittal lasers are shown in this drawing. The green and red coronal laser system is not shown.

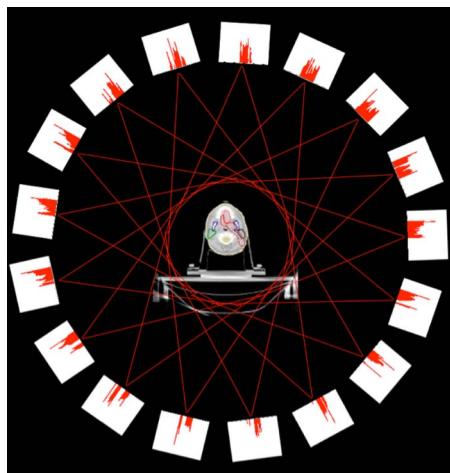


FIG. 6. Illustration of MLC use. Normalized leaf opening times are shown for every third projection of a gantry rotation during a head and neck treatment. Each of the 17 inserts shows the relative opening time (height of bar) of each of the 64 MLC leaves (represented by 64 bars along the bottom axis of each insert) during the selected projections. In these particular projections, the outer leaves are never opened since these beamlets do not pass through the tumor volume.

IV. SYSTEM SPECIFIC ACCEPTANCE AND COMMISSIONING ASPECTS

In addition to the dose delivery method and respective hardware, another unique aspect of the system is that all tomotherapy planning systems use a common beam model (several early machines had unique beam models. However, some of these early machines have subsequently been recommissioned for use with the common beam model). Each machine is adjusted in the factory such that the beam parameters match this common beam model. During the on-site acceptance testing procedure (ATP), it is verified that machine parameters still match the common beam model. Many aspects of the traditional machine commissioning tasks hence do not apply to the TomoTherapy machines. Other traditional

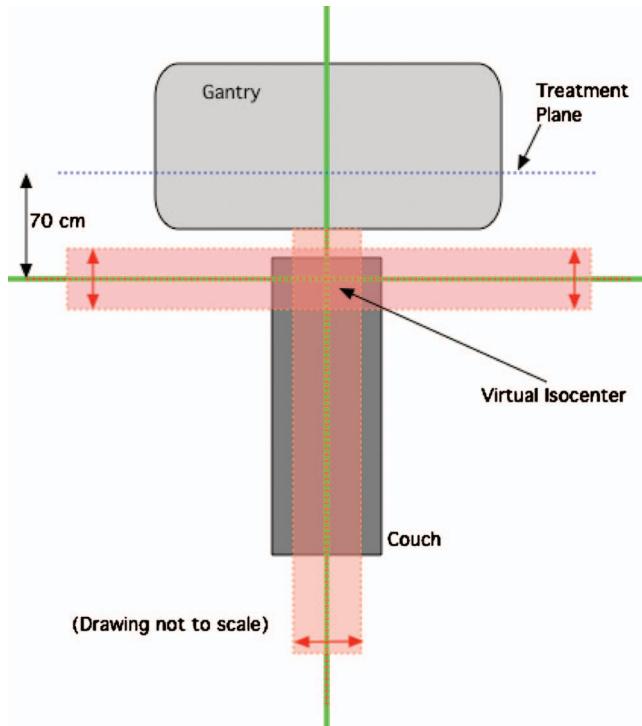


FIG. 7. A schematic drawing of the laser arrangement in the treatment room as seen from the ceiling. The green lasers are fixed and the red lasers are movable. If homed, the red laser projections overlay the green lasers. The pink box indicates the approximate area that can be occupied by the red laser system.

commissioning procedures such as the collection of baseline data for all periodic QA procedures still apply to the helical tomotherapy units.

It is recommended by this Task Group that an on-site physicist be actively involved in the acceptance testing process. He/she should collect and archive the ATP data provided by TomoTherapy, Inc. For all periodic consistency tests, the baseline data should be measured soon after machine acceptance and prior to the first treatment. All other recommended daily, monthly, quarterly, and annual QA tests should be performed once prior to the first treatment. Many of the recommended annual QA aspects are covered during the ATP process. For example, the current ATP protocol includes the mechanical alignment and beam parameter tests described in Secs. V B 1 and V B 2. Tests that are covered in the ATP process do not need to be repeated prior to the first treatment provided that the on-site physicist was actively involved in the ATP process as recommended.

V. TREATMENT DELIVERY FOR HELICAL TOMOTHERAPY

V.A. Introduction

Helical tomotherapy beam delivery is unique in its dynamics and therefore requires quality assurance tests that are tailored to this delivery technique. Some tests are similar to those performed on a conventional linear accelerator, while others are helical tomotherapy-specific.

Frequently, one aspect of the machine can be tested in different ways ranging from traditional test procedures to procedures that make use of on-board detector data acquired during helical tomotherapy procedures. Users have developed and reported tomotherapy specific test procedures.^{5–7} Many of the test procedures developed by the vendor use the on-board detector while other tests are film-based. For those users that wish to use detector data, we have included in Appendix E a discussion on where the data are located and how it can be accessed. The film-based tests can be performed with radiographic or radiochromic films.

Since helical tomotherapy is still a relatively new modality, it is anticipated that test procedures will continue to evolve. The intent of this chapter is to describe what aspects of the machine should be tested. Examples of test procedures that have been developed by users or the vendor are provided. However, over time, new test procedures will likely be developed and it is not the intent of this chapter to dictate specific procedures and thus prohibit the use of better test procedures and equipment in the future.

V.A.1. Unique aspects of helical tomotherapy treatment delivery

Helical tomotherapy utilizes a dynamic delivery in which the gantry, treatment couch, and MLC leaves are all in motion during treatment. This results in highly conformal radiotherapy treatments. The complexity of the delivery is hidden from the end user due to the extensive integration and automation of the tomotherapy control systems.

There are several unique aspects of the TomoTherapy beam delivery system that the physicist needs to recognize. The machine output is defined in terms of absorbed dose per unit time rather than the traditional units of dose per monitor unit. Consequently, treatment plan parameters such as gantry rotation, table motion, and MLC openings are all time-based. A constant dose rate is assumed for treatment planning purposes and plans are terminated after the calculated time elapsed.

Two parallel-plate ion chambers are located upstream of the y-jaw and their purpose is to monitor that the dose rate is within an acceptable window. After machine calibration, the signal levels from the transmission chambers and their variation are monitored. These signal levels are referred to as the nominal rate. The establishment of the nominal rate values is performed by the vendor during ATP. Two separate monitor chamber based dose rate tests are enforced. The treatment will be terminated if (i) the monitor chamber readings differ by more than 50% from their nominal rate for more than 3 s or (ii) the monitor chamber readings differ by more than 5% from their nominal rate for more than three consecutive rolling 10 s windows. A new 10 s window is started each second such that a continuous dose rate between 50% and 95% of the nominal dose rate would trigger an interlock after 12 s. These two dose rate tests are applied to each of the two chambers independently, such that a dose rate violation detected by either chamber will interlock treatment.

The dosimetric effect that is induced by a dose rate deviation prior to treatment interruption cannot be estimated easily. Since the target volume moves through the beam plane during treatment, target volumes that have already moved out of the beam plane are not affected and neither are target volumes that have yet to move into the beam plane. Only the tissue volume that is treated during the dose rate fluctuation period is affected. The affected volume is hence defined by the fan-beam slice width plus the distance the couch moves during the dose rate fluctuation period. The fraction of the effected irradiation time depends on plan parameters. A given target voxel is scheduled to be in the beam plane for a period of time equal to the gantry rotation period divided by the pitch value. Furthermore, the dosimetric effect will depend on the MLC pattern that is executed during the dose rate fluctuation period. Hence, the dosimetric effect of dose rate fluctuations are plan-specific but are typically limited to a fraction of the irradiated volume for a fraction of its scheduled irradiation time.

The monitor chamber assembly consists of two sealed parallel-plate transmission chambers. One chamber is not segmented and the radius of the collection volume is approximately 7 cm. The signal from this volume is used to derive the monitor unit 1 signal. The second chamber is segmented into an inner volume and an outer ring volume. The inner volume has radius of approximately 5 cm. The signal from this inner volume is used to derive the monitor unit 2 signal. The outer ring is further divided into six segments. The signals from these outer segments are not used. The monitor chamber signals are accessible to the user via the auxiliary data monitoring system.

The monitor unit readings that are displayed on the operator screen are derived from the monitor chamber signals. The monitor chamber signals are scaled such that the displayed monitor units numerically agree with the machine output as expressed in cGy/min measured at a depth of 1.5 cm with an SAD of 85 cm and a 5×40 cm² static field. This scaling process is performed by the vendor during ATP. The displayed monitor unit rate is not the instantaneous rate but the average dose rate since the beginning of the procedure. Starting with software version 4.0, the displayed dose rate for treatment procedures is the average rate over the last 10 s, excluding the warm-up period. If 10 s have not yet elapsed since the end of warm-up, the display shows the average rate since warm-up. For QA procedures, the warm-up period is included in the displayed rate.

The output is unstable when the beam is initially turned on. This beam instability is anticipated and all MLC leaves are closed for the initial 10 s of every planned delivery. If the user generates test procedures outside of the treatment planning system, it is recommended to instruct the MLC to be closed for at least the initial 10 s of the procedure.

The procedure timing, subsystem synchronization, and procedure termination are managed via a primary timer. Three independent computer clocks are used as backup timers that will each terminate the beam 6 s after a scheduled procedure time has elapsed.

V.B. Periodic quality assurance

Throughout this section, procedures are used that require machine operation in nonstandard mode, e.g., a static gantry position may be required or noncommissioned y-jaw settings may be requested. While the user can generate these procedures on the operator station (see Appendix B), the majority of the required procedures are made available by the vendor. In this chapter, QA tests for mechanical alignment, beam parameters, synchronicity, and miscellaneous aspects are described. The calibration procedure is also contained in this chapter.

V.B.1. Mechanical alignments

Several mechanical alignments must be tested annually and whenever the alignment could be compromised. In this report, particular alignments are recommended for testing. The procedures developed by the vendor to test these alignments are acceptable test procedures. However, alternative test procedure may be developed by the user. Most tests use film dosimetry and common film or image analysis tools can be used for analysis. The vendor can also supply film analysis tools.

The first set of tests (Secs. V B 1 a, V B 1 b, and V B 1 c) check the alignment of the radiation source (i.e., the linac) against the y-jaw, MLC, and rotation plane. The second set of tests (Secs. V B 1 d, V B 1 e, and V B 1 f) check the alignment of the y-jaw and MLC with the rotation plane as well as the centering of each treatment slice.

V.B.1.a. y-jaw centering. The alignment of the radiation source in the y-direction is checked against the y-jaw. This test is performed to check that the source is centered in the collimated field. This alignment needs to be checked if any component is replaced or moved that can affect this alignment. It is recommended to check the y-jaw centering annually.

The procedure uses a 2 mm y-jaw opening that is moved in 11 steps along the y-direction. A narrow y-jaw setting amplifies the sensitivity of this test. The beam is turned on for a fixed amount of time with the y-jaw opening shifted 24, 20, 15, 10, 5, 0, -5, -10, -15, -20, and -24 mm off-axis. At each step the output is measured with a stationary long active volume ion chamber located at isocenter. The vendor uses an Exradin A17 chamber for this test. The chamber must have a linear response over a length sufficient to measure the output of the shifted beams.

The output is plotted as a function of axial jaw shift. The source is aligned with the y-jaw when beam output is at its peak, as determined by a parabolic fit to the data. An example data set from this procedure is shown in Fig. 8. The respective jaw shift may be found by using the derivative of the curve to find the apex of the parabola, which corresponds to the peak output. In the given example the derivative is, $\partial\text{signal}/\partial x = -0.0162x + 0.0079$, where x is the jaw shift in mm and the peak output is at a jaw shift of 0.49 mm. The y-jaw focus point is located 5 cm above the x-ray source (i.e., 90 cm above the isocenter), which means that the source shift is magnified by a factor of 18 (i.e., 90/5) at

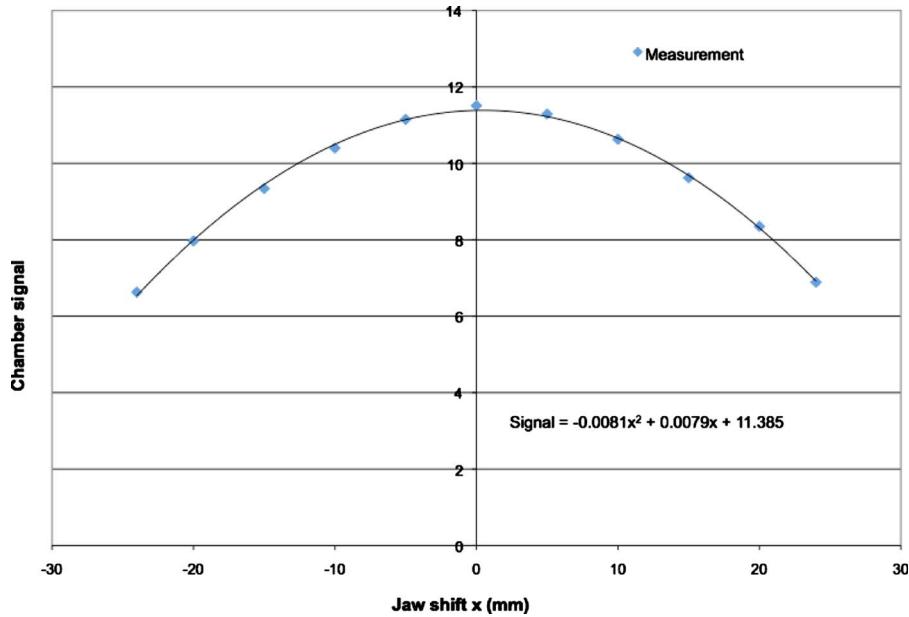


FIG. 8. An example of data measured during a y-jaw centering procedure. The measured data are fitted with a parabolic curve.

isocenter and the actual source misalignment is 0.03 mm (i.e., 0.49/18) for the given example. The vendor specification states the source position should agree with its nominal position (established at time of commissioning) within 0.3 mm. The Task Group recommends adherence to this tolerance value.

V.B.1.b. x-alignment of source. The position of the source in the x-direction is checked against the MLC position. For this test the MLC tongue and groove (T&G) effect is utilized. This effect is caused by the T&G design of the leaves that prevents a direct path for radiation to pass through when adjacent leaves are closed. A consequence of this design is a difference in the fluence output if two adjacent leaves open in sequence versus a simultaneous opening.

The T&G effect is minimized if the MLC is focused on the source. The latter fact can be used to test the source to MLC alignment. The vendor uses the MVCT detector array to collect output profiles with all even-numbered MLC leaves opened and then with all odd-numbered MLC leaves opened. This delivery sequence will maximize the T&G effect. To test the x-alignment of the source, the odd-numbered leaf profiles and even-numbered leaf profiles are added and divided by an output profile that is collected with all MLC leaves open. This normalized T&G profile should be symmetric about the center if the source is properly aligned with the MLC. Figure 9 shows normalized T&G data. An “out-of-focus” value is calculated based on the right-left asymmetry of the profile. For the purpose of calculating the out-of-focus value, the T&G profile is divided into two sides. For both sides, the average T&G signal and the standard deviation of the T&G signal is calculated. The smaller of the two average T&G signals is divided by the larger average T&G signal to calculate a ratio a that expresses the symmetry of the absolute signal. To express the symmetry of the standard deviations, two sums are calculated by separately adding each

standard deviation to the overall mean T&G signal, i.e., mean signal over both sides. The smaller of the two sums is divided by the larger sum to calculate a parameter b . The vendor’s out-of-focus value is based on the following formula:

$$\% \text{ out-of-focus} = 100\% \times (1 - (a + b)/2). \quad (1)$$

An empirical relationship between this value and the numerical source lateral offset has been established by the vendor. The vendor specifies a maximum out-of-focus tolerance of 2%, which corresponds to a lateral source position offset of 0.34 mm. The Task Group recommends that this test be performed in cooperation with the vendor to facilitate data collection and analysis. However, a film-based T&G procedure has been described in the literature and it can be used to independently verify the symmetry in the T&G profile.⁸ The Task Group recommends adopting the vendor’s tolerance for the x-alignment of the source.

V.B.1.c. y-jaw divergence/beam centering. The alignment of the y-jaw with the beam plane must be checked to assure that the central transverse axis of the treatment beam intersects the rotational axis perpendicularly, i.e., points straight down in a lateral view when the gantry is at 0° and that the beam diverges symmetrically around the plane of the gantry

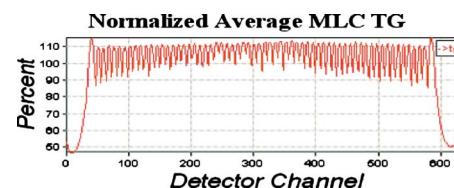


FIG. 9. The normalized tongue and groove data collected with the on-board detector array. An out-of-focus value of 1.05% was calculated from these data.

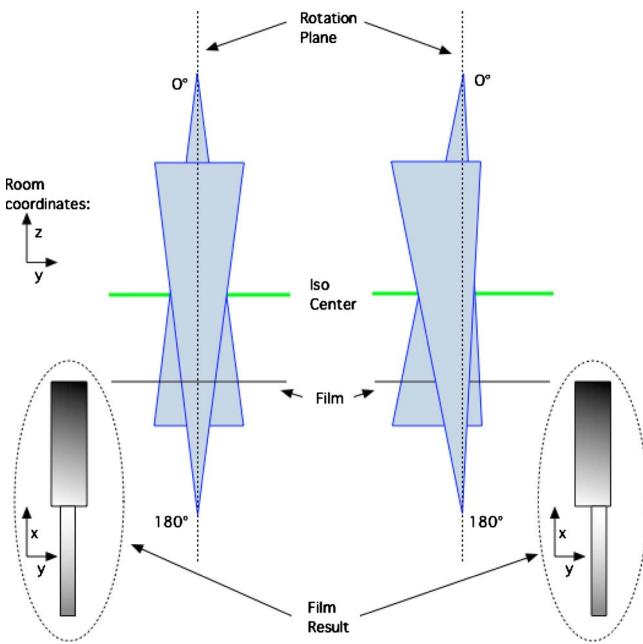


FIG. 10. Schematic of test setup for the y-divergence test. Schematic film results are shown as well. In the picture on the right hand side, the beam does not diverge symmetrically to the axis of rotation. This situation would require an adjustment of the jaw encoders.

rotation. This alignment needs to be checked if any component is replaced or moved that can affect this alignment. It is recommended to check the y-jaw/beam centering annually.

The following test procedure is acceptable to check the y-jaw divergence. A film is positioned horizontally between solid water plates (depth of 2 cm) and is positioned below the isocenter that is defined by the stationary green lasers. The film should be positioned as far as possible from the source to maximize the sensitivity of the test. Typically, the achievable distance is about 23–25 cm below isocenter. The collimation is set to define a nominal clinical field and the gantry is positioned at 0°. The MLC field is defined so that only leaves on one side of the central axis are open during exposure. The film is irradiated with the beam pointing straight down. The gantry is rotated 180° and a second irradiation is done using the same treatment slice width and MLC pattern. Figure 10 illustrates this test procedure.

A developed film of an acceptable y-divergence test is shown in Fig. 11. To test that the beam divergence is centered on the plane of gantry rotation, the center of both fields is measured. Analysis of the film involves overlaying profiles A1 and B1 of the two fields. The center of each beam is

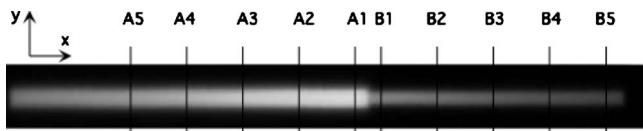


FIG. 11. Film exposure testing the alignment of the beam axial axis with the plane of rotation. For numerical analysis of the y-jaw to gantry rotation plane alignment (Sec. V B 1 d), the y-profiles are measured at several off-axis distances that cover the length of the shorter of the two beams.

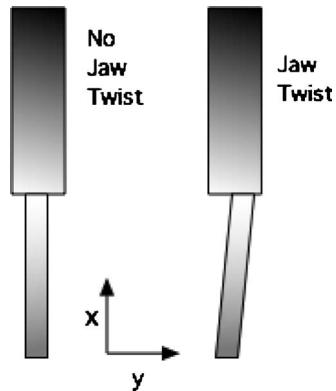


FIG. 12. Illustrations of jaw twist film results.

defined by the center of full width at half maximum (FWHM) for each beam profile (A1 and B1). A difference between the two field centers can be translated to a beam divergence at isocenter via similar triangles, i.e., divergence at isocenter=the measured difference between fields on the film multiplied by [85 cm/(2×d)], where d is the distance from the isocenter that the film was located at. For example, with a film located 25 cm below isocenter, a 0.3 mm difference between the beam centers on the film would translate into a beam divergence at isocenter of 0.51 mm [i.e., $0.3 \text{ mm} \times (85/50)$].

The divergence of the beam axis from perpendicular at isocenter should be 0.5 mm or less per the vendor's specification. The Task Group recommends adherence to this tolerance value.

V.B.1.d. y-jaw/gantry rotation plane alignment. It should be tested that the y-jaw is parallel to the plane of rotation. This needs to be checked on an annual basis and anytime that this alignment can be compromised. The film results from the y-jaw divergence/beam centering test can be used in this analysis. Figure 12 shows sketches of acceptable and unacceptable film results.

In this instance the film profile is interrogated at several points along both fields (Positions A5–A1 and B1–B5 in Fig. 11). The y-position of the profile center is defined as the midpoint between 50% intensity penumbral position. This position is noted in both x and y for the thick and thin profiles and recorded separately. The results are plotted and the slope of the resultant straight line is ascertained. Note that the physical jaw twist equals half the angle between the fields as measured on the film. The physical jaw twist should be less than 0.5°. This is the vendor specified tolerance and the Task Group recommends adherence to this tolerance value. This tolerance ensures that the dose distribution at an off-axis distance of 10 cm has a spatial accuracy of 1 mm.

V.B.1.e. Treatment field centering. All clinical treatment fields must share a common center. This alignment should be checked if any component is replaced or moved in a way that can effect this alignment. It is recommended to check the field centering annually.

To test the field centering, a film can be placed perpendicularly to the beam axis at an 85 cm source-to-film dis-



FIG. 13. Film for test of clinical beam axial centering.

tance under a stationary vertical field. The use of solid water build-up (1–2 cm) is recommended. The control sinogram is set so that MLC leaves 11–18, 29–36, and 47–54 remain open. The y-jaws are set to the nominal width of 2.5 cm and the film is irradiated. The MLC is then set to open leaves 2–9, 20–28, 38–45, and 56–63 and movable y-jaws are set to one of the other clinical beam widths. Please refer to the MLC discussion in Sec. III for the MLC leaf numbering convention.

The film is irradiated a second time and developed. In the example shown in Fig. 13, the calibrated field of 5.0 cm is tested against the clinical 2.5 cm field. Profiles taken across the different treatment slice widths should show an agreement of the field centers within 0.5 mm at isocenter per the vendor's recommendation. The task group recommends adherence to this tolerance value. The test should be repeated for each clinical field.

V.B.1.f. MLC alignment test. The lateral alignment of the MLC relative to the center of rotation should be tested on an annual basis or after MLC replacement. Similarly, it should be tested that the MLC is aligned parallel to the rotational plane.

A film-based test can be used to test these two parameters. A film is positioned at isocenter and two central MLC leaves (32 and 33) are opened in addition to two off-center leaves (27 and 28). The film is exposed with the gantry at 0° . The gantry is moved to 180° and only the two off-center leaves are opened. The developed film should look somewhat like Fig. 14. The two outer areas should be parallel to each other (the MLC is oriented parallel to the plane of rotation). The central area should be centered between the two outer areas (no MLC lateral offset). The difference in distance between the two outer fields from the central field is used to calculate the MLC offset. It should be pointed out that any MLC offset

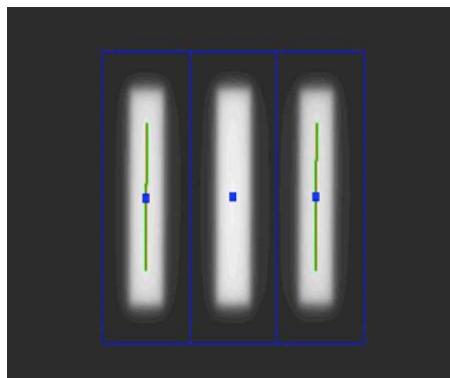


FIG. 14. MLC alignment/twist test.

and twist is magnified by a factor of 2 if the difference between the two outer field offsets from the central fields and the twist is measured using the above film procedure since misalignments are added from each of the two exposures. Hence, the MLC offset is equal to the difference between the right and left field offsets from the center divided by 2.

Per vendor specification, the MLC offset should be less than 1.5 mm at the isocenter and the MLC twist should be less than 0.5° . The Task Group recommends that the vendor's specification be adopted.

V.B.2. Beam parameters

The unique design of the TomoTherapy treatment head results in unique beam profiles. For example, the absence of a flattening filter results in cone shaped transverse beam profiles. Monte Carlo calculations of the tomotherapy beam characteristics have been described in detail by Jeraj *et al.*⁹ and Sterpin *et al.*¹⁰

For the purpose of routine quality assurance the consistency of the percentage depth dose, transverse, and longitudinal beam profiles, as well as the beam output should be monitored. Recommended frequencies and tolerances are discussed in the following sections. If any of these parameters vary beyond acceptable tolerance, adjustments of the machine parameters may be necessary. These adjustments require operation of the machine in service mode. Ideally, adjustments are performed by the field service engineer (FSE) and verified by the local medical physicist. At the physicist's discretion, output adjustments can also be performed and verified by the local physicist. Adjustment of the beam energy and/or beam profiles should be performed by the FSE and verified by the local physicist.

V.B.2.a. Beam quality. Agreement between the beam quality modeled in the planning systems and the measured beam quality should be tested. An example of a measured PDD is shown in Fig. 15. For comparison the modeled PDD is shown.

The standard tomotherapy PDD at a depth of 10 cm is reduced in comparison to that of a typical 6 MV linac beam due to the shorter SSD and the lower inherent energy that is due to the flattening filter free design of the tomotherapy units. However, the beam is filtered uniformly to remove low energy components.

Multiple techniques exist to measure a PDD curve and to monitor the beam energy consistency. For example, the consistency of the beam energy can be determined with a tissue maximum ratio (TMR) curve measured in a water-equivalent phantom with a simultaneous measurement of the dose rate at two depths or by measuring the beam attenuation with filters of different effective thickness.

In accordance with TG-142, the tolerance for beam quality variations is 1% for the PDD_{10} or TMR_{10}^{20} . The consistency of the beam quality should be tested on a monthly basis. This frequency is higher than the corresponding annual test recommended in TG-142. The reason for this increased test frequency is that targets wear more rapidly on TomoTherapy units than what one typically encounters in C-arm

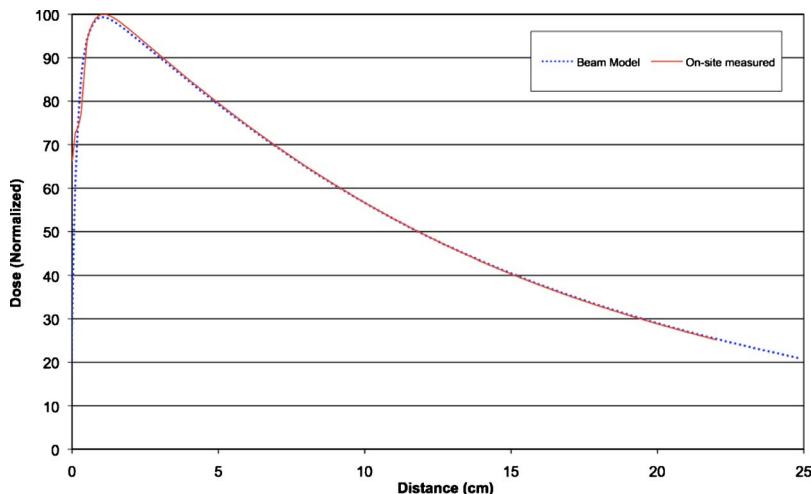


FIG. 15. Example of a PDD curve ($2.5 \times 40 \text{ cm}^2$ field) measured in water tank and the modeled PDD. Data were acquired at an SSD of 85 cm.

linacs. The beam quality is changing continuously throughout the lifetime of the target, but may exhibit significant dosimetric changes near the end. Accordingly, the user is advised to monitor the beam energy diligently and perhaps even further increase the frequency of beam quality monitoring if initial signs of target wear appear.¹¹ On an annual basis, agreement with the beam model should be verified for each commissioned treatment slice width. The beam model currently consists of PDD data in water. Hence, on an annual basis water tank data needs to be acquired for comparison with the beam data. The dimensions of water tanks are limited by the physical dimensions of the TomoTherapy bore (i.e., 85 cm). Third-party vendors have developed water tank systems that can be used in a TomoTherapy unit.

V.B.2.b. Cone (transverse) beam profiles. TomoTherapy units do not use a flattening filter and the transverse beam profiles are cone shaped. The intensity at the beam edge falls to approximately 50% of the central axis value. This is illustrated in Fig. 16. In accordance with TG-142, the consistency

of the transverse beam profile size should be monitored monthly and be compared to the beam model on an annual basis. To accommodate machines without flattening filters, a beam profile consistency tolerance of 1% is specified in TG-142 for monthly beam profile tests. This value corresponds to the average absolute difference for multiple off-axis ratio measurements that are within the core of the beam (e.g., 80% of field size). The difference is specified with respect to baseline data acquired at time of commissioning. Annually, consistency of the beam profiles should be assessed against the beam model. The beam model data are available from the vendor at the time of machine installation and commissioning. Consistency can be assessed using the monthly scoring method and tolerance values.

Cone profiles can, for example, be monitored using the on-board MVCT detector system, but data access may require assistance from the TomoTherapy service engineer. Due to variations in the detector efficiency with off-axis distance, the detector data are not used to determine the beam

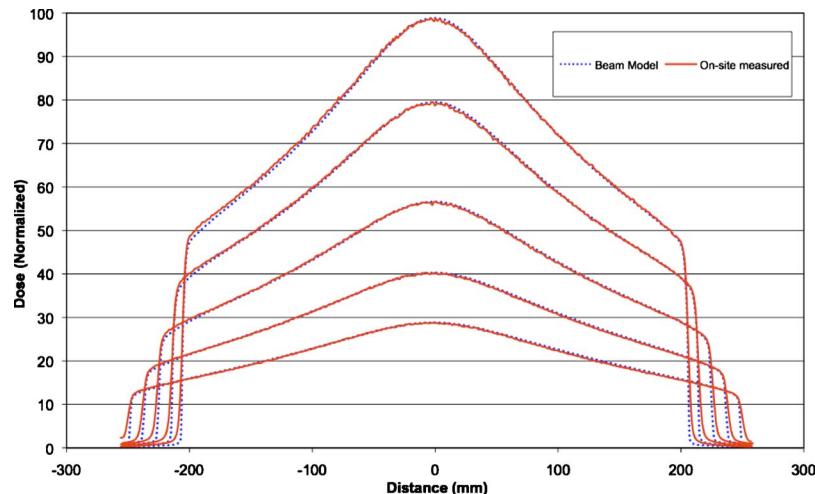


FIG. 16. Example of transverse beam profiles measured in a water tank ($2.5 \times 40 \text{ cm}^2$ field) and the respective modeled beam profiles. Data were acquired at an SSD of 85 cm and at depths of 15, 50, 100, 150, and 200 mm.

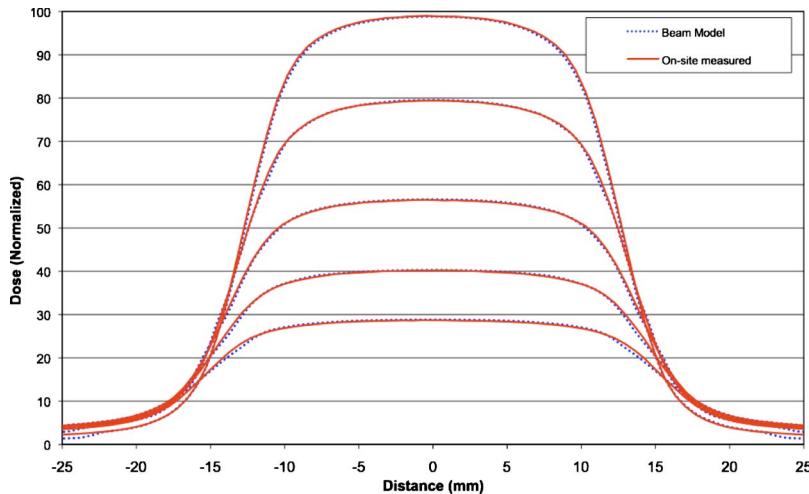


FIG. 17. Example of longitudinal beam profiles measured in a water tank and the respective modeled beam profiles. Data were acquired at an SSD of 85 cm and at depths of 15, 50, 100, 150, and 200 mm.

profile. However, changes in the beam profile result in changes of the measured detector data. Analysis of the detector data is hence a tool to test the consistency of the cone-beam profiles.^{5,12} Third-party vendors have created suitable diode arrays for cone profile measurements.¹² Finally, film can be used to monitor profile consistency. Similar to possible PDD changes at the end of the target life, changes in the cone-beam profiles have been reported with target wear.¹² On a monthly basis, the transverse beam profiles should be monitored for at least one commissioned treatment slice width. On an annual basis, the agreement of the transverse beam profiles with the beam model should be tested for all commissioned treatment slice widths. Since the beam model is currently available as beam profiles in water, water tank data should be measured on an annual basis.

Inherent to the use of the on-board detector system is the assumption that the off-axis detector response remains constant over time. This assumption is not explicitly tested. The detector is rigidly attached to the gantry such that a mechanical shift is unlikely. However, if profile changes are detected with the detector system that cannot be explained by target wear or component replacements, the response of the detector system should be verified against an independent measurement such as film or diode arrays. The annual acquisition of water tank data serves as an inherent check of the detector system consistency.

V.B.2.c. Longitudinal beam profiles. The constancy of the longitudinal beam profiles is particularly important for helical tomotherapy. The dose to the patient is the integration of the longitudinal beam profile shape with couch motion (ignoring leaf modulation) and the delivered dose will therefore change if the beam profile changes.¹³ For example, the delivered dose will change by approximately $\pm 10\%$ if the 1 cm beam profile changes in width by 10%, i.e., 1 mm. A careful monitoring of the beam's FWHM is hence recommended. While the constancy of the transverse beam profiles is also a test of the beam quality consistency, the longitudinal beam profile constancy test is primarily a slice width test and the

beam width at half maximum is recommended for monitoring. An example of modeled and on-site measured longitudinal beam profiles is shown in Fig. 17. The consistency of the longitudinal profiles should be monitored monthly for all commissioned slice widths. Several acceptable monitoring methods exist. An electrometer can be used to sample the collected charge of an ion chamber at a frequency of several Hz, while the couch is used to move the ion chamber along the longitudinal beam profile. Note that this test procedure relies on uniform couch motion. If the profile tests fail, the uniformity of the couch motion should be evaluated (Please see Sec. V B 3 b: Couch speed uniformity). Alternatively, film dosimetry can be used to monitor the longitudinal beam profiles for consistency. The profile's FWHM should not vary by more than 1%. Hence the absolute tolerance on FWHM changes is treatment slice width specific, i.e., 0.5, 0.25, and 0.1 mm, for the 5.0, 2.5, and 1.0 cm treatment slice widths, respectively. Of the three slice widths, the 1 cm treatment slice width is the most likely to fail the 1% FWHM tolerance. Note that this test is sensitive to the setup and a failed test result should prompt setup verification. If the test result continues to fail, corrective actions (such as jaw encoder adjustments) can be performed by the vendor.

Any treatment plan that is generated in the treatment planning system requires accurate jaw settings for dosimetric accuracy. Thus, the jaw setting accuracy is inherently tested with each clinical treatment plan QA as described in Sec. VII B 3 and with the rotational output test described in Sec. V B 2 d (Output constancy). While TG-142 recommends a daily check on collimator size indicator, this Task Group recommends an explicit test of the longitudinal beam profiles on a monthly basis. More frequent testing of the longitudinal beam profiles could be prompted by failures of the treatment plan QA results.

Agreement of the measured profiles with the beam model should be verified annually. Currently water tank data should be acquired annually to enable comparison with the beam model data.

V.B.2.d. Output constancy. The consistency of the output should be monitored on a daily basis. It is recommended that the output is monitored using a stationary and/or rotational procedure. The output of the TomoTherapy unit is sensitive to the machine's operating temperature and the output should only be checked when the machine is within 2 °C of its nominal operating temperature (i.e., 40 °C). This operating temperature is monitored and regulated via a water heating and cooling circuit.

If the static output is monitored on a daily basis the rotational output should be monitored on a weekly basis and vice versa. For the stationary procedure, the gantry is stationary and a treatment field can be delivered for a specified time. Since the dose rate is initially unstable, all MLC leaves should be closed for at least the first 10 s of this procedure. A rotational procedure that mimics a patient treatment, i.e., uses a rotating gantry, moving couch, and modulated leaf opening times, should be used to test for dosimetric consistency. This procedure should be generated in the TPS.

An ion chamber or a different dosimeter with similar precision can be used for these consistency tests. The daily output checks should be consistent within a 3% window. On a monthly basis, a calibrated ion chamber should be used to measure the output using static and rotational procedures. If an ion chamber is used for the daily output check, a different chamber should be used for the monthly check. Both monthly output checks should be consistent within a 2% window. These tolerances and frequencies are in accord with those recommended in TG-142.³

Both output checks should be within the tolerance window. If both outputs drift in parallel, the machine output can be adjusted to rectify the situation. A more difficult situation presents itself if both outputs drift apart and only one output is within the required window. The machine service history should be reviewed to see if the beginning of the drift coincides with machine maintenance events. For example, an MLC replacement could require a replanning of the rotational procedure due to the updated leaf latency data in the TPS (please see Sec. VIII E, "Major component replacement"). The rotational output variation data should be reviewed to see if the output variations with gantry angles changed in phase or amplitude.

Tomotherapy procedures are time-based, i.e., the beam is terminated after a specified time elapses. This technique relies on constant beam output and is therefore sensitive to dose rate fluctuations. For a detailed description of the tomotherapy dose rate monitoring system, please refer to Sec. V A 1, "Unique aspects of helical tomotherapy treatment delivery." The dose rate monitoring system is based on chamber signals from two separate transmission chambers. These signals are converted to monitor unit 1 and 2 readings for display and reporting. The two raw chamber signals have separate conversion factors such that the two monitor unit rates can be numerically identical. On a monthly basis, it should be tested that the two monitor unit rate displays are consistent to within 2%. A drift between the displayed monitor units indicates a drift in the raw count rates between the two chambers. However, to re-establish that both dose rate

interlocks have identical trigger levels, a reset of the nominal count rate based trigger level is required. A readjustment of two signal-to-MU conversion factors only affects the MU display but does not affect the actual trigger level. A re-establishment of the nominal count rate based trigger levels should be performed in cooperation with the vendor. The transmission chambers are only used to monitor the dose rates, i.e., they are used to interrupt a procedure if the dose rate is out of tolerance. They are not used to terminate the beam at the end of a procedure since the beam termination is time-based.

Output variations with gantry angle, i.e., rotational output variations should be monitored on a monthly basis. This test is similar to the output constancy versus gantry angle test recommended annually in TG-142. However, the rotational output on a tomotherapy unit is measured while the gantry continuously rotates. The increased test frequency that is recommended in this task group is based on the fact that the time-based output is sensitive to dose rate fluctuations with gantry angle. The rotational output variations are typically reproducible over several rotations with random variations (one standard variation) of the order of 1%–2%.¹⁴ No information is available regarding the long-term reproducibility of the output variation with gantry rotation.

For the rotational output variation test procedure, all MLC leaves should be open and the gantry should rotate continuously. For example, rotational output measurements can be performed with an ion chamber that is placed at the isocenter or by monitoring the monitor chamber signal as a function of gantry angle.¹⁵ The monitor chamber signal for each projection is recorded and saved as part of the patient archive (see Appendix E). To avoid beam attenuation in the treatment couch, the couch must be removed from the treatment plane, i.e., moved out of the bore, when ion chamber data are acquired.

If rotational output variation data are measured by a field service engineer as part of field service maintenance plan, the clinical physicist may review these data in lieu of a monthly measurement. The vendor's tolerance limit for the output variation with gantry angle is $\pm 2\%$ of the mean output. The tolerance for the similar TG-142 output constancy versus gantry angle test is defined relative to baseline only.³ The Task Group recommends adherence to the vendor's tolerance value. This recommendation is based on recent findings reported in the literature.^{11,14}

Since the rotational output variation is not accounted for in the treatment planning process its dosimetric effect was investigated in two recent publications. The difference in the delivered dose distribution from the planned dose distribution is smaller than the output variation since a voxel typically is irradiated from multiple gantry angles.^{11,14} Flynn *et al.*¹⁴ established a formula to calculate the acceptable amplitude of output variations as a function of the random output variations. The acceptability criterion required that the delivered dose has at least a 95% probability to be within 2% of the planned dose for all dose voxels. According to this formula the largest acceptable systematic amplitude A equals $0.34 \times (10 - \beta)$, where β is the random component of the

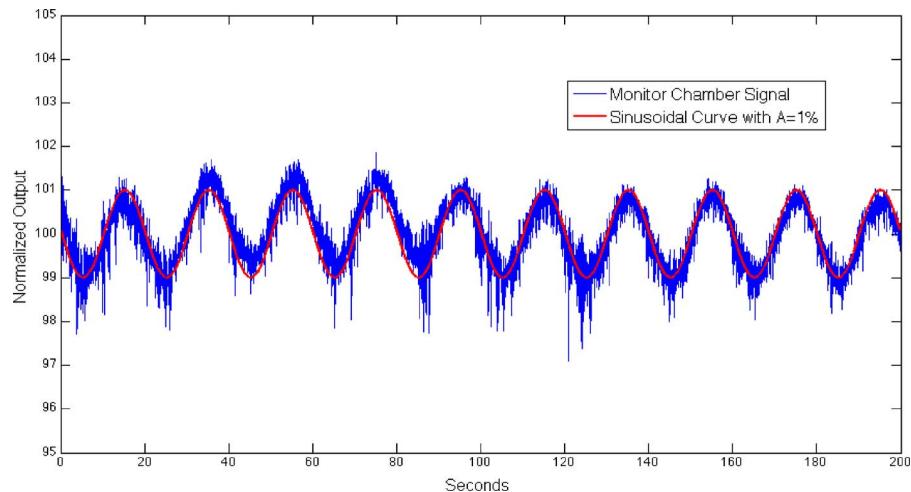


FIG. 18. Measured output variation with gantry rotation. The gantry rotation period was 20 s. A sinusoidal curve with amplitude of 1% is also shown.

output variation. Flynn *et al.*¹⁴ consequently conclude that the vendor tolerance window of 2% is more conservative than necessary. Figure 18 shows an example of measured rotation variation data. The systematic and random (one standard variation) variation of the measured data was 1%. For this case, a systematic variation with an amplitude of 3% would have fulfilled Flynn's criteria.

V.B.3. Synchrony tests

The delivery of a helical tomotherapy plan requires synchronization between the gantry rotation and table movement. Any inaccuracy or drift in these parameters over the course of a treatment would compromise treatment accuracy. The defined tests assume standard treatment scenarios, i.e., a target with longitudinal extension up to about 20 cm. When treatments involve more complex procedures (such as TBI or CSA irradiation), these tests should be modified accordingly.

V.B.3.a. Gantry angle consistency. The ability of the system to correctly identify gantry angles should be tested periodically. It is recommended that this feature be tested quarterly. The following is an example test procedure.⁶

This test involves positioning two films parallel to the rotation plane and separated on either side of the virtual isocenter by 3 cm. A delivery sequence is defined that specifies a slice width of 2.5 cm and a pitch of 0.1 for a minimum of 40 rotations. The control sinogram is set to open the middle two leaves (32 and 33) at projections centered at 0°, 120°, and 240°. Using a horizontal line marked on the films during setup, the resulting star pattern can be checked for the correct initial angles at the start of treatment and the ability to reproduce this pattern after 24 rotations. The gantry angles should be reproducible with a tolerance of 1°.

V.B.3.b. Couch speed uniformity. The ability of the system to correctly synchronize the couch position with the beam delivery needs to be tested periodically. It is recommended to test this quarterly. The following is an example test procedure. This procedure tests for uniform couch motion.⁶

A film with 1.5 cm buildup is taped to the tabletop. An irradiation is done with a static gantry in the 0° position, the

collimation set to 1 cm, all MLC leaves are opened. A couch travel distance of 20 cm for the course of the irradiation should be programmed using a couch speed that is representative of what is used clinically (e.g., 0.3–0.5 mm/s for 2.5 cm treatment slice width). The film is scanned and a profile is generated along the axis of couch travel. The relative optical density along this line should vary by less than 2%. Note that this test procedure relies on stable beam output. If this test fails, the beam output stability for static gantry procedures should be evaluated.

V.B.3.c. Couch translation/gantry rotation. The synchronization between couch translation and gantry rotation should be tested on a quarterly basis. The following describes an example test procedure.⁶

In this test, a film with 1.5 cm buildup is placed on the couch. A rotational irradiation is used with the nominal 1.0 cm beam and a pitch of 1 for 13 rotations. The control sinogram is set to open all the leaves for half a rotation on the second, seventh, and 12th rotation. The resulting film is scanned and a profile is produced along the direction of table travel. The resulting profile should show maxima 5 cm apart to within 1 mm.

V.B.4. Miscellaneous aspects

V.B.4.a. Interrupted treatment procedures. If a treatment is interrupted, the helical tomotherapy system can be used to generate a procedure to complete the treatment. The correct generation of this completion procedure should be tested monthly. This test should be performed for all commissioned slice widths on a rotating monthly schedule such that each month, one of the commissioned slice widths is scheduled for testing and each slice width will be tested every 2–3 months depending on the number of commissioned slice widths.

The following is an example test. A baseline treatment is delivered to a phantom and a coronal dose distribution is measured with film. The treatment is repeated with a new film and interrupted during the course of the treatment. A completion procedure is generated and the treatment is com-

pleted. Based on the developed films, the interrupted treatment should differ from the completed procedure by no more than 3% in its delivered dose and the overall length (FWHM) of the dose distribution in the y-direction should differ by no more than 1 mm. Since this test relies on a consistent phantom position for the interrupted and completion procedure, it is recommended to generate and deliver the completion procedure immediately after the initial treatment procedure is interrupted. It is recommended that the phantom not be moved between the deliveries of these two procedures.

V.B.4.b. Laser localization. Patients are typically positioned for treatment on the helical tomotherapy couch by aligning skin marks with wall-mounted external lasers. In theory, the use of pretreatment MVCT imaging decreases the importance of the external lasers for patient localization. In clinical practice, the use of the external lasers reduces patient rotation and aids the patient positioning process. As such, the external lasers used for helical tomotherapy units should be maintained to the same standards as used for other imaging and treatment units used in radiation oncology.

The accurate longitudinal spacing between the stationary, i.e., green, laser plane and the treatment isocenter should be tested annually using a small radiation field and a film that is marked at the virtual isocenter according to the stationary laser. The center of the radiation field should agree with the laser position to within 1 mm. The treatment field should be parallel to the laser to within 0.3° (1 mm offset at 20 cm from center). The concurrence of the virtual isocenter location and the center of the imaging plane in the x- and z-directions can be tested by imaging an object located at the intersection of the stationary lasers. This object should appear in the central MVCT pixel. Since the MVCT voxel dimensions in the “Scan”-tab are 0.8 mm in the x- and z-directions this test can test coincidence to within about ±1 mm.

The accurate movement of the movable laser with respect to the stationary laser should be tested monthly using a pre-defined plan with known red to green laser offsets. The red laser movements with respect to the green laser should be within 1 mm of the planned movement.

At initialization, the green and red lasers should coincide within 1.5 mm for non-SBRT/SRS and within 1 mm for SBRT/SRS treatments. This should be tested daily. The laser systems are independent of each other and if it is found that the two systems do not coincide upon system initialization, the physicist must investigate which of the two laser systems has changed. This test inherently tests the stability of both laser systems.

V.B.4.c. Treatment couch. Tests of the treatment couch are recommended on a monthly basis. The digital readout, couch pitch, roll, and yaw, as well as the couch sag should be tested.

The agreement between physical distances traveled and the digital readout should be tested. Over a distance of 20 cm, the agreement should be within 1 mm. Since the vertical couch position causes a longitudinal shift of the couch, the proper longitudinal position in the room coordinate system should be checked at different couch heights.

The leveling of the stationary couch should be tested and the pitch and roll should be less than 0.5°. The longitudinal couch movement should be perpendicular to the treatment plane. This can be tested by checking the couch alignment against the sagittal laser at different longitudinal couch positions. Over the distance of 20 cm, the lateral couch position should deviate by less than 1 mm. At the isocenter, the couch sag between the virtual isocenter and the treatment plane should be less than 5 mm for an unloaded couch per the vendor’s specifications.

V.B.5. Calibration

V.B.5.a. TG-51 equivalent calibration of the static beam. The development and clinical use of helical tomotherapy units has presented a challenge to the medical physics community. Helical tomotherapy units require a calibration of their dose output in the same manner and with the same accuracy as performed for conventional C-arm-gantry-based therapeutic accelerators. The recommended protocol for clinical reference dosimetry of high-energy photons in North America is the American Association of Physicists in Medicine TG-51 report.¹⁶ This protocol is based on an ionization chamber having a ⁶⁰Co absorbed-dose to water calibration factor from an Accredited Dosimetry Calibration Laboratory (ADCL), the National Institute of Standards and Technology (NIST) or the National Research Council (NRC) in Canada. The formalism used by the TG-51 protocol is the following:

$$D_w^Q = M \cdot k_Q \cdot N_{D,w}^{^{60}\text{Co}}, \quad (2)$$

where D_w^Q is the absorbed-dose to water at the point of measurement of the ionization chamber when it is absent, M is the fully corrected electrometer reading, $N_{D,w}^{^{60}\text{Co}}$ is the ⁶⁰Co absorbed-dose to water calibration coefficient, and k_Q is the beam quality conversion factor, which accounts for the change in the absorbed-dose to water calibration coefficient between the beam quality of interest Q and the ⁶⁰Co beam quality for which the absorbed-dose calibration factor was determined by the ADCL. The k_Q values to be used with the TG-51 protocol have been tabulated in TG-51 as a function of the percent depth dose specified at 10 cm and 100 cm SSD for a $10 \times 10 \text{ cm}^2$ reference field size in the clean, electron contamination-free photon beam. For several commercially available radiation therapy devices, it is not possible to measure the percent depth dose under these reference conditions. In recognition of this problem, the AAPM has formed a “Working Group on Dosimetry Calibration Protocols for Beams that are not Compliant with TG-51” to develop appropriate calibration procedures in collaboration with the International Atomic Energy Agency (IAEA).

The helical tomotherapy physical limitations do not permit a $10 \times 10 \text{ cm}^2$ field size at 100 cm SSD. However, a $5 \text{ cm} \times 10 \text{ cm}$ field size can be set at 85 cm SSD. In the longitudinal (y) direction, the maximum field dimension is 5 cm. Furthermore, there is a maximum distance of only 28 cm from isocenter to the lowest extend of couch position. This does not allow for an accurate measurement of the photon component percent depth dose at a 10 cm depth at 100 cm

SSD since there would not be sufficient phantom material for appropriate backscatter. In addition, since the helical tomotherapy unit does not have a flattening filter, depth dose data are slightly different than the depth dose data for similar nominal photon energies that have passed through a flattening filter. Since the TG-51 geometrical PDD reference conditions cannot be achieved, an alternate method of determining the helical tomotherapy beam quality is needed that will allow the use of the TG-51 tabulated k_Q values when performing a reference calibration of the helical tomotherapy unit.

The IAEA-AAPM joint committee proposed a formalism to determine the absorbed-dose to water to a static beam under specific helical tomotherapy reference conditions.¹⁷ This field is called a *machine-specific reference* (msr) field. The msr field is a static field that uses reference conditions that are achievable on a helical tomotherapy machine (i.e., a $5 \times 10 \text{ cm}^2$ field size at an SSD of 85 cm).

The Task Group recommends that this proposed formalism be followed until a formal protocol is established. The following equation, which is an extension of the TG-51 calibration protocol, details the proposed calculation of the absorbed-dose to water (the proposed formalism uses the

IAEA TRS-398 nomenclature.¹⁸ This nomenclature is adapted hence forth to facilitate comparison with the original publication of Alfonso *et al.*¹⁷):

$$D_{w,Q_{\text{msr}}}^{f_{\text{msr}}} = M_{Q_{\text{msr}}}^{f_{\text{msr}}} \cdot N_{D,w,Q_0} \cdot k_{Q,Q_0} \cdot k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}, \quad (3)$$

where Q is the beam quality [%dd(10)_x] of the conventional reference field $10 \times 10 \text{ cm}^2$ at 100 cm SSD according to TG-51 protocol; Q_{msr} is the beam quality [%dd(10)_x] of the machine-specific reference field f_{msr} ($5 \times 10 \text{ cm}^2$ field at 85 cm SSD); $M_{Q_{\text{msr}}}^{f_{\text{msr}}}$ is the corrected reading of the dosimeter for the field f_{msr} ; N_{D,w,Q_0} is the absorbed-dose to water calibration factor for a reference beam quality Q_0 (usually ^{60}Co) determined by the standards laboratory (ADCL or NRC); k_{Q,Q_0} is the beam quality correction factor for beam quality Q of the conventional reference field f_{ref} ($10 \times 10 \text{ cm}^2$ at 100 cm SSD); and $k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}$ is the factor to correct for the differences between the conditions of field size, geometry, phantom material, and beam quality of the conventional reference field f_{ref} and the machine-specific reference field f_{msr} .

A key product in the equation presented above is $k_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}$, which converts the calibration factor from calibration beam to the machine-specific reference beam, i.e.,

$$K_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}} = \frac{[(L/\rho)_{\text{air}}^{\text{water}} P_{\text{wall}} P_{\text{repl}} P_{\text{cel}}]_{\text{HT(SSD=85 cm,FS=5}\times 10 \text{ cm}^2,\text{depth=10 cm)}}}{[(L/\rho)_{\text{air}}^{\text{water}} P_{\text{wall}} P_{\text{repl}} P_{\text{cel}}]_{^{60}\text{Co(SSD=100 cm,FS=10}\times 10 \text{ cm}^2,\text{depth=10 cm)}}}, \quad (4)$$

where $(L/\rho)_{\text{air}}^{\text{water}}$ is the ratio of the mean restricted mass collision stopping power; P_{wall} is the ionization chamber wall correction factor; P_{repl} is the fluence and gradient correction factor; and P_{cel} is a correction factor for the presence of a central electrode.

A method to determine this correction factor is described by Thomas *et al.*¹⁹ In their publication, the correction factor is called $k_{Q(\text{HT TG-51})}$, where HT stands for helical tomo-

therapy. Since the calibration correction factor k_Q is specified in TG-51 as a function of the percentage depth dose at 10 cm depth in a $10 \times 10 \text{ cm}^2$ field size at 100 cm SSD, i.e., %dd(10)_{x[HT TG-51]}, Thomas derived a conversion function for this specifier to the beam quality %dd(10)_{x[HT ref]} measured in the tomotherapy reference field (10 cm depth, 85 cm SSD, $5 \times 10 \text{ cm}^2$ field size). The relationship was plotted and a third order polynomial [Eq. (5)] was fitted to the data as seen in Fig. 19.

The polynomial as derived by Thomas *et al.* is expressed in Eq. (5),

$$\begin{aligned} \%dd(10)_{x[\text{HT TG-51}]} &= 1.35805 \cdot (\%dd_{(10)x[\text{HT ref}]})^3 \\ &\quad - 244.493 \cdot (\%dd_{(10)x[\text{HT ref}]})^2 \\ &\quad + 14672.98 \cdot \%dd_{(10)x[\text{HT ref}]} \\ &\quad - 293479.4. \end{aligned} \quad (5)$$

The maximum error in the fit of Eq. (5) is 0.3%. In order to use this relationship shown in Eq. (5), one must measure %dd(10)_{x[HT ref]} with an ionization chamber of the appropriate size. Since the helical tomotherapy photon beam is unflattened, the beam profile in the cross-plane direction is peaked and there exists only a small portion of the profile (<2 cm) where the beam may be considered uniform and

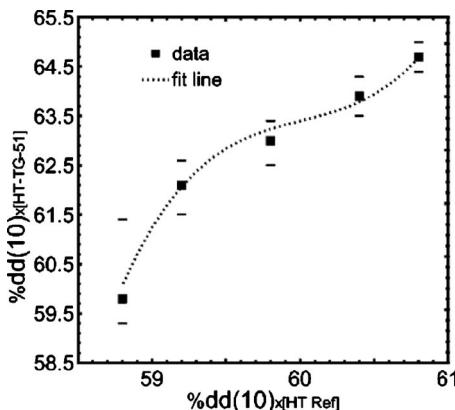


Fig. 19. The relationship between %dd(10)_{x[HT ref]} and %dd(10)_{x[HT TG-51]}. [Reproduced from Thomas *et al.* (Ref. 19)].

TABLE I. Values of k_Q for photon beams as a function of the beam quality $\%dd(10)_x$ for cylindrical ionization chambers commonly used for clinical reference dosimetry. The tabulated values can be interpolated linearly in $\%dd(10)_x$. The ionization chamber specifications are found in Table III of the TG-51 protocol. Values for the A1SL chamber are from Thomas *et al.* (Ref. 19).

Ion chamber	k_Q		
	Beam quality specifier $\%dd(10)_x$		
	58	63	66
Capintec PR-05/PR-05P	0.999	0.997	0.995
Exradin Al Shonka ^a	0.999	0.998	0.996
Exradin A12 Farmer	1	0.999	0.996
Exradin A1SL miniature Shonka	0.999	0.998	0.996
PTWN30001 0.6cc Farmer ^b	1	0.996	0.992
PTW N30002 0.6cc all Graphite	1	0.997	0.994
PTW N30004 0.6cc Graphite	1	0.998	0.995
PTW 31003 0.3cc waterproof ^c	1	0.996	0.992
WellhoferIC-10/IC-5	1	0.99	0.996

^aThe cavity radius of the A1 here is 2 mm although in the past Exradin has designated chambers with another radius as A1.

^bPTW N30001 is equivalent to the PTW N23333 it replaced.

^cPTW N31003 is equivalent to the PTW N233641 it replaced.

flat. The $\%dd(10)_{x[\text{HT ref}]}$ should only be measured with ionization chambers whose transverse diameter is smaller than the flat portion of the curve. This size requirement will ensure that the percent depth dose measurements are made in the flat portion of the beam minimizing volume averaging and reducing any error associated with centering the chamber in the beam. Conventional farmer chambers, such as those listed in Table I, whose diameter do not exceed 6.3 mm are small enough to fulfill this requirement.

The relationship shown in Fig. 19 was derived based on using an Exradin A1SL ionization chamber (Standard Imaging, Middleton, WI), but is applicable to other ionization chambers as long as the ionization chamber size limitations are met and correct percent depth dose data are measured incorporating the correct shift ($0.6r_{\text{cav}}$) to the effective point of measurement as defined by TG-51.

Another consideration in determining the helical tomotherapy unit beam quality is that any small error in the resulting $\%dd(10)_{x[\text{HT ref}]}$ will not significantly affect the k_Q value used in the calculation of the reference absorbed dose. For the range of $\%dd(10)_{x[\text{HT ref}]}$ values, i.e., 60%–64%, associated with the measured $\%dd(10)_{x[\text{HT ref}]}$ values on a helical tomotherapy unit, the k_Q values are nearly constant for the most commonly used cylindrical ionization chambers found in TG-51 and Thomas *et al.*, varying from 0.999 to 0.995, respectively.^{16,19} Any small error in the determination of $\%dd(10)_{x[\text{HT TG-51}]}$ will result in an error of typically no more than 0.1% in the final calculation of the reference absorbed dose.

The method recommended by this Task Group to determine the helical tomotherapy beam quality and the resulting

$k_{Q,Q_0} \times k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}$ product is to use the equivalent beam quality specifier technique described by Thomas *et al.*¹⁹ described above. This particular method requires the physicist to determine the beam quality specifier $\%dd(10)_{x[\text{HT ref}]}$, i.e., the percent depth dose in water at 10 cm depth at 85 cm SSD for a $5 \times 10 \text{ cm}^2$ field size and use the relationship defined by Thomas *et al.* to determine the equivalent beam quality specifier $\%dd(10)_{x[\text{HT TG-51}]}$. Once the equivalent beam specifier $\%dd(10)_{x[\text{HT TG-51}]}$ is known, the k_Q values listed in Table I and TG-51 are used to substitute the $k_{Q,Q_0} \times k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}$ product in Eq. (3). It should be noted that Table I is a reproduction of Table I from TG-51 and includes the k_Q values for the Exradin A1SL ionization chamber calculated by Thomas *et al.*^{19,20}

The calibration protocol for the helical tomotherapy unit is then similar to the procedures stated in the TG-51 protocol.

- (1) Position the ionization chamber in a water phantom such that the center electrode is at a depth of 10 cm at 85 cm SSD or SAD for a $5 \times 10 \text{ cm}^2$ field size. Allow the ionization chamber to equilibrate to the temperature of the phantom which should be at room temperature.
- (2) Record the temperature and pressure readings to determine the temperature/pressure correction, P_{TP} .
- (3) Take ionization readings per unit time at full bias to obtain M_{raw} readings.
- (4) Take ionization readings per unit time at half bias to obtain your M_{raw}^L readings to determine the ion recombination factor P_{ion} per TG-51.
- (5) Take ionization readings per unit time at the opposite polarity of the full bias reading to obtain your M_{raw}^+ readings to determine the polarity correction P_{pol} per TG-51.
- (6) Calculate the corrected ionization chamber reading per TG-51:

$$M_{Q_{\text{msr}}}^{f_{\text{msr}}} = M_{\text{raw}} \cdot P_{\text{TP}} \cdot P_{\text{ion}} \cdot P_{\text{pol}} \cdot P_{\text{elec}}. \quad (6)$$

- (7) Calculate the dose to water per unit time at a depth of 10 cm using

$$D_{w,Q_{\text{msr}}}^{f_{\text{msr}}} = M_{Q_{\text{msr}}}^{f_{\text{msr}}} \cdot N_{D,w,Q_0} \cdot k_{Q,Q_0} \cdot k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}. \quad (7)$$

- (8) Calculate the dose to water per unit time at d_{max} using the clinical $\%dd(10)$ for SSD setup or the clinical TMR(10) for SAD setup.

One can be assisted by the worksheet in Appendix A for calculation of the static output of the helical tomotherapy machine. The worksheet is based on worksheet A of the TG-51 protocol.¹⁶

Although the static output calibration is done in a delivery mode that is not used for the treatment of patients, it forms a valuable part of the machine QA. This mode excludes all treatment dynamics and allows the determination of a single but fundamental machine characteristic. In addition, the static output calibration satisfies most state regulations that require the physicist to calibrate their machine once a year using an established calibration protocol. The methodology

described above is a simple extension of the TG-51 protocol and as such should satisfy the annual calibration requirement within the state regulations.

V.B.5.b. Output calibration (rotational procedure). Since patients are not treated with a stationary unmodulated beam, but rather with a rotating beam the output of the helical tomotherapy unit should be verified under these conditions. The IAEA/AAPM formalism mentioned earlier has addressed this issue for helical tomotherapy machines.¹⁷ In addition to static-field dosimetry it allows a second calibration route that is based on the delivery of composite fields. The formalism suggests that the physicist will develop a *plan-class specific reference* (pcsr) field and perform the measurements within this field to determine the output of the machine as it rotates about the calibration phantom. This pcsr field according to the IAEA/AAPM formalism “is as close as possible to a final clinical delivery scheme, but delivers a homogeneous absorbed dose to an extended and geometrically simple target volume.”

The pcsr field should be designed to provide a uniform dose over a region exceeding the dimensions of the reference detector. While the IAEA/AAPM formalism does not specify the particulars of the pcsr field, the recommendation of this task group is to generate a treatment plan that delivers a uniform dose of 2 Gy to a target of 8 cm diameter and 10 cm length in a 30 cm diameter water-equivalent phantom that has a minimum length of 15 cm. The vendor supplied Virtual Water™ phantom fulfills these requirements. It is recommended to use a 5 cm treatment slice width and a pitch of 0.287. For a detailed discussion of the treatment planning parameters and a discussion of phantom-based treatment plans the reader is referred to Sec. VII. The cylindrical water-equivalent phantom is imaged using a CT scanner and a treatment plan to deliver a homogeneous dose to the pcsr field is developed. The phantom should be scanned without the ionization chamber present. After the plan has been calculated, the volume that will be occupied by the active chamber volume is identified in the CT image and the average calculated dose to this volume is used for comparison with the measurements.

The phantom is placed on the treatment couch with the appropriate ionization chamber located in the center of the pcsr field. Ionization measurements (accumulating charge for the time interval to deliver the plan) are collected while delivering the plan with the homogeneous dose distribution.

The absorbed dose in a pcsr field can be calculated using the following equation, which is an extension of Eq. (3).

$$D_{w,Q_{\text{pcsr}}}^{f_{\text{pcsr}}} = M_{Q_{\text{pcsr}}}^{f_{\text{pcsr}}} \cdot N_{D,w,Q_o} \cdot k_{Q,Q_o} \cdot k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}} \cdot k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}, \quad (8)$$

where $M_{Q_{\text{msr}}}^{f_{\text{pcsr}}}$ is the corrected reading of the dosimeter in the field f_{pcsr} ; $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ is the factor to correct for the differences between the conditions of field size, geometry, phantom material, and beam quality of the machine-specific reference field f_{msr} and the plan-class specific reference field f_{pcsr} . $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ is equal to 1.003 for most commonly used ionization chambers. (In the IAEA/AAPM formalism, a $k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}}$ value of 0.997 is listed for helical tomotherapy msr field

sizes of 5×10 cm². For helical tomotherapy, pcsr field deliveries with 5, 2.5, and 1 cm field $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ values of 1.000, 1.000, and 0.997 are listed for a NE2611 chamber.¹⁷ This allows the calculation of a $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ value of 1.003 for 5 cm and 2.5 cm pcsr field deliveries. However, the reported $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ factors have a significant standard uncertainty of 0.8%.¹⁷ Revised $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ factors may be published in the future and appropriate adjustment to the $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ factor may be required at that time.)

The physicist should follow the same procedure as outlined for the static beam output calibration to determine the beam quality for the machine-specific reference field, %dd(10)_{x[HT TG-51]} and using Thomas *et al.*’s relationship determine the beam quality of the conventional reference field %dd(10)_{x[HT ref]}. Knowing the beam quality, one can determine the $k_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}}$ product for the specific chamber used in the calibration. The corrected meter reading for the pcsr field $M_{Q_{\text{pcsr}}}^{f_{\text{pcsr}}}$ should be determined as outlined in the worksheet in Appendix A. The worksheet in Appendix A can be used to assist in the calculation of the absorbed dose to the plan-class specific reference field $D_{w,Q_{\text{pcsr}}}^{f_{\text{pcsr}}}$ per Eq. (8). The absorbed-dose to water for the pcsr field is delivered in the same mode that is used to deliver patient treatments. The absorbed dose determined under the pcsr conditions can be compared to the value calculated by the tomotherapy planning software. If differences between the calculated and measured dose are identified that are in excess of 1%, it is recommended by this task group to make adjustments to the machine output.

The static calibration procedure described in Sec. V B 5 a should form part of the calibration procedure, but its use is limited since the expected output under static conditions cannot be compared to an expected value from the planning system. The calibration of the tomotherapy unit via pcsr fields is hence the relevant calibration route.¹⁷

V.B.5.c. Independent verification of calibration. It is recommended that an independent verification of the tomotherapy calibration be performed prior to the initial patient treatment and that it is repeated on an annual basis. The Radiological Physics Center in Houston (rpc.mdanderson.org/RPC/home.htm) offers a mail-in TLD monitoring service that can be used for an independent verification by NCI clinical trials participants. Other facilities are advised to contact one of the for-fee remote auditing services such as Radiation Dosimetry Services (www.mdanderson.org/education-and-research/resources-for-professionals/scientific-resources/core-facilities-and-services/radiation-dosimetry-services/index.html). Local regulation may also require an independent verification of machine calibration.

VI. TREATMENT IMAGING FOR HELICAL TOMOTHERAPY

VI.A. Introduction

In addition to its ability to deliver IMRT, the TomoTherapy system also has the ability to obtain images of the

patient in the treatment position prior to each treatment. These images are acquired to check and correct, if necessary, the patient's position for treatment. Inaccurate patient positioning will result in a geographic misplacement of the dose distribution.

The AAPM TG-142 report includes recommendations on serial and cone-beam CT for image guidance.³ Periodic tests of geometric accuracy, image quality, and imaging dose are recommended in TG-142. The intent of Sec. VI A 1 is to describe respective quality assurance procedures associated with the imaging aspect of the TomoTherapy unit.

VI.A.1. Unique aspects of megavoltage CT imaging

The radiation beam that is used for imaging on the TomoTherapy unit is generated by the same linear accelerator that is used to generate the treatment beam. Therefore, the beam energy is in the megavoltage range and the image modality is referred to as MVCT imaging. For MVCT imaging, the accelerator is adjusted such that the nominal energy of the incident electron beam is 3.5 MeV.⁹ The detector used in the TomoTherapy system is an arc-shaped CT xenon detector that has been described previously.^{21–23} The standard image matrix size is 512×512 pixels and the field-of-view has a diameter of 40 cm. A filtered back-projection algorithm is used for image reconstruction.²³

On the user interface, the operator is tasked with the selection of the scan length and the slice thickness. Three pitch values (1, 2, and 3), are pre-programmed; these are referred to as fine, normal, and coarse, respectively. The standard y-jaw setting for the imaging mode is 4 mm and the pre-programmed pitch values correspond to a nominal slice thickness of 2, 4, and 6 mm. The rotational period during the image acquisition is fixed at 10 s. Using a half-scan reconstruction technique, this translates to an acquisition rate of 1 slice per 5 s. The imaging dose depends on the selected pitch and the thickness of the imaged anatomy, but it is typically in the range of 1–3 cGy.²⁴ The total scan time depends on the number of selected slices.

The TomoTherapy operator station includes image registration tools for manual or automatic rigid-body registration. The automatic registration tools are typically faster than manual image registration, but it is important that automatically registered images are checked for accuracy by an experienced user.

The dimensions of the kVCT and MVCT image voxels are different in size. The kVCT image, which has a variable field-of-view, is typically down-sampled to a 256×256 matrix upon import to the TPS while the MVCT image has a 512×512 matrix size with a 40 cm field-of-view. During automatic image registration, a nearest neighbor approach is used for image interpolation.

A registration accuracy on the order of one-half voxel dimension can be expected for phantom MVCT to kVCT image registrations under these ideal conditions.^{25,26} The larger of the two voxel dimensions, kVCT or MVCT, is the limiting one. In the y-direction, the MVCT voxel size varies

with the imaging pitch, and the superior-inferior registration precision reduces with an increase in the MVCT slice thickness.²⁶

VI.B. Periodic quality assurance

VI.B.1. Spatial/geometry tests

The primary purpose of MVCT imaging is image guidance. Accordingly, the geometric accuracy of the reconstructed images and the accuracy and consistency of the image registration procedure should be tested. Appropriate phantom-based test procedures are described below.

It should be pointed out that the image registration precision will depend on the available image content, i.e., it could depend on the test phantom itself. For example, a high contrast object that is easy to identify in both images (e.g., a metal ball of 1–2 mm diameter) can be registered more precisely than a phantom that varies little in the superior-inferior direction. Similarly, the scan range and parameters influence the available information and this can affect the registration precision.^{26,27} It should further be understood that registering patient images can be more subjective depending on the anatomical site because anatomical changes in the patient can add a level of complexity and subjectivity that is absent from rigid phantom alignments. The clinical registration precision can be determined using actual patient images, clinical operators, and clinical alignment techniques.²⁸

VI.B.1.a. Geometric distortions. The accurate reconstruction of an object in the MVCT image in terms of dimension and orientation can be tested with a rigid phantom of known dimensions and orientation. The recommended test frequency is monthly. The vendor supplied cylindrical Virtual WaterTM phantom or a phantom of similar size can be used.

Distances between embedded objects in the x-, y-, and z-directions, and the orientation of the phantom as they appear in the MVCT image can be compared to the physical distances and orientation of the phantom. The use of small fiducial markers that are embedded or attached to the phantom will increase the precision of this test particularly in the longitudinal direction where the phantom exterior surfaces are parallel to the imaging plane and are hence subject to volume averaging effects. Spatial information from the MVCT image can be deduced using the cursor position read-out function available in the software. The use of a “fine” scan, i.e., a nominal slice thickness of 2 mm, is recommended for this scan. On the MVCT image, the orientation of the phantom should be correct. The MVCT images themselves should be free of unacceptable reconstruction artifacts. A minimum scan length of 20 cm is recommended for this test to approximate a typical scan length that is used in clinical routine. The dimension of the embedded objects or distances between fiducial markers as measured in the MVCT image should be within 2 and 1 mm of the physical distances for non-SRS/SBRT and SRS/SBRT treatments, respectively. The recommended test frequency and tolerances are in accord with those recommended in TG-142.

The accurate reconstruction of the MVCT image in terms of dimension and orientation should also be tested after sys-

tem maintenance work that can affect the hardware or software components that relate to the imaging system.

VI.B.1.b. Imaging/treatment/laser coordinate coincidence.

The coincidence between the treatment and imaging coordinate system should be tested for any IGRT system. The meaning of this test changes somewhat for systems that use the treatment beam for image acquisition such as the tomotherapy MVCT system. While the beam source is identical for MVCT-based systems, the image acquisition, reconstruction, and registration involves hardware and software components that could induce discrepancies in the coordinate coincidence. It is therefore recommended to perform, on an annual basis and after software upgrades, a phantom-based end-to-end test of the image registration and treatment chain. For this test, a phantom will undergo the same chain of events that a patient would undergo. The phantom is imaged, a plan is generated in the TPS, MVCT imaging is used to check the phantom alignment, and finally the phantom is treated. The dose distribution within the phantom is tested for accuracy to establish image and treatment coordinate coincidence.

The phantom needs to contain either a film-based dosimeter or some other means of extracting a dose distribution for comparison with the dose distribution calculated in the treatment planning software. For example, ion chamber or diode arrays allow a direct measurement of the dose distribution in the phantom. Similarly, the vendor supplied Virtual Water™ phantom allows the placement of a film in the coronal or sagittal plane, and this phantom can be used for this test. In this case, the delivered dose distribution should be registered relative to the phantom. This registration can be performed within the TomoTherapy DQA panel with the aid of the “General” registration tool available in the DQA analysis panel. This registration tool allows a film registration that is based on any two points that can be identified on the film and in the CT image. Alternatively, the dose plane can be exported from the treatment planning system and the registration can be performed using third-party software. This test assesses the combined accuracy of the image registration and dose delivery process. A similar test is described in the literature by Soisson *et al.*²⁹ The tolerance should accommodate geographic uncertainties in the image registration and dose calculation. If each geographic uncertainty is assumed to be on the order of a voxel dimension or less, the tolerance of this test can be calculated by summing the two uncertainties in quadrature. Recommended tolerances for the treatment and imaging coordinate coincidence is 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatment machines. The imaging parameters and dose calculation grids may need to be chosen accordingly.

The annual test checks coincidence of the treatment and imaging system coordinates. A simultaneous test of the green laser system coincidence with the imaging system allows the establishment of the green laser system as a reference for daily and monthly consistency tests. This coincidence can be verified by checking that, post image registration, the green laser position on the phantom is in agreement with the intended position as indicated in the treatment planning sys-

tem. When this test is performed, it must be kept in mind that the couch height may sag if a phantom is aligned at the virtual isocenter and is then moved to the treatment plane. Typically, the couch sag is on the order of 3 mm if vendor supplied cylindrical Virtual Water™ phantom is positioned on top of the couch. To avoid this offset, the phantom location with respect to the green laser should be checked at the treatment plane. Recommended tolerances for this test are 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatment machines.

The use of the green laser system as a surrogate is convenient since its operation is independent of the TomoTherapy machine operation and its position is thus not affected by the machine software or hardware upgrades.

On a daily basis, it is recommended to test the accurate location of the reconstructed image with respect to the green laser system to test the accurate location of the image coordinates with respect to the treatment coordinate. For this test, an object, i.e., a phantom with a high contrast object, is aligned with the red or green laser system and is scanned. The location of the object in the reconstructed MVCT image should agree with the actual location of this object with respect to the stationary green laser system. The tolerance for this test is 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatments. The use of the fine MVCT scan mode is recommended. A daily test of the treatment and imaging coordinate system coincidence with the given tolerances is in accord with recommendations made in TG-142.

Since accurate MVCT to kVCT image registration relies on accurate MVCT image localization, the above coincidence can be verified during the image registration test described in Sec. VI B 1 c.

VI.B.1.c. Image registration and alignment (position/repositioning). It is recommended to test the accuracy of the image registration and alignment process on a daily basis with a position/reposition test. The creation of a “phantom” patient plan can be used to test multiple aspects of the system. For example, a phantom that is intentionally and reproducibly misaligned prior to MVCT imaging can be scanned and registered to monitor the functionality and consistency of the image guidance process. A visual inspection of the image for image artifacts can be done at the same time. The image registration process should be reproducible to within 1 mm for phantoms that contain a high contrast object. Use of the fine scan option is recommended. The post registration positioning process should also be executed and actual couch and red laser shifts should match the intended shifts within 1 mm. The vendor supplied cylindrical Virtual Water™ phantom can be used for this test. The final, postregistration and alignment, positioning of the phantom should be accurate with respect to the green laser to within 1 mm. A daily position/repositioning test with identical tolerances is recommended in TG-142. An example phantom plan that tests, among other aspects, the consistency of the image registration and alignment process is described in Appendix D.

VI.B.2. Image quality tests

Image quality and dosimetry tests are recommended to quantify the initial performance of the system and to monitor this performance periodically. Quantitative tests at the time of machine acceptance allow the user to judge the performance of their system relative to recommended values. Periodic monitoring allows the user to quantify degradations in imaging parameters.

Image degradation could indicate suboptimal performance of the beam collimation, MVCT detector system, or variations in the MVCT beam with target wear. The accuracy of the primary y-jaws in defining the MVCT slice width in the longitudinal direction can influence the patient dose. If the fan beam is wider than intended, unnecessary dose will be delivered to the patient. The appearance of ring artifacts in the image points to a malfunction in the detector system. The Hounsfield unit (HU) to electron density conversion can also vary with target wear.

The image noise, uniformity, spatial resolution, contrast, and the MVCT dose are recommended for monitoring. The CT number reproducibility and image uniformity are essential if the MVCT images are used for dose calculations. Accordingly, the monthly MVCT QA protocol will vary with the intended MVCT use. Monthly tests of the image quality are in accord with TG-142 recommendations.

VI.B.2.a. Random uncertainty in pixel value (noise). To test image noise, an image of a water or water-equivalent uniform phantom can be used. The noise can be assessed by calculating the standard deviation σ_{CT} of the HUs in a region-of-interest (ROI). Noise is expressed relative to the linear attenuation coefficient of water μ_{water} and is corrected for the contrast scale (CS) of the scanner.²² Hence, the

$$\text{Noise} = \sigma_{CT} \times CS \times 100/\mu_{water} \quad (9)$$

where

$$CS = (\mu_{polycarbonate} - \mu_{water}) / (\text{HU}_{polycarbonate} - \text{HU}_{water}). \quad (10)$$

Using the above methodology noise values of 3.7–3.8 have been published for MVCT images.³⁰ This corresponds to a standard deviation of about 35–36 HU in a homogeneous water bath. When selecting the region-of-interest, the user should avoid areas of known image artifacts such as the “button” artifact that is frequently seen in the center of MVCT images. The button artifact is a region of enhanced density that is about 10 mm in diameter. It is an artifact of the rapidly changing detector response in the central region of the detector array.

It is recommended to determine the noise in the MVCT image using a cylindrical uniform phantom with a diameter of at least 20 cm. The vendor supplied cylindrical Virtual WaterTM phantom contains a uniform section that can be used to determine the image noise. It is recommended to monitor the noise level on a monthly basis. The vendor does not issue a recommendation for acceptable noise levels and the acceptability of the measured noise level is at the user’s discretion. Typical noise levels in the central region of the MVCT image

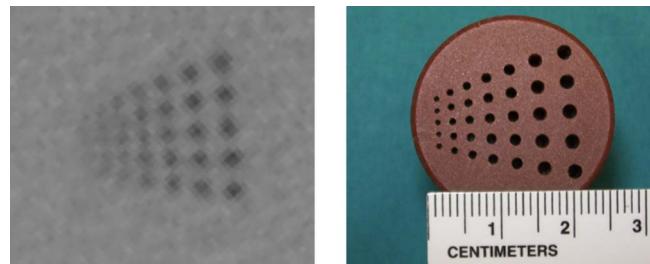


FIG. 20. MVCT image of the high contrast resolution plug that is shown on the left. The largest hole is 2 mm in diameter and the diameter is reduced in 0.2 mm steps for the smaller holes, i.e., the smallest hole has a diameter of 0.8 mm.

are around 50–70 HU (one standard deviation) while lower values (i.e., 25–35 HU) can be expected in the periphery of the image.

VI.B.2.b. Image uniformity. The uniformity can be assessed by measuring the average HU in smaller ROIs (about 5 mm in radius) that are located in the center and periphery of the phantom. The largest difference between any peripheral HU and the central HU is determined.

It is recommended to determine the uniformity in the MVCT image using a cylindrical uniform phantom with a diameter of at least 20 cm. The vendor supplied cylindrical Virtual WaterTM phantom contains a uniform section that can be used to determine the image uniformity. It is recommended to monitor the image uniformity on a monthly basis.

If the MVCT image is used for dose calculation, the largest HU difference between the peripheral and the central ROIs should be less than 25 HU. A 25 HU difference in water would translate to a 2.5% variation in the calculated density of water.

VI.B.2.c. Spatial resolution. The spatial resolution can be measured with a high contrast hole pair test pattern. TomoTherapy provides a resolution plug that can be used for this test. This plug can be inserted into the vendor supplied cylindrical Virtual WaterTM phantom. Alternatively, the resolution insert of an AAPM CT Performance Phantom (Cardinal Health, Hicksville, NY) or any similar spatial resolution insert can be used for this test. A monthly check of the MVCT image resolution should be performed. Figure 20 shows an MVCT image of a high contrast resolution test plug.

Visual inspection of a hole pattern indicated that MVCT images that are reconstructed with the typical 512×512 pixel matrix allow the resolution of a 1.25 mm high contrast object.³⁰ The vendor specifies a minimum resolution of a 1.6 mm high contrast object.

VI.B.2.d. Contrast. The low contrast visibility can be measured by inserting various density test plugs supplied by the vendor in the vendor supplied cylindrical Virtual WaterTM phantom. On a monthly basis, the visibility of the identical test plugs can be checked. This test relies on the operator and is subjective in nature. However, a significant loss in contrast resolution will be detectable. Figure 21 shows an MVCT scan of the Virtual WaterTM phantom that is loaded with test plugs of varying densities.

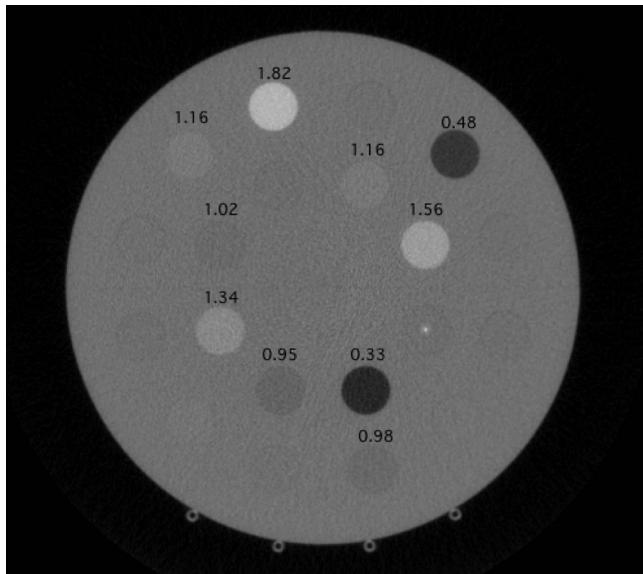


FIG. 21. MVCT image of the Virtual Water™ phantom loaded with various test plugs for a contrast and spatial resolution test. The numbers state some of the nominal plug densities in g/cm^3 .

VI.B.2.e. CT number to density calibration. The relationship of MVCT number to electron or mass density is different from that observed in kVCT scanners. This is due to the difference in physical interaction probabilities in the two beams. In the megavoltage energy range, Compton interactions are dominant even in high Z materials. Consequently, the MVCT number to physical density calibration table is expected to reflect a linear relationship.

TomoTherapy has a commercial software package called “PLANNED ADAPTIVE” that facilitates the use of MVCT images for retrospective dose calculations to evaluate the dose distribution in the anatomy of the day. If MVCT images are used in this manner, a MVCT to density calibration must be commissioned and the reproducibility of the HU calibration should be monitored on a monthly basis. Similarly, if MVCT images are used for treatment planning, an accurate HU calibration must be used.

To commission the use of MVCT images for dose calculations, a commercial CT number calibration phantom can be used. The vendor supplied cylindrical Virtual Water™ phantom contains Virtual Water™ density plugs that can be exchanged with different density plugs for this purpose. A set of density plugs ranging from lung to bonelike densities is available from TomoTherapy. A MVCT scan of the calibration phantom is obtained and a MVCT number to density table can be established. The TomoTherapy TPS expects HU calibrations in terms of mass density rather than the more common relative electron density. These tables are called image value-to-density calibration tables (IVDTs) in the TomoTherapy TPS. An IVDT editor is available to commission and edit the IVDTs. After the IVDT is commissioned, its accuracy can be tested by recalculating the dose distribution of a phantom plan in the MVCT image of the phantom. Any rigid phantom, e.g., the vendor supplied cylindrical Virtual Water™ phantom can be used for this test. The original

kVCT-based dose distribution should agree with the MVCT-based dose distribution. The PLANNED ADAPTIVE software facilitates a dose volume histogram comparison. The original and recalculated DVH should agree to within 2%.

If MVCT images are used for dose calculations, the reproducibility of this calibration curve should be monitored on a monthly basis with a subset of density plugs that cover lung, bone, and waterlike densities. The vendor supplied cylindrical Virtual Water™ phantom loaded with the appropriate density plugs can be used for this test. Any uncertainty in the HU calibration translates into dosimetric uncertainties in the MVCT-based dose calculation. The dosimetric impact of HU variations depends on what part of the calibration curve is affected. A shift in the water-equivalent HU has a larger impact than a shift in the bone equivalent HU since a typical patient image contains more water-equivalent density material than bonelike materials. Calibration curves that differed by 20 HU near water-equivalent densities and by up to 50 and 80 HU in lunglike and bonelike densities resulted in dosimetric differences of typically 2% or less for tomotherapy treatment plans.³¹ Monthly HU calibration tests should test that the HU for water-equivalent materials varies by less than 30 HU and that lung and bonelike materials result in HUs that are within 50 HU of the nominal value established at time of machine acceptance.

VI.B.3. MVCT dosimetry

A multiple slice average dose (MSAD) measurement can be performed to measure the dose in phantom and to check the consistency of the imaging dose over time. Measurements are obtained with a calibrated ionization chamber that is located at a point of interest in a phantom, such as the vendor supplied Virtual Water™ phantom described in Sec. II. The scan ranges should cover the complete phantom. The dose measured at the ionization chamber location includes dose that is accumulated while the sensitive chamber volume is imaged as well as scatter dose accumulated when the neighboring slices are imaged. A simple cylindrical phantom or test plug that accommodates a calibrated ionization chamber such as a Farmer or an A1SL chamber can be used. The chamber specific TG-51 calibration factor can be used to convert the charge to dose. No adjustments for the image beam quality or irradiation conditions is recommended since the MVCT dose does not need to be measured with the same accuracy as the treatment dose.

The imaging dose will depend on the selected imaging mode and phantom but for the vendor supplied cylindrical Virtual Water™ phantom that is imaged in the “NORMAL” mode, a MSAD dose of 1–3 cGy can be expected.²⁴ Since the imaging beam is in the megavoltage range and the image is acquired in a helical fashion, the imaging dose is fairly uniform and the position of the ion chamber within the phantom is not critical. The same position should, however, be used for the consistency tests. It is recommended to monitor the imaging dose on a quarterly basis. While TG-142 recommends an annual measurement of the imaging dose a more frequent measurement is recommended for tomotherapy ma-

chines since MVCT images tend to be acquired on a frequent, i.e., daily, basis for each patient. Unexplained increases in the MVCT dose should be investigated.

VI.B.4. Image export for analysis

The analysis of MVCT images in terms of Hounsfield units cannot be done conveniently with the standard TomoTherapy software. For example, the TomoTherapy software has no tools to select a ROI for the calculation of mean HU and their standard deviation. To facilitate the analysis of MVCT images, it is therefore recommended to export the MVCT image from the TomoTherapy database and use third-party software for analysis. Using the DICOM export feature in the TomoTherapy software, it is possible to send MVCT images to a DICOM receiver. The Image-Guided Therapy QA Center (ITC) at Washington University in St. Louis supplies a convenient and free-of-charge DICOM receiver software package (DICOMPiler) (<http://itc.wustl.edu/DICOMPiler/index.htm>) that can be installed on a PC. Once exported, any image analysis software package [e.g., IMAGEJ from the National Institute of Health (NIH) (<http://rsb.info.nih.gov/ij/>)] can be used to analyze the HU distribution in a region-of-interest. Alternatively, DICOM export to a third-party treatment planning system can be investigated since appropriate image analysis tools may be available within these systems.

VII. TREATMENT PLANNING FOR HELICAL TOMOTHERAPY

VII.A. Introduction

The AAPM TG-53 report describes the QA guidelines for clinical 3D conformal radiotherapy treatment planning.³² Not all of the issued guidelines apply to helical tomotherapy IMRT treatment planning, however, many aspects of these guidelines, e.g., the geometric tests of the TPS directly apply. Other aspects, such as the dosimetric verification of the TPS, apply but have to be adjusted to account for the specific workings of the TPS. In addition, for IMRT plans it is standard to check individual patient plans for accuracy. The intent of this chapter is to describe the treatment planning QA tests and their frequencies.

VII.A.1. Unique aspects of helical tomotherapy treatment planning

Since all TomoTherapy planning systems contain a common beam model, the traditional commissioning tasks of beam data entering and beam modeling do not apply to the tomotherapy planning system. There are no tools available in the treatment planning system to view the beam data that is used by the beam model. There are, however, two MLC-specific data files that are used by the planning system. These data files contain leaf latency and leaf specific fluence output data. In addition to these MLC-specific files, each machine has a specific set of y-jaw fluence output factors. These y-jaw fluence output factors specify the fluence of the 2.5 and 1.0 cm treatment slice fields relative to the 5.0 cm treat-

ment slice field output. The fluence output for the 5 cm treatment slice width is a common value used by all TomoTherapy treatment planning systems.

After machine acceptance, the on-site physicist is left with site-specific tasks such as the generation of a kVCT scanner specific CT number to mass density calibration curve and the setup of connectivity of the helical tomotherapy TPS to external hardware. In the TomoTherapy TPS, Hounsfield units are calibrated against mass density rather than the more common relative electron density.

TomoTherapy's Hi-ART II TPS is exclusively used for planning. No other commercial TPS is available to generate treatment plans for delivery with TomoTherapy machines. There are a number of unique aspects of this TPS that are either due to the unique treatment delivery or are due to the specific working of this TPS. An understanding of these aspects is in the interest of treatment plan quality.

Due to its unique treatment delivery technique, unique planning parameters need to be chosen during the generation of a helical tomotherapy plan. For each plan, the treatment slice width, pitch, and modulation factor need to be selected.

The treatment slice width is the fan-beam width that is defined by the collimating y-jaws in the longitudinal direction at isocenter. Typically, three commissioned treatment slice widths (1.0, 2.5, and 5.0 cm) are available for selection.

The pitch value is defined as the ratio of the couch travel per gantry rotation to the treatment slice width and it is recommended to be less than 1. To increase dose homogeneity, pitch values less than 0.5 are typically used.³³ For off-axis targets, dose heterogeneities due to beam divergence and the cyclic nature of rotational beam delivery are possible. This "thread" or ripple effect increases with the treatment slice widths, pitch values, and off-axis distance.³⁴ An empirical study of this effect showed that for all treatment slice widths, the relationship between the size of the thread effect and the pitch contains minima at pitch values equal to $0.86/n$, where n is an integer.³⁴ For example, for a 2.5 cm treatment slice width and a pitch value of 0.287, the thread effect has a value of about 1% (peak-to-trough) at an off-axis distance of 5 cm. Changing the pitch value to 0.5 increases the thread effect to about 3% for the same conditions. However, the thread effect has little clinical impact for targets that are located on-axis.

If the dose per fraction is significantly higher than 2 Gy it may be necessary to reduce the pitch value to about 0.2 or less. The delivery of a higher dose requires the gantry to rotate slower and this may conflict with a required minimum gantry rotation speed of one rotation per minute. A reduction of the pitch value means that the target voxel is within the beam plane for more gantry rotations. This allows the gantry to rotate faster and enables the delivery of higher doses per fraction.

The modulation factor is defined as the longest leaf opening time divided by the average of all nonzero leaf opening times. The longest leaf opening time is significant because it determines the gantry rotation speed that is used during the delivery. The modulation factor that the user selects in the planning software is the maximum allowed modulation factor that is available to the optimization software. Often, the

final treatment plan has smaller modulation factors. The final modulation factor, called the “actual MF,” is listed on the plan printout. A higher modulation factor may improve the plan quality and higher MFs are typically used for more complex target volumes. Typically, user selected modulation factors range from 1.5 to 3.5.

Treatment slice width, pitch, and modulation factor play important roles in the quality of the plan as well as the treatment time. The selection of a larger treatment slice width reduces the treatment time but may reduce dose conformity in the superior-inferior dimension. The selection of a smaller pitch value does not necessarily increase the treatment time since the gantry rotation speed is variable and can range from 15–60 s per rotation. Starting with the TomoTherapy software release 4.0, the maximum gantry speed will change from 15 to 12 s per rotation. A smaller pitch allows a faster gantry speed since a given voxel will experience more gantry rotations and less dose per rotation needs to be delivered. However, if the gantry is rotating at its maximum speed, a smaller pitch may increase the treatment time because the leaves are then forced to stay closed for a longer fraction of time. If the gantry rotation speed is reported to be at its maximum the user may wish to increase the pitch to prevent this loss of treatment efficiency.³⁵ A reduction of the modulation factor typically increases the gantry rotation speed and reduces the treatment time. However, this is only true if the gantry is not already rotating at its fastest speed. Similarly, an increase in modulation factor may not necessarily decrease the gantry rotation speed.

Once the plan parameters are selected, the dose distribution for each beamlet that passes through the target is calculated. The number of beamlets for a given plan depends on the slice width, pitch values, target volume, and shape. The beamlet calculation can be batched. The dose calculation engine uses the convolution/superposition method.³⁶ Once this beamlet calculation step is completed, the optimization process begins. A least square optimization method is used to optimize the objective function.³³

Unlike conventional linear accelerators, helical tomotherapy treatments are terminated by time. The treatment planning system assumes a constant dose rate (about 850 cGy/min at a depth of 1.5 cm with an SSD of 85 cm and a $5 \times 40 \text{ cm}^2$ static field). During the final dose computation and creation of the leaf control sinograms, the helical tomotherapy planning system uses measured MLC leaf latency data to determine the final programmed leaf opening times. At this final dose calculation, leaf opening times shorter than 20 ms are deleted from the control sinogram since they are too small in relationship to the actual leaf transition times. The final dose calculation reflects these changes and therefore it is possible to observe slight changes between the planned and final DVHs. The plan approval should be based on this final dose distribution.

Upon import into the helical tomotherapy system, the planning CT data set is typically down-sampled to an axial grid of 256×256 voxels. However, if the imported CT data set is extraordinary large, the user can choose to down-sample the CT data set to 128×128 voxels. The CT slice

width is maintained. “Coarse,” “normal,” and “fine” calculation grids are available in the helical tomotherapy planning system. Dose calculation in fine mode results in a dose calculation grid that equals the imported CT data grid; normal and coarse modes result in dose calculations for every 2×2 or 4×4 imported CT voxels in the axial image, respectively. A coarser calculation grid may compromise the accuracy of dose volume histograms, particularly when the structures are small. Clinical significance of this may depend on the importance of the critical structures, their location relative to the PTV volumes, and the dose gradients within the structure. A finer dose calculation grid requires more computation time. The dose computation time scales directly with the number of voxels.

A collection of tomotherapy-specific treatment planning tips is located in Appendix F.

VII.B. Periodic quality assurance

Periodic geometric and dosimetric validation tests are recommended. Due to the system’s complexity and uniqueness, independent dose calculation is nontrivial. The development of an independent dose calculation algorithm was recently explored by Gibbons *et al.*,³⁷ however, more commonly a dosimetric verification of the patient plan by measurement is performed.

VII.B.1. Geometric validation tests

TG-53 supplies guidance in regard to the image data import.³² CT parameters such as pixel dimension and slice thickness should transfer correctly to the TPS. The image orientation (left-right, head-foot) must be correct. Text information about the patient orientation such as head-first-supine must transfer correctly from the CT scanner to the TPS. Image grayscale values must also transfer correctly. Most TomoTherapy users import the CT data into a third-party TPS system for contouring. The contours and CT data are then sent from this third-party system to the TomoTherapy TPS. Any test on the CT import should use the same route. CT scans of well defined phantoms, e.g., the vendor supplied cylindrical Virtual Water™ phantom, can be imported via the typical clinical workflow to the TPS to verify CT orientation, dimensions, grayscale values, and attached text data. The phantom dimension in the tomotherapy TPS should be within a kVCT voxel dimension of the physical dimension of the phantom. The accompanying structure set must transfer correctly from the third-party planning system to the TomoTherapy planning system. The location, dimension, and orientation of the structure set in relation to the kVCT images should be correct.

The geometric validation tests should be performed annually and after updates on any system that is involved in the CT acquisition and transfer process.

It should be kept in mind that the helical tomotherapy system down-samples the planning CT data set to 256×256 voxels. The associated structure set is not down-sampled upon import to the TomoTherapy system.

VII.B.2. Dosimetric validation tests

While the dosimetric commissioning tests contained in TG-53 may not directly apply to the testing of the tomotherapy system, the overall goal, i.e., testing of the dosimetric accuracy, applies to the tomotherapy TPS. Phantom based end-to-end tests are well suited to perform dosimetric verification tests. In these tests, phantoms are treated like patients in the sense that they undergo the same imaging, contouring, planning, and plan delivery steps that patients would undergo.

For dosimetric verifications, phantoms must be used that allow the measurement of dose with calibrated ionization chambers. Please refer to Sec. V B 5 for a discussion of acceptable ion chambers and specific correction factors for rotational tomotherapy deliveries. The standard cylindrical Virtual Water™ test phantom that is supplied with each treatment unit is well suited for the dosimetric verification tests. In this phantom, thimble ionization chambers (the vendor supplied cylindrical Virtual Water™ phantom is designed to accommodate A1SL chambers that are commercially available from Standard Imaging Inc., of Middleton, WI) can be placed at multiple locations.

Plans designed to treat on-axis and off-axis cylindrical targets should be generated for each commissioned slice width. A normal dose calculation grid should be used for the dose calculation. Targets should have volumes that are significantly larger than the sensitive volume of the ionization chamber. At a minimum, two targets, one centered at the center of rotation as indicated by the stationary green lasers and one off-axis target, should be treated in one plan or two separate plans. The AAPM Task Group Report 119 on “IMRT commissioning: Multiple institution planning and dosimetry comparisons” has produced a set of test plans and the physicist may want to review this document for guidance.³⁸

There is no fundamental difference between the plans generated for the dosimetric verification and the plan generated for the pCSR-field calibration in Sec. V B 5 b and for the largest commissioned slice width the same plan can be used for both purposes.

Multiple point dose measurements should be performed in high and low dose regions. Dose gradient regions can be verified with multiple point dose measurements or planar dosimeters such as film or detector arrays. The acceptability criteria for dosimetric verifications are debated in the community. TG-53 lists dosimetric criteria but clarifies that these

criteria are “collective expectation” values rather than requirements.³² For 3D TPS systems, Van Dyk³⁹ listed acceptability criteria of 3% of the reference dose for high and low dose regions with low dose gradients and a 3 mm spatial agreement in high dose gradient regions. These values do not apply to areas of dose build-up or build-down. The recent TG-119 report provides helpful benchmark data that can be consulted for comparison when commissioning IMRT systems. In the TG-119 Report, a 3%/3mm gamma criteria were used for the evaluation of planar dose distributions.

Acceptability criteria for IMRT plans are currently formulated by the International Commission on Radiation Units and Measurements (ICRU) and will be published in a forthcoming ICRU report. Until the publication of this report, the Task Group recommends the use of 3%/3mm criteria for the dosimetric evaluation of the tomotherapy system. For the generated tomotherapy plans, point dose measurements should agree with the calculated dose to within 3% of the prescription dose or satisfy a 3 mm distance to agreement criterion. To evaluate the dosimetric pass rates the benchmark data provided by TG-119 can be consulted.

Ideally, a set of non-homogeneous phantoms should be available for testing prior to the start of patient treatment. Furthermore the verification of the calculated dose in regions other than unit density tissue is desirable. Several commercial phantoms exist for this purpose. However, in-house phantoms can be assembled to serve this purpose.

The dosimetric verification of the TPS should be performed after TPS software maintenance and annually.

VII.B.3. Clinical treatment plan QA

Once the planning system is used clinically each patient plan needs to be double checked for accuracy. Since no commercial solution for independent recalculation of helical tomotherapy dose distribution exists, current practice is to calculate each individual plan in a phantom geometry such that it can be dosimetrically verified by measurement. This current practice may evolve over time and alternative test procedures may be developed to replace the current one.

In the helical tomotherapy literature, dose recalculation of the treatment plan into a phantom geometry is called a DQA procedure. Tools to facilitate the DQA planning and analysis are integrated in the TomoTherapy planning software package. The DQA process requires that a CT scan of the phantom is imported into the tomotherapy planning system. After the calculation of the dose distribution in the phantom, point

TABLE II. Recommendations and tolerance limits for daily quality assurance procedures.

Daily test	Purpose	Tolerance limit	Report section
Output—Rotational or static	Consistency	3%	V.B.2.d
Image/laser coordinate coincidence	Accuracy	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.b
Image registration/alignment	Accuracy	1 mm	VI.B.1.c
Red laser initialization	red=green laser	1.5–1 mm (non-SRS/SBRT-SRS/SBRT)	V.B.4.b

doses and planar dose distributions can be compared to measurements. A planar dose distribution can be exported from the tomotherapy system and this feature can be used for comparison with diode or ionization chamber arrays. Van Esch *et al.*⁴⁰ reported the use of an ionization chamber array for the dosimetric verification of tomotherapy plans. The use of a device that incorporates two orthogonal diode arrays for tomotherapy IMRT QA is reported by Guerts *et al.*⁴¹

It should be understood that the DQA plan verification does not test all aspects of the calculated treatment plan in the patient anatomy. For example, an incorrect mass density table could be applied during the patient plan calculation. This error will not be detected in a DQA procedure. Similarly, the correct replacement of the CT couch with the tomotherapy couch in the patient plan is not tested in the DQA process.

Most users currently use the vendor supplied cylindrical Virtual WaterTM phantom for the patient plan verification and this is an acceptable verification procedure. In this process, a single point dose is measured with an ionization chamber and a single 2D dose distribution is measured with film. The measured ionization chamber points should be within 3% of the dose calculated with the TPS. If the measured ionization chamber point differs by more than 3% but less than 5%, it is recommended that the physicist investigate the discrepancy. At the discretion of the physicist and attending physician,

treatment can be continued. If the discrepancy exceeds 5%, a thorough investigation is recommended prior to patient treatment. During the process of generating a DQA plan, the requested phantom position can be changed in the TPS and care should be taken to position the phantom such that the ionization chamber point is in a high dose and low dose gradient region. An ionization chamber measurement in such a region minimizes the problems associated with dose variations over the effective volume of the chamber. However, even larger low gradient dose regions are produced by the superposition of smaller fields and the user should be aware of uncertainties associated with small field dosimetry such as the potential lack of electronic equilibrium.

Analysis of the film plane is more revealing if the expected dose map contains both high and low dose regions. For planar dosimetry, a rectangle that encompasses the area within 5 mm from the phantom edge should be analyzed for a gamma coefficient.⁴² It is the experience of the TG-148 Task Group that tomotherapy DQA plans that are calculated on a normal dose grid have typical gamma pass rate of at least 90% when a 3% dose difference/3 mm distance to agreement gamma criterion is used. The 3% dose difference is based on the prescription dose. If film dosimetry is used for the gamma analysis, the film dose can be scaled to match the ionization chamber reading in the target dose. While the TPS software facilitates the calculation of a gamma index, it

TABLE III. Recommendations and tolerance limits for monthly quality assurance procedures.

Monthly test	Purpose	Tolerance limit	Report section
Beam parameters			
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Monitor chamber constancy	Constancy between monitor chambers	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference in field core	V.B.2.b
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
Alignment and Misc.			
Interrupted procedure	Agreement with uninterrupted Proc.	3%	V.B.4.a
Red laser movement	Correct movement	1 mm	V.B.4.b
Treatment couch	Digital readout versus actual movement	1 mm	V.B.4.c
Treatment couch	Level	0.5°	V.B.4.c
Treatment couch	Longitudinal motion alignment	1 mm	V.B.4.c
Treatment couch	Sag	5 mm	V.B.4.c
MVCT			
Geometric distortions	Dimension, orientation	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.a
Noise	Monitor image quality	Consistency with baseline	VI.B.2.a
Uniformity	Monitor image quality	Consistency with baseline	VI.B.2.b
Spatial resolution	Monitor image quality	1.6 mm object	VI.B.2.c
Contrast	Monitor image quality	Consistency with baseline	VI.B.2.d
<i>(if MVCT is used for dose calc.)</i>			
Uniformity	Monitor image quality	25 HU	VI.B.2.b
HU (water test plug)	Monitor HU accuracy	within ±HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within ±HU 50 of baseline	VI.B.2.e

TABLE IV. Recommendations and tolerance limits for quarterly quality assurance procedures.

Quarterly test	Purpose	Tolerance limit	Report section
Synchronicity			
Gantry angle	Correct and consistent	1°	V.B.3.a
Couch speed uniformity	Uniform	2% dose nonuniformity	V.B.3.b
Couch translation per gantry rotation	Synchrony	1 mm per 5 cm	V.B.3.c
MVCT			
Dose	Monitor image dose	Consistency with baseline	VI.B.3

does not currently allow the selection of a region of interest for analysis. Hence, the evaluation of the pass criteria requires export and analysis of the measured and calculated dose distributions with third-party analysis programs. At the discretion of the on-site physicist(s), a visual evaluation of the calculated gamma distribution may suffice.

If DQA results are outside the tolerance level, the clinical physicist needs to investigate. Initially, the phantom setup should be verified along with the correct extraction of the calculated point dose from the TPS. It should also be investigated if the ionization chamber measurement is in or near a high-gradient region. While this scenario should be avoided,

TABLE V. Recommendations and tolerance limits for annual quality assurance procedures.

Annual test	Purpose	Tolerance limit	Report section
Mechanical alignments			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
y-jaw/gantry rotation plane alignment	y-jaw alignment with axis of rotation	0.5°	V.B.1.d
Treatment beam field centering	Common center	0.5 mm at iso	V.B.1.e
MLC lateral offset	MLC alignment with center of rotation	1.5 mm at iso	V.B.1.f
MLC twist	Alignment with beam plane	0.5°	V.B.1.f
Beam parameters			
Beam quality (each slice width)	Agreement with model	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile (each slice width)	Agreement with model	1% average difference in field core	V.B.2.b
Longitudinal profiles (each slice width)	Agreement with model	1% of slice width at FWHM	V.B.2.c
TG-51 calibration	Calibration	1%	V.B.5
Misc.			
Axial green laser (distance and twist)	Nominal distance to iso	1 mm/0.3°	V.B.4.b
Sagittal/coronal green laser	Alignment with axis of rotation	±1 mm	V.B.4.b
MVCT			
Imaging/treatment/laser coordinate coincidence	accurate location of dose	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.b
Treatment planning system			
<i>CT data import</i>			
Dimension of object in TPS	Agreement with physical dimension	1 kVCT voxel	IV.B.2
CT voxel dimensions	Correct transfer	Pass/fail	IV.B.2
CT orientation	Correct transfer	Pass/fail	IV.B.2
CT gray scale values	Correct transfer	Pass/fail	IV.B.2
Associated text info	Correct transfer	Pass/fail	IV.B.2
<i>Structure set import</i>			
Dimension of structure	Agreement with contouring software	1 kVCT voxel	IV.B.2
Location of structure	Agreement with contouring software	Pass/fail	IV.B.2
Orientation of structure	Agreement with contouring software	Pass/fail	IV.B.2
<i>Dosimetric verification</i>			
Point dose in low gradient area	Agreement with TPS	Within 3%	IV.B.3
Point dose in high gradient	Agreement with TPS	3%/3 mm	IV.B.3

TABLE VI. Recommendations and tolerance limits for quality assurance procedures post major component replacement.

After major component replacement test	Purpose	Tolerance limit	Report section
Magnetron/SSM			
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference in field core	V.B.2.b
Longitudinal profile	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
<i>(if MVCT is used for dose calc.)</i>			
HU (water test plug)	Monitor HU accuracy	within \pm HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within \pm HU 50 of baseline	VI.B.2.e
Linac/target			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference	V.B.2.b
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
<i>(if MVCT is used for dose calc.)</i>			
HU (water test plug)	Monitor HU accuracy	within \pm HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within \pm HU 50 of baseline	VI.B.2.e
y-jaw (actuators/encoders)			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
y-jaw/gantry rotation plane alignment	y-jaw alignment with axis of rotation	0.5°	V.B.1.d
Treatment beam field centering	Common center	0.5 mm at iso	V.B.1.e
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
MLC			
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
MLC lateral offset	MLC alignment with center of rotation	1.5 mm at iso	V.B.1.f
MLC twist	Alignment with beam plane	0.5°	V.B.1.f
DQA/phantom plan	Agreement with TPS	3%	VII.B.5

a small target volume may result in the chamber being placed in or near such a high gradient. If the target is considerably off-axis and the plan was generated with a large pitch value or slice width, the measurement point may be in an inhomogeneous area due to the thread effect. Volume averaging and distance to agreement techniques can be used judiciously when DQA discrepancies are investigated.

A drift in the machine output can lead to unacceptable DQA results. A repeat of a previous or a standard DQA plan can be useful for this analysis. An analysis of the daily out-

put checks could also be helpful. An adjustment of the machine output may be required. It is recommended that the physicist has a standard IMRT plan available for each treatment slice width. Phantom plans or previous DQA plans for representative clinical scenarios can be used for this purpose. These plans would have similarities in gantry speed, leaf opening times, etc., and a repeat of these plans may help to determine if the measured dose discrepancy is specific to a plan or uniform for all plans.

The use of short leaf opening times has been associated

with possible DQA discrepancies.³⁵ Shorter leaf opening times occur if plans use low pitch values. Planning with a higher pitch value (around 0.287 for a prescription dose of 2 Gy) will reduce this delivery uncertainty.

VII.C. MVCT-based treatment planning

Metallic implants cause fewer image artifacts in MVCT images compared to standard kVCT images. MVCT-based treatment planning can hence be of advantage for patients that have artificial implants and in whom regular kVCT artifacts hinder treatment planning.⁴³

If MVCT images are used for treatment planning purposes, it is recommended that an up-to-date MVCT to mass density table be measured immediately before or after the patient planning image is acquired. This recommendation is based on the observation that the MVCT Hounsfield numbers are susceptible to changes in the imaging beam that are secondary to target wear and other factors that are still under investigation. It is also recommended to obtain a scan of the DQA phantom at the same time. This latter scan should be used in the DQA process of the MVCT-based treatment plan. The measured MVCT density table should be applied to the patient and DQA phantom MVCT images. Furthermore, it is recommended to contour areas of high density such as metallic hip implants and to prohibit beam entrance through these areas. This is done to avoid uncertainties in the beam attenuation calculations associated with high-density materials. These uncertainties have two sources: (1) The fluence attenuation tables have data up to a maximum density of 4 g/cm³ and for higher densities the TPS defaults to using this maximum density and (2) the IVDT tables for MVCT images will need to be extended to high-density materials.

VIII. SUMMARY AND RECOMMENDATIONS

In this chapter, the QA aspects discussed in the previous chapters are summarized and arranged according to their recommended frequencies. Recommendations on what to QA after machine service work are also listed in the chapter for several service scenarios.

VIII.A. Daily

On a daily basis, the beam output should be monitored. The output consistency should be measured under static and/or rotational conditions. If the static output is monitored on a daily basis, the rotational output should be monitored on a weekly basis and vice versa. The correct initialization of the laser system should be checked. After the image registration, the automatic couch and red laser adjustment should be tested daily. It should be checked visually that the MVCT quality is consistent with that accepted at time of commissioning and that there are no gross artifacts in the image. It should be checked that the image registration process is operating consistently. An example procedure that combines several tests in one procedure is outlined in Appendix D. Table II summarizes the recommendations for daily QA.

Standard safety tests are not included in this list. They should be performed per recommendations detailed in TG-142.³

VIII.B. Monthly

Monthly tests cover beam parameter consistency tests, MVCT tests and miscellaneous aspects. Table III summarizes the recommended tests and their tolerance limits. Standard safety tests such as interlock testing are not covered in the table but should be performed per recommendations detailed in TG-142.³

VIII.C. Quarterly

On a quarterly basis, the gantry angle and the uniformity of the couch movement should be tested. The synchrony between couch translations and gantry rotations should also be tested at this interval. The MVCT dosimetry should be done quarterly. Table IV summarizes the recommended tests and their tolerance limits.

VIII.D. Annual

Annual tests contain mechanical alignment, beam parameters, and miscellaneous test items. MVCT registration and an end-to-end test of the registration process should be performed as well as several treatment planning system tests. Table V summarizes the recommended tests and their tolerance limits.

VIII.E. Major component replacement

The replacement of major components necessitates QA tests. These tests obviously depend on the particular service issues. Recommended post service tests are discussed for several scenarios. Table VI summarizes the recommended QA test for four service scenarios.

Magnetron/solid state modulator (SSM): A replacement of the magnetron or SSM can change beam parameters such as output and beam energy. It is recommended that the user tests beam output, energy, and longitudinal as well as lateral profiles. The beam parameters only need to be tested for one slice width. It is the intent of these tests to check that the parameters are consistent with the baseline values. A repeat of the monthly QA procedures of these beam parameters should be sufficient to establish consistency with nominal values. If MVCT images are used for dose calculations, the monthly QA test for HU accuracy should be performed. Post service, a DQA or phantom plan should be checked and verified for agreement with calculations. This last step also forces the user to exercise all functions (imaging registration and treatment) that are used for regular treatments. This tests that the system is fully operational.

Linac or target: A replacement of the target requires a movement of the Linac during the process. The source alignment (Sects. V B 1 a, V B 1 b, and V B 1 c) needs to be tested post-target/linac replacement. In addition, all tests that are recommended post magnetron/SSM replacement should be performed post-target/linac alignment.

Y-jaw: Work on the y-jaws, actuators, or encoder necessitates a verification of the y-jaw alignment and longitudinal beam profiles. The jaw centering, divergence, and alignment with the rotation plane should be checked in addition to the treatment field centering. Longitudinal beam profiles should be collected and checked for agreement with the reference beam data. In addition to a beam output check, DQA or phantom plans should be checked for each commissioned slice width and verified for agreement with calculations.

MLC: Replacement of the MLC requires MLC alignment tests to be performed. The MLC lateral offset as well as the MLC twist should be tested. The vendor includes MLC-

specific leaf latency data in the treatment planning system. It is not possible to adjust the leaf latency for a given MLC. Instead, the vendor will measure and update these data in the TPS after a MLC replacement. These data are used at the time of "Final Dose" calculation and therefore are only applied to plans that are generated subsequently. Existing plans are not altered. It is therefore recommended to repeat several DQA plans for existing patients to ensure that these are within acceptable tolerance. Plans with short leaf opening times may be more sensitive and should be included in the group of plans that is selected for this test. If DQA plans are out of tolerance the user may have to replan selected cases.

APPENDIX A: WORKSHEET A: HELICAL TOMOTHERAPY PHOTON BEAM CALIBRATION**1. Site data**

Institution:

Physicist:

Date:

Accelerator:

Model & serial number:

2. Instrumentation**a. Chamber model:**

Serial number:

Cavity inner radius (r_{cav}):

cm

Waterproof: yes no If no, is waterproofing \leq 1 mm PMMA or thin latex?: yes no **b. Electrometer model:**

Serial number:

i. P_{elec} , electrom. corr. factor:

C/C or C/rdg

c. Calibration factor N_{D,W,Q_o} :

Gy/C (or Gy/rdg)

Date of report (not to exceed 2 years):

3. Measurement Conditions (choose step a. or step b.)**a. Static Beam Output** (5 cm x 10 cm, measurement at 10 cm depth water equivalent)i. Distance (SSD or SAD): _____ cm SSD or SAD ii. Field size: _____ cm^2 on surface (SSD setup): at detector (SAD setup):

iii. Irradiation time: _____ min

b. Rotational Beam Output (8 cm diameter x 10 cm long homogeneous dose volume
within a 30 cm diameter water equivalent phantom)

i. Axial collimation: _____ cm

4. Beam Quality

Measure beam quality specifier %dd(10)_{x(HT ref)} [FS=5 cm × 10 cm, 85 cm SSD, % depth-dose at 10 cm depth for curve shifted upstream by $0.6r_{cav}$]

Field size 5 cm x 10 cm on surface, SSD = 85 cm: yes no

a. %dd(10)_{x(HT ref)} : _____

Using the following equation or Figure 19 to determine %dd(10)_{x(HT TG-51)} :

$$\begin{aligned} \%dd(10)_{x[HT\ TG-51]} &= 1.35805 \cdot (\%dd_{(10)x[HT\ ref]})^3 \\ &- 244.493 \cdot (\%dd_{(10)x[HT\ ref]})^2 \\ &+ 14672.98 \cdot \%dd_{(10)x[HT\ ref]} \\ &- 293479.4 \end{aligned}$$

b. %dd(10)_{x(HT TG-51)}: _____

5. Determination of $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$

Chamber model used to get $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$: _____

a. $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$ [Table 1]: _____

6. Temperature/pressure Correction

a. Temperature: _____ °C

b. Pressure: _____ kPa $\left[= \text{mmHg} \frac{101.33}{760} \right]$

c. P_{TP} : _____ $\left[P_{TP} = \left(\frac{273.2 + 6a}{295.2} \right) \left(\frac{101.33}{6b} \right) \right]$

7. Polarity correction

M_{raw}^+ : _____ C or rdg

M_{raw}^- : _____ C or rdg

a. M_{raw} (for polarity of calibration): _____ C or rdg

b. P_{pol} : _____ $\left[P_{pol} = \left| \frac{(M_{raw}^+ - M_{raw}^-)}{2M_{raw}} \right| \right]$

8. P_{ion} measurementsOperating voltage = V_H : _____ VLower voltage V_L : _____ V M_{raw}^H : _____ C or rdg M_{raw}^L : _____ C or rdg

a. $P_{ion}(V_H)$: _____

$$P_{ion}(V_H) = \left(1 - \frac{V_H}{V_L} \right) \left/ \left(\frac{M_{raw}^H}{M_{raw}^L} - \frac{V_H}{V_L} \right) \right.$$

If $P_{ion} > 1.05$, another ion chamber should be used.**9. Corrected ion. ch. rdg. M for msr or pcsr field:**

$$M_{corr} = P_{ion} P_{TP} P_{elec} P_{Pol} M_{raw} = [8a \cdot 6c \cdot 2b \cdot i \cdot 7b \cdot 7a] = _____$$

10. Dose to water at 10 cm depth for Static Beam Output:

a. $D_{w,Q_{msr}}^{f_{msr}} = M_{Q_{msr}}^{f_{msr}} \cdot N_{D,w,Q_0} \cdot [k_{Q,Q_0}^{f_{msr}, f_{ref}}] = [9 \cdot 2c \cdot 5a] = _____$ Gy

b. Dose/ min at 10 cm depth: _____ Gy/min [10a/3a.iii]

c. Clinical % $dd(10)$ for SSD setup / 100: _____

or clinical TMR(10) for SAD setup: _____

Dose / min at d_{max} : _____ Gy/min [10b/10c]**11. Correction factor between conventional reference field and plan-case specific reference field**

$$k_{Q_{pcsr}, Q_{msr}}^{f_{pcsr}, f_{msr}} : 1.003$$

12. Dose to pcsr field for Rotational Beam Output:

$$D_{w,Q_{pcsr}}^{f_{pcsr}} = M_{Q_{pcsr}}^{f_{pcsr}} \cdot N_{D,w,Q_0} \cdot [k_{Q,Q_0}^{f_{msr}, f_{ref}}] \cdot k_{Q_{pcsr}, Q_{msr}}^{f_{pcsr}, f_{msr}} = [9 \cdot 2c \cdot 5a \cdot 11] = _____$$
 Gy

APPENDIX B: NOTE ON CONTROL XML FILES AND CONTROL SINOGRAMS

Typically, the machine receives operating instructions via XML files that are generated at the end of the treatment planning process. To pass instructions to the machine independently of the treatment planning system requires that the user generate an XML file. Tools to generate XML files are included in the operator station software. These files contain, among others, instructions on gantry position, table movements, and MLC opening patterns. The vendor supplies a number of XML files and the associated binary MLC control files (control sinograms) that can be used to run some of the procedures detailed in this report. If the user wants to generate their own XML files, it is recommended to select an existing XML file and modify it according to the user's intentions. These files can be viewed, modified, and saved using the operator station software. Details of how to develop XML files can be found in the TomoTherapy documentation (Calibration Data Tool Guide, Version 3.X).

Embedded in the XML file is a reference to a binary file referred to as the control sinogram which controls the timing of the binary MLC leaves during treatment delivery. The control sinogram is a binary file with 64 columns. Each column contains a value ranging from 0.0 to 1.0. These values are normalized opening times for each leaf. Leaf opening times must be supplied for each leaf and projection. The sinogram files must therefore have a minimum number of rows that is equal to the number of delivered projections. The duration of each projection is defined elsewhere in the XML file.

APPENDIX C: RADIATION SAFETY

IMRT techniques have raised unique room-shielding concerns that are mainly due to increased workloads. In addition to room shielding, leakage concerns have been raised for some systems since the increased workload may affect the whole body doses that the patient receives.⁴⁴

Shielding and leakage concerns specific to helical tomotherapy have been addressed in the literature.⁴⁵⁻⁴⁹ The continuous rotation of the gantry complicates the traditional usage factor that accounts for the particular beam direction employed. Additionally, due to the exclusive IMRT treatment mode, the workload is significantly larger than with traditional accelerators. Workloads of 10^6 MU per week are often assumed for shielding calculations, which is about an order of magnitude greater than the workload for non-IMRT accelerators.⁴⁶ However, since helical tomotherapy was designed exclusively as an IMRT machine, extra shielding was designed into the accelerator head. This extra shielding is assembled around the linac to (i) protect the patient from unwanted exposure and to (ii) reduce linac leakage. In addition, a beam stop was added to the machine that provides over two orders of magnitude of primary beam attenuation. Continuous gantry rotation also serves to decrease the contribution of primary beam exposure since it limits the time any point is exposed to the primary beam. There is actually more exposure due to backscattered leakage radiation than

due to direct primary radiation at 2 m from the isocenter. Due to differences in energy between primary and leakage radiation and different effective source positions, that ratio may change as a function of shielding wall distance and thickness. A final but significant advantage for room-shielding designs is that helical tomotherapy units only have a single nominal 6 MV beam energy.

Patient scatter is approximately the same as with all external beam radiation therapy since the patient integral dose is approximately the same regardless of the modality. The effect of the unique tomotherapy design is that backscattered leakage radiation dominates shielding concerns. Tomotherapy provides a site-planning guide which lists a polar plot of leakage levels versus distance and angle from the isocenter to assist in shielding design.

In general, helical tomotherapy units can safely be installed in most bunkers with standard-density concrete walls 3.5 to 4.0 ft thick. Of course, each proposed bunker must be extensively analyzed. Furthermore, goal exposure levels do vary according to the site specifics. To verify shielding requirements post install, access to an integrating survey meter is helpful.

Exposure due to scattered radiation at the door is similar to that of conventional machines. Radiation at the door consists mostly of scattered leakage radiation. As such, it is of much lower energy. McGinley⁵⁰ has calculated such scattered photon radiation to be less than 0.3 MeV. Therefore, a 1/4 in. lead liner in a wood door is usually more than sufficient for shielding. Exact entrance exposure is dependent on maze length and width and overall room size and geometry.

TomoTherapy, Inc. will soon offer a new product, "TomoDirect." This will allow the gantry to operate in a static gantry mode while the couch translates and MLC leaves modulate. This will decrease beam-on time for some treatments more suitable for nonrotating delivery. It is not yet known how TomoDirect will affect shielding requirements. Most likely, required shielding will only decrease because TomoDirect was designed to decrease beam-on time.

The unique features of the tomotherapy unit may conflict with certain local regulations such as regulations on field flatness and symmetry. Local regulations should be interrogated for possible conflicts. Regulatory exemptions may have to be applied for.

APPENDIX D: EXAMPLE OF DAILY TEST PROCEDURES

With the gantry at a static position the beam output can be tested. The rotational output (or integral dose) can be tested with a phantom patient plan. This procedure is generated in the TPS. During the plan generation, the movable red lasers can be intentionally offset from the alignment marks. The offsets should be similar to what is typically encountered in the clinic. A daily MVCT scan, registration, and alignment of this phantom then serves to test the laser functionality, image registration, and automatic couch alignment procedure. The final phantom position can be checked against the green laser system by marking the expected green laser projection on the

phantom. If the phantom is always placed in the same location on the couch (e.g., phantom position can be marked on couch), the consistency of the initial table readout is also tested. After alignment, the delivery of the correct dose can be verified, i.e., the rotational output can be tested. All tests can be done with the vendor supplied cylindrical Virtual WaterTM phantom. However, some users have designed phantoms specifically for daily QA of TomoTherapy units.⁷

APPENDIX E: PATIENT ARCHIVES

The user can generate an archive of a patient plan at any time using the patient archiving tool integrated in the planning station or operator station software. This patient archive contains a wealth of information: Planning parameters, kVCT and MVCT images, planned MLC sinograms, recorded detector data sinograms, recorded monitor chamber signal, and more. Some of this information is stored in binary format in separate files that are part of the archive. Each patient archive contains an XML file that is labeled with the patient's name. This XML file contains numerical information (e.g., registration offsets) and provides the file names for the MVCT or detector sinogram files. The patient archive can then be searched for this file. A third-party XML viewer is recommended to view the XML file and third-party software, e.g., MATLAB (The MathWorks, Inc., Natick, MA), can be used to read, display, and analyze image or sinogram files. Detector data can also be extracted immediately after a procedure is completed using a tomotherapy quality assurance tool that is commercially available from the vendor.

APPENDIX F: TREATMENT PLANNING TIPS

Like other IMRT TPS, the helical tomotherapy planning system is driven by dose-based objectives, their associated penalties, and ROI-based weighting factors. For tumor or target volumes, minimum and maximum dose values and their respective penalties are used in addition to a DVH-based prescription point. Sensitive structure objectives are described by a maximum dose, a DVH-based constraint, and their respective penalties. However, it is important to recognize that in the helical tomotherapy TPS, the DVH-based prescription for one selected target structure is a hard constraint, which means that it is always met. The optimized treatment plan is scaled after each iteration to satisfy this DVH-based prescription dose.

The treatment planning system prompts the user to divide regions of interest into two groups: (i) Tumors and (ii) sensitive structures. If ROIs in the same group overlap, the voxels contained in the overlap region can only be assigned to one or the other structure for the purpose of plan optimization and dose volume histogram calculations. The overlap priority setting governs to which structure the voxel belongs. It is therefore possible that in the case of overlapping structures, the DVH statistics may not completely reflect the volume of interest. It is important that all involved parties understand this. However, in future software releases, the use

of overlap priorities may change and the user needs to be aware how these priority settings are used in their current software release.

There are two sets of lasers used in helical tomotherapy planning and delivery. Fixed green lasers define a virtual isocenter that is nominally 70 cm away from the gantry (treatment and imaging beam) isocenter. A movable red laser system is used for patient positioning. During the treatment planning process, the red lasers can be requested to point toward the patient's setup marks. The physical movement of the red lasers in the treatment room is restricted to a maximum distance of about 20 cm from the green laser system at isocenter. The exact value depends on the particular laser placement in the room and is site-specific. During treatment planning, it is possible to request larger movements of the red laser system. However, these requests result in a hardware error interrupt (i.e., a nondeliverable procedure) once these plans are selected for treatment. This scenario can be avoided if a smaller laser separation is selected. The selected distance should allow for possible further red laser movements after image registration. The axial laser settings are most susceptible to this issue and the position of the axial green laser with respect to the patient can be adjusted in the planning system to alleviate this problem.

During treatment the patient is moved in the longitudinal (i.e., y) direction through the rotating fan-beam plane. The fan beam is used for treatment as soon as the superior target edge enters the beam plane and the treatment is completed only after the inferior target edge leaves the beam plane. Consequently, an area equivalent to the longitudinal dimension of the fan beam is exposed superior and inferior to the target volume. It is recommended that the treatment planning CT volume extends superior and inferiorly beyond the target volume by a length sufficient to include any irradiated volume. Taking beam divergence into account this is typically satisfied if the CT volume extends by a distance larger than two treatment slice widths.

^{a)}Conflict of interest: Dr. Gustavo Olivera is an employee of TomoTherapy, Inc. and has a financial interest in TomoTherapy, Inc. Dr. Olivera served as an industry consultant to this task group. Dr. John Balog owns TomoTherapy stock. Dr. Katja Langen holds a research agreement with TomoTherapy, Inc.

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QA for helical tomotherapy: Report of the AAPM Task Group 148^{a)}

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Helical tomotherapy is a relatively new modality with integrated treatment planning and delivery hardware for radiation therapy treatments. In view of the uniqueness of the hardware design of the helical tomotherapy unit and its implications in routine quality assurance, the Therapy Physics Committee of the American Association of Physicists in Medicine commissioned Task Group 148 to review this modality and make recommendations for quality assurance related methodologies. The specific objectives of this Task Group are: (a) To discuss quality assurance techniques, frequencies, and tolerances and (b) discuss dosimetric verification techniques applicable to this unit. This report summarizes the findings of the Task Group and aims to provide the practicing clinical medical physicist with the insight into the technology that is necessary to establish an independent and comprehensive quality assurance program for a helical tomotherapy unit. The emphasis of the report is to describe the rationale for the proposed QA program and to provide example tests that can be performed, drawing from the collective experience of the task group members and the published literature. It is expected that as technology continues to evolve, so will the test procedures that may be used in the future to perform comprehensive quality assurance for helical tomotherapy units. © 2010 American Association of Physicists in Medicine. [DOI: 10.1118/1.3462971]

Key words: helical tomotherapy, quality assurance

We dedicate this task group report to the memory of Sam Jeswani. Sam was a great enthusiast of the tomotherapy technology and a tireless customer champion. Sam was the Director of Customer Relations at TomoTherapy, Inc. and a friend to many of us. Sam died during the terrorist attacks in Mumbai in November 2008.

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I. INTRODUCTION

Task Group Report 40 outlines a comprehensive quality assurance (QA) program in radiation oncology that applies to any external beam radiation therapy equipment.¹ A code of practice specific to radiotherapy accelerators is provided by Task Group Report 45.² Both reports are comprehensive in nature and supply fundamental guidelines to the medical physics community.

With the introduction of new technology into the field of radiation oncology, a need arises to provide guidelines that are tailored to these newer treatment modalities. The quality assurance of newer technologies is addressed in Task Group Report 142.³ While TG-142 provides the foundation for QA guidelines of newer technologies, there are several commercially available technologies that are sufficiently different from C-arm type accelerators and require a unique set of QA recommendations. One such technology is helical tomotherapy. It is therefore the intent of this Task Group Report to provide QA guidelines for helical tomotherapy that, while based on TG-142 guidelines, are specifically adapted to this technology.

There are a fair number of the TG-142 QA recommendations that can be directly applied to helical tomotherapy (e.g., output constancy). Whenever possible, guidelines from TG-142 and other relevant task group reports have been adopted in this report. However, several traditional QA recommendations are not applicable (e.g., light field tests) to helical tomotherapy. On the other hand, important aspects of the tomotherapy treatment modality are not tested with traditional QA tests. This Task Group Report provides a comprehensive set of recommendations on all aspects of the helical tomotherapy system that should be tested and the respective recommended test frequencies. References to existing Task Group Reports are made throughout this report where appropriate. General QA guidelines such as the establishment of a departmental comprehensive QA program, as described in TG-40 are not discussed in this report.

Helical tomotherapy is an intensity modulated radiation therapy (IMRT) delivery technique that was developed at the University of Wisconsin-Madison and was later commercialized by TomoTherapy, Inc. of Madison, Wisconsin.⁴ TomoTherapy, Inc. is the only vendor that markets and manufactures treatment units that use this delivery process. Procedures and recommendations discussed in this report are therefore specific to TomoTherapy's treatment units. TomoTherapy units combine IMRT treatment delivery and megavoltage computed tomography (MVCT) imaging capabilities. The units were introduced into clinical routine in 2003. Currently, more than 280 units have been installed worldwide. It is anticipated that additional Tomotherapy-specific treatment techniques will be developed in the future. Static gantry angle and dynamic y-jaw modes are currently under development. These techniques are not considered in this report. Quality assurance procedures specific to these techniques will have to be developed once those techniques become commercially available.

In this Task Group Report, an overview of the Tomo-

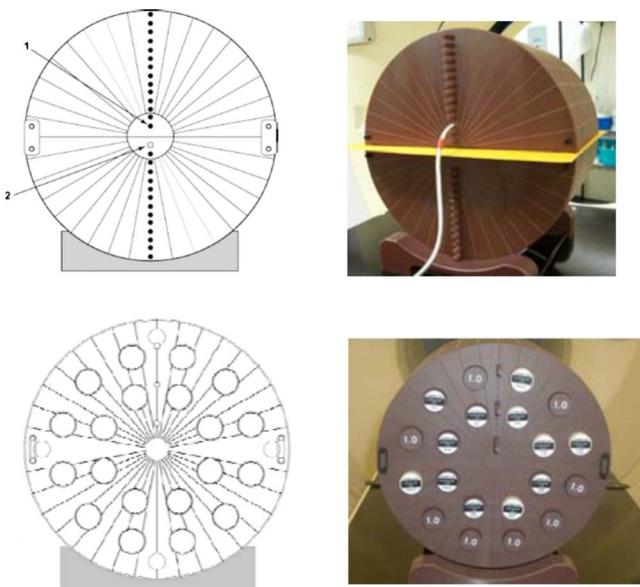


FIG. 1. Top row: Drawing and picture of a front view of the vendor supplied Virtual Water™ phantom. Each of the black circles (e.g., arrow 1) contains a Virtual Water™ plug that can be removed (arrow 2) for ion chamber insertion. The picture of the front view shows the phantom with a film inserted in the coronal plane and an ion chamber located above the film plane. Lower row: Drawing and picture of the back view of the phantom. There are 20 holes for insertion of test plugs. All holes can be filled with Virtual Water™ plugs or with a set of density calibration plugs as shown in the photo. Resolution and ion chamber plugs are also available.

Therapy system and its unique aspects is provided. Delivery, imaging, and treatment planning quality assurance are discussed in three chapters of this report. Quality assurance aspects are summarized according to their recommended frequency in Sec. VIII. The Appendix contains a collection of useful discussions that we hope will be of interest to the practicing medical physicist.

II. GLOSSARY AND ABBREVIATIONS

Virtual Water™ phantom: A cylindrical Virtual Water™ phantom that is supplied by TomoTherapy, Inc. Tomotherapy users commonly refer to this phantom as the “cheese” phantom. This phantom can be used for various quality assurance procedures. The phantom comes apart in two hemicylinders and has holes for placing ion chambers as well as plugs for CT density tests. It has a diameter of 30 cm and a length of 18 cm. Figure 1 shows diagrams and pictures of this phantom.

TomoTherapy coordinate system convention: TomoTherapy uses the following machine coordinate system naming convention: When the patient is positioned head-first-supine on the couch, +x points toward patient’s left side, +y points toward the patient’s head, and +z points toward the patient’s anterior side. This coordinate system is fixed, i.e., it does not rotate with the gantry. Figure 2 shows a picture of the treatment unit with the coordinate system superimposed.

DQA: Delivery quality assurance. This procedure is integrated in the TomoTherapy planning system. The patient plan is recalculated in a new CT anatomy. This new CT

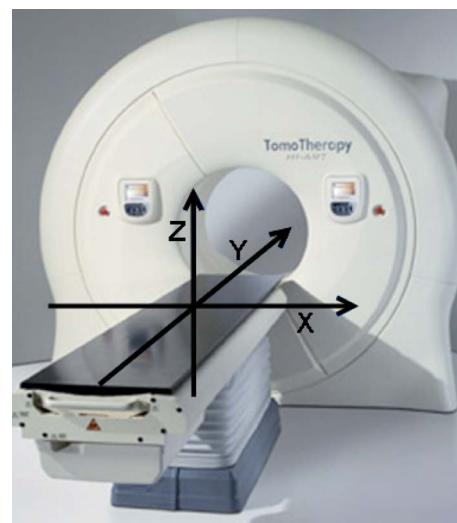


FIG. 2. The coordinate system used by TomoTherapy.

anatomy is typically a phantom. The DQA plan can then be delivered and the measured dose in the phantom can be compared to the calculated dose for quality assurance.

Field width/slice width: The longitudinal extent (i.e., in y-direction) of the fan beam is frequently referred to as field width in the literature. In this document, we follow the normal diagnostic radiology convention and use the term “slice width” to refer to the longitudinal extent of the treatment field.

Helical tomotherapy: The specific delivery technique.

Modulation factor: Longest leaf opening time in a plan divided by the average opening time of all nonzero leaf opening times.

MVCT: Megavoltage computed tomography.

Output: The TomoTherapy plans are based on time rather than on monitor units. The output of the machine is therefore measured in dose per unit time. Throughout this Task Group, the term output is used in this sense.

Pitch: The pitch is defined as the ratio of the couch travel per gantry rotation divided by the treatment slice width.

Sinogram: A binary file that contains data for each projection. There are several types of sinograms, such as imaging sinograms derived from detector data or control sinograms that contain fluence or MLC data for each projection or pulse.

Treatment plane: This plane marks the area that is defined by the center of the radiation field in the longitudinal (y) direction. In the x- and z-directions, this plane is parallel to the rotating fan beam.

TomoTherapy: Company that produces and markets a system that is based on a helical tomotherapy delivery technique.

Virtual isocenter: The treatment plane is located inside the bore and for convenient patient setup a virtual isocenter is defined 70 cm from the treatment isocenter in the negative y-direction. As with CT simulation, the virtual isocenter is located outside the bore and is localized via laser projections.

XML file: An XML file is generated at the end of the

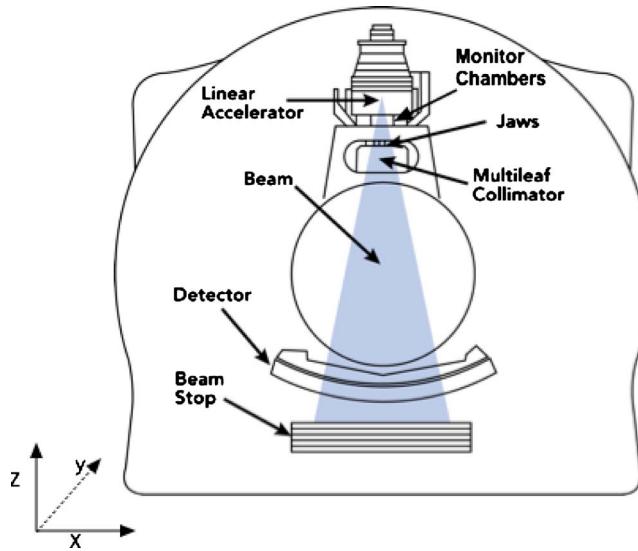


FIG. 3. Diagram of the main components of a TomoTherapy unit.

treatment planning process by the planning software and contains delivery instructions for the various machine components. To generate delivery instructions for QA tests, these files can also be generated independently of the treatment planning system (TPS). Tools to accomplish this are included in the operator station software.

III. SYSTEM OVERVIEW

The TomoTherapy system uses a unique geometry that resembles that of a helical CT scanner. The beam is generated by a 6 MV linear accelerator that is mounted on a slip ring gantry. The beam passes through a primary collimator and is further collimated into a fan-beam shape by an adjustable jaw. For further collimation, a binary multileaf collimator (MLC) is used. During treatment, the ring gantry continuously rotates while the patient is continuously translated through the rotating beam plane. The dose is thus delivered in a helical fashion. The ring gantry also contains a detector system that is mounted opposite the accelerator and is used to collect data for MVCT acquisition. A beam stopper is used to reduce room-shielding requirements. Figure 3 shows the general layout of the tomotherapy unit. The distance from the source to the center of rotation is 85 cm. The distance from the source to the detector is 145 cm. The Tomotherapy machine currently employs a standard detector array from a third generation CT scanner. This detector is not focused on the source but on a point that is proximal to the source. The diameter of the bore is 85 cm.

The fan beam has an extension of 40 cm in the lateral (x) direction at isocenter. In the superior-inferior, or y-direction, the beam is collimated by an adjustable jaw. In principle, this y-jaw can collimate the beam to any size that is smaller or equal to 5 cm but typically, only three distinct treatment slice widths are commissioned in the treatment planning system for clinical use. These fields have an extension of 1.0, 2.5, and 5.0 cm at isocenter in the y-direction. Figure 4 shows a

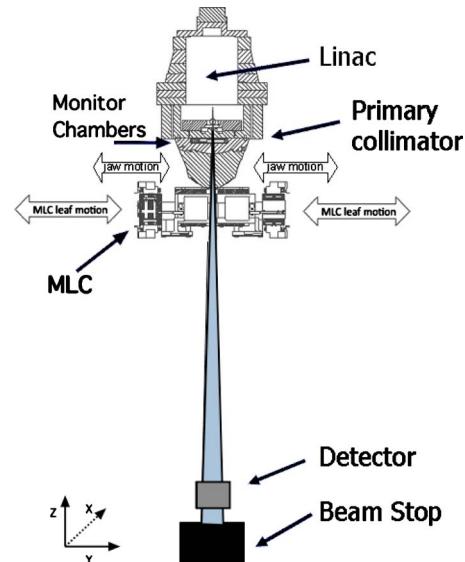


FIG. 4. Lateral view of the beam collimation components. The linac is at the 12 o'clock position in this drawing.

diagram of the lateral view of the linac and collimation system. The TomoTherapy units do not have field flattening filters.

A binary 64 leaf collimator is used to divide the fan beam in the x-direction (with the linac at 12 o'clock). The MLC leaves travel in the y-direction as indicated in Fig. 4. Each MLC leaf is either closed or open and intensity modulation is achieved via leaf specific opening times. The MLC is pneumatically driven. It consists of two separate MLC banks. If the leaves are closed, they move across the entire treatment slice width and stop at a position beyond the treatment field under the opposite jaw. This allows a rapid transitioning (about 20 ms) of the leaf. The leaves are made from 95% tungsten and are 10 cm thick. The MLC is only focused in the lateral direction. Figure 5 shows a diagram and a photo of the MLC. The diagram also shows the MLC leaf numbering convention. All even-numbered leaves belong to the rear (located in +Y direction from isocenter) MLC bank and the odd-numbered leaves belong to the front (located in -y direction from the isocenter) MLC bank.

A beamlet is defined as the part of the treatment beam that one MLC leaf covers. The y-dimension of each beamlet at the isocenter depends on the y-jaw setting; the size of each beamlet in the x-direction is 0.625 cm (40 cm divided by 64 leaves) at the isocenter.

For the purpose of treatment planning each rotation is divided into 51 sections. These are called projections. For each projection, each MLC leaf has a unique opening time. A leaf may be open for most of the duration of the projection (with adjustments for leaf transitioning times), for part of it, or may never open during a given projection. Figure 6 illustrates the use of the MLC system during a gantry rotation for a head and neck treatment. Only every third projection is shown.

The gantry rotates clockwise if viewed from the foot of the patient couch or in the view shown in Fig. 3. The gantry

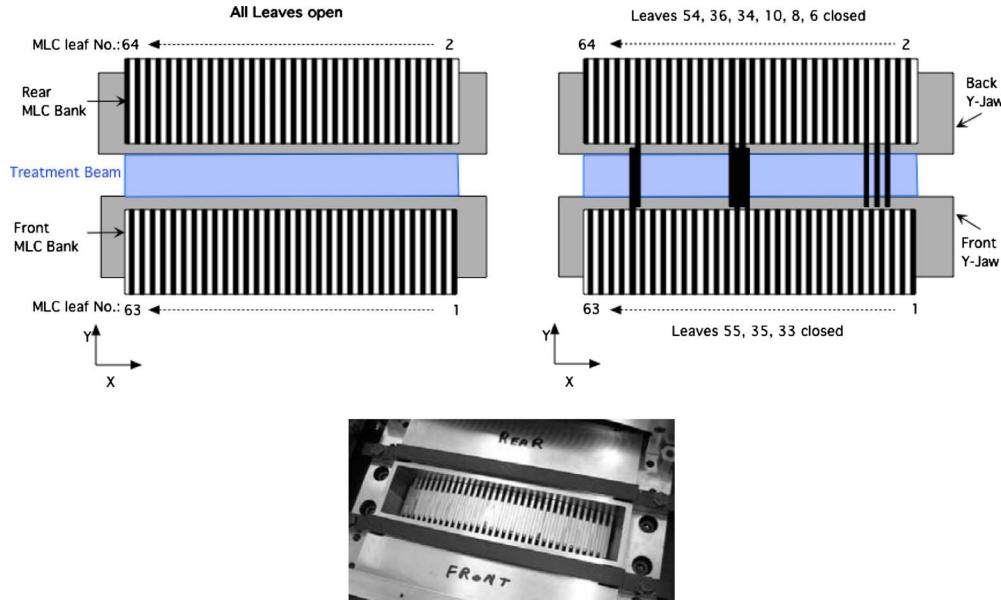


FIG. 5. A schematic drawing of the TomoTherapy MLC. The drawing on the left shows the MLC with all leaves open. The right hand drawing shows the MLC with several leaves closed. A photo of the MLC with all leaves closed is also shown. In the drawings, the MLC is in the 6 o'clock position and the observer looks down from the isocenter.

angle naming conventions conform to the International Electrotechnical Commission standard, i.e., the gantry angle is zero if the beam points downward in the vertical direction. The gantry angle increases from 0° to 359° with a clockwise rotation of the gantry.

Besides the machine hardware, two laser systems are installed in the room whose arrangement is different than what is typically found in a treatment room. The treatment plane is inside the bore and for patient setup purposes a virtual isocenter is defined outside of the bore. The distance from the virtual to the treatment plane isocenter is 70 cm in the

y-direction. A fixed green laser system is used to project laser lines to the virtual isocenter. In addition, a movable red laser system is installed in the room. This laser system is similar to the laser marking systems commonly found in a CT simulator suite. The red lasers are mounted on tracks along which the laser can move. In their “home” position, the red laser lines will project to the virtual isocenter. In total, there are five red laser units in the room (two coronal, two axial, and one sagittal laser). In the treatment planning system, the red lasers can be requested to project lines to the patient setup marks. Hence, the red laser position is plan-specific. The patient may be aligned to the red or green laser system and depending on its use, the green laser system may be turned on or off during patient treatments. However, the green laser system is often used for physics tests. Figure 7 shows a diagram of the laser arrangement in the room. Only lateral and sagittal lasers are shown in this drawing. The green and red coronal laser system is not shown.

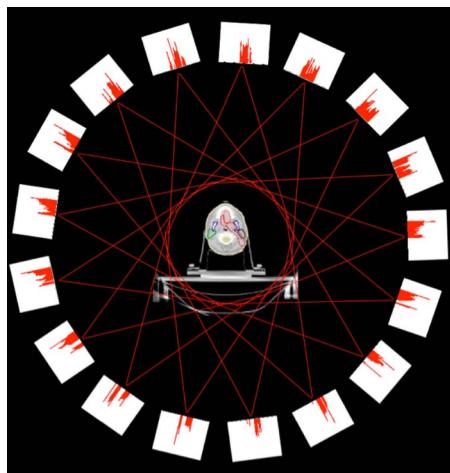


FIG. 6. Illustration of MLC use. Normalized leaf opening times are shown for every third projection of a gantry rotation during a head and neck treatment. Each of the 17 inserts shows the relative opening time (height of bar) of each of the 64 MLC leaves (represented by 64 bars along the bottom axis of each insert) during the selected projections. In these particular projections, the outer leaves are never opened since these beamlets do not pass through the tumor volume.

IV. SYSTEM SPECIFIC ACCEPTANCE AND COMMISSIONING ASPECTS

In addition to the dose delivery method and respective hardware, another unique aspect of the system is that all tomotherapy planning systems use a common beam model (several early machines had unique beam models. However, some of these early machines have subsequently been recommissioned for use with the common beam model). Each machine is adjusted in the factory such that the beam parameters match this common beam model. During the on-site acceptance testing procedure (ATP), it is verified that machine parameters still match the common beam model. Many aspects of the traditional machine commissioning tasks hence do not apply to the TomoTherapy machines. Other traditional

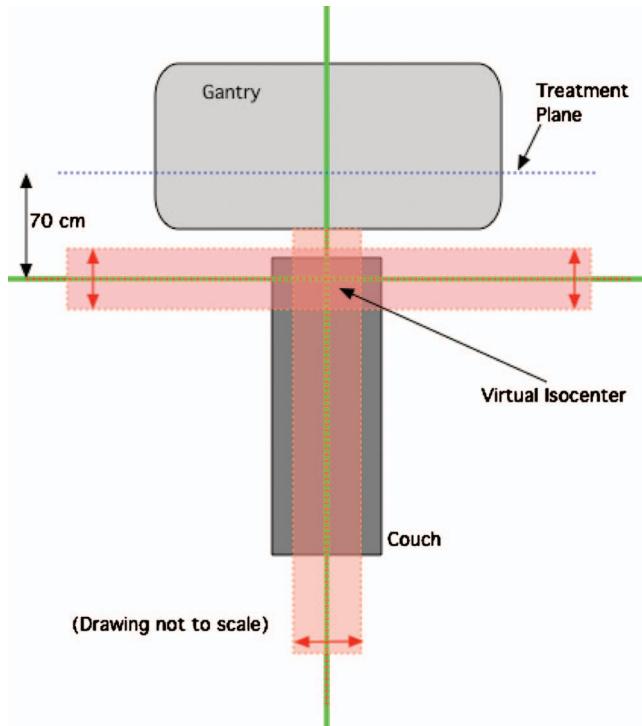


FIG. 7. A schematic drawing of the laser arrangement in the treatment room as seen from the ceiling. The green lasers are fixed and the red lasers are movable. If homed, the red laser projections overlay the green lasers. The pink box indicates the approximate area that can be occupied by the red laser system.

commissioning procedures such as the collection of baseline data for all periodic QA procedures still apply to the helical tomotherapy units.

It is recommended by this Task Group that an on-site physicist be actively involved in the acceptance testing process. He/she should collect and archive the ATP data provided by TomoTherapy, Inc. For all periodic consistency tests, the baseline data should be measured soon after machine acceptance and prior to the first treatment. All other recommended daily, monthly, quarterly, and annual QA tests should be performed once prior to the first treatment. Many of the recommended annual QA aspects are covered during the ATP process. For example, the current ATP protocol includes the mechanical alignment and beam parameter tests described in Secs. V B 1 and V B 2. Tests that are covered in the ATP process do not need to be repeated prior to the first treatment provided that the on-site physicist was actively involved in the ATP process as recommended.

V. TREATMENT DELIVERY FOR HELICAL TOMOTHERAPY

V.A. Introduction

Helical tomotherapy beam delivery is unique in its dynamics and therefore requires quality assurance tests that are tailored to this delivery technique. Some tests are similar to those performed on a conventional linear accelerator, while others are helical tomotherapy-specific.

Frequently, one aspect of the machine can be tested in different ways ranging from traditional test procedures to procedures that make use of on-board detector data acquired during helical tomotherapy procedures. Users have developed and reported tomotherapy specific test procedures.^{5–7} Many of the test procedures developed by the vendor use the on-board detector while other tests are film-based. For those users that wish to use detector data, we have included in Appendix E a discussion on where the data are located and how it can be accessed. The film-based tests can be performed with radiographic or radiochromic films.

Since helical tomotherapy is still a relatively new modality, it is anticipated that test procedures will continue to evolve. The intent of this chapter is to describe what aspects of the machine should be tested. Examples of test procedures that have been developed by users or the vendor are provided. However, over time, new test procedures will likely be developed and it is not the intent of this chapter to dictate specific procedures and thus prohibit the use of better test procedures and equipment in the future.

V.A.1. Unique aspects of helical tomotherapy treatment delivery

Helical tomotherapy utilizes a dynamic delivery in which the gantry, treatment couch, and MLC leaves are all in motion during treatment. This results in highly conformal radiotherapy treatments. The complexity of the delivery is hidden from the end user due to the extensive integration and automation of the tomotherapy control systems.

There are several unique aspects of the TomoTherapy beam delivery system that the physicist needs to recognize. The machine output is defined in terms of absorbed dose per unit time rather than the traditional units of dose per monitor unit. Consequently, treatment plan parameters such as gantry rotation, table motion, and MLC openings are all time-based. A constant dose rate is assumed for treatment planning purposes and plans are terminated after the calculated time elapsed.

Two parallel-plate ion chambers are located upstream of the y-jaw and their purpose is to monitor that the dose rate is within an acceptable window. After machine calibration, the signal levels from the transmission chambers and their variation are monitored. These signal levels are referred to as the nominal rate. The establishment of the nominal rate values is performed by the vendor during ATP. Two separate monitor chamber based dose rate tests are enforced. The treatment will be terminated if (i) the monitor chamber readings differ by more than 50% from their nominal rate for more than 3 s or (ii) the monitor chamber readings differ by more than 5% from their nominal rate for more than three consecutive rolling 10 s windows. A new 10 s window is started each second such that a continuous dose rate between 50% and 95% of the nominal dose rate would trigger an interlock after 12 s. These two dose rate tests are applied to each of the two chambers independently, such that a dose rate violation detected by either chamber will interlock treatment.

The dosimetric effect that is induced by a dose rate deviation prior to treatment interruption cannot be estimated easily. Since the target volume moves through the beam plane during treatment, target volumes that have already moved out of the beam plane are not affected and neither are target volumes that have yet to move into the beam plane. Only the tissue volume that is treated during the dose rate fluctuation period is affected. The affected volume is hence defined by the fan-beam slice width plus the distance the couch moves during the dose rate fluctuation period. The fraction of the effected irradiation time depends on plan parameters. A given target voxel is scheduled to be in the beam plane for a period of time equal to the gantry rotation period divided by the pitch value. Furthermore, the dosimetric effect will depend on the MLC pattern that is executed during the dose rate fluctuation period. Hence, the dosimetric effect of dose rate fluctuations are plan-specific but are typically limited to a fraction of the irradiated volume for a fraction of its scheduled irradiation time.

The monitor chamber assembly consists of two sealed parallel-plate transmission chambers. One chamber is not segmented and the radius of the collection volume is approximately 7 cm. The signal from this volume is used to derive the monitor unit 1 signal. The second chamber is segmented into an inner volume and an outer ring volume. The inner volume has radius of approximately 5 cm. The signal from this inner volume is used to derive the monitor unit 2 signal. The outer ring is further divided into six segments. The signals from these outer segments are not used. The monitor chamber signals are accessible to the user via the auxiliary data monitoring system.

The monitor unit readings that are displayed on the operator screen are derived from the monitor chamber signals. The monitor chamber signals are scaled such that the displayed monitor units numerically agree with the machine output as expressed in cGy/min measured at a depth of 1.5 cm with an SAD of 85 cm and a 5×40 cm² static field. This scaling process is performed by the vendor during ATP. The displayed monitor unit rate is not the instantaneous rate but the average dose rate since the beginning of the procedure. Starting with software version 4.0, the displayed dose rate for treatment procedures is the average rate over the last 10 s, excluding the warm-up period. If 10 s have not yet elapsed since the end of warm-up, the display shows the average rate since warm-up. For QA procedures, the warm-up period is included in the displayed rate.

The output is unstable when the beam is initially turned on. This beam instability is anticipated and all MLC leaves are closed for the initial 10 s of every planned delivery. If the user generates test procedures outside of the treatment planning system, it is recommended to instruct the MLC to be closed for at least the initial 10 s of the procedure.

The procedure timing, subsystem synchronization, and procedure termination are managed via a primary timer. Three independent computer clocks are used as backup timers that will each terminate the beam 6 s after a scheduled procedure time has elapsed.

V.B. Periodic quality assurance

Throughout this section, procedures are used that require machine operation in nonstandard mode, e.g., a static gantry position may be required or noncommissioned y-jaw settings may be requested. While the user can generate these procedures on the operator station (see Appendix B), the majority of the required procedures are made available by the vendor. In this chapter, QA tests for mechanical alignment, beam parameters, synchronicity, and miscellaneous aspects are described. The calibration procedure is also contained in this chapter.

V.B.1. Mechanical alignments

Several mechanical alignments must be tested annually and whenever the alignment could be compromised. In this report, particular alignments are recommended for testing. The procedures developed by the vendor to test these alignments are acceptable test procedures. However, alternative test procedure may be developed by the user. Most tests use film dosimetry and common film or image analysis tools can be used for analysis. The vendor can also supply film analysis tools.

The first set of tests (Secs. V B 1 a, V B 1 b, and V B 1 c) check the alignment of the radiation source (i.e., the linac) against the y-jaw, MLC, and rotation plane. The second set of tests (Secs. V B 1 d, V B 1 e, and V B 1 f) check the alignment of the y-jaw and MLC with the rotation plane as well as the centering of each treatment slice.

V.B.1.a. y-jaw centering. The alignment of the radiation source in the y-direction is checked against the y-jaw. This test is performed to check that the source is centered in the collimated field. This alignment needs to be checked if any component is replaced or moved that can affect this alignment. It is recommended to check the y-jaw centering annually.

The procedure uses a 2 mm y-jaw opening that is moved in 11 steps along the y-direction. A narrow y-jaw setting amplifies the sensitivity of this test. The beam is turned on for a fixed amount of time with the y-jaw opening shifted 24, 20, 15, 10, 5, 0, -5, -10, -15, -20, and -24 mm off-axis. At each step the output is measured with a stationary long active volume ion chamber located at isocenter. The vendor uses an Exradin A17 chamber for this test. The chamber must have a linear response over a length sufficient to measure the output of the shifted beams.

The output is plotted as a function of axial jaw shift. The source is aligned with the y-jaw when beam output is at its peak, as determined by a parabolic fit to the data. An example data set from this procedure is shown in Fig. 8. The respective jaw shift may be found by using the derivative of the curve to find the apex of the parabola, which corresponds to the peak output. In the given example the derivative is, $\partial\text{signal}/\partial x = -0.0162x + 0.0079$, where x is the jaw shift in mm and the peak output is at a jaw shift of 0.49 mm. The y-jaw focus point is located 5 cm above the x-ray source (i.e., 90 cm above the isocenter), which means that the source shift is magnified by a factor of 18 (i.e., 90/5) at

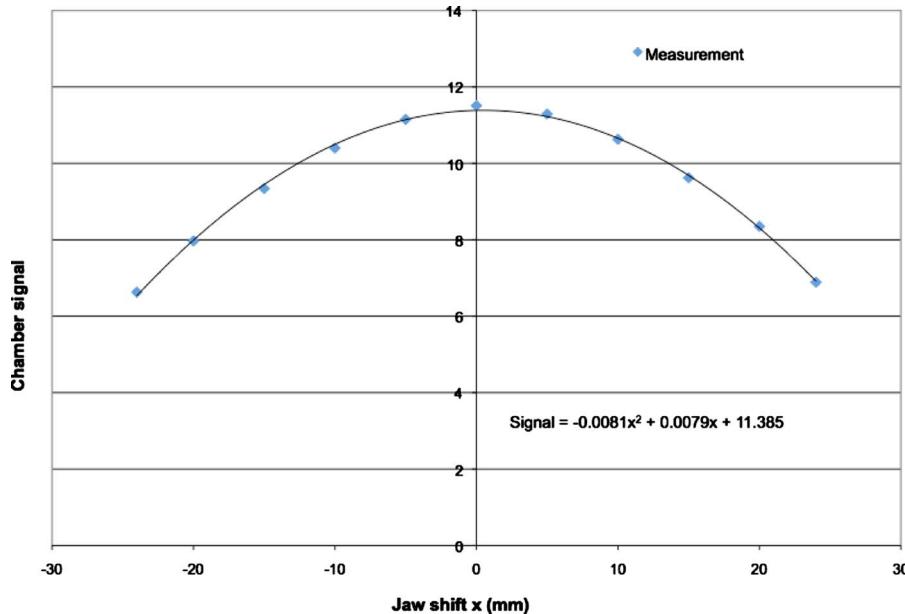


FIG. 8. An example of data measured during a y-jaw centering procedure. The measured data are fitted with a parabolic curve.

isocenter and the actual source misalignment is 0.03 mm (i.e., 0.49/18) for the given example. The vendor specification states the source position should agree with its nominal position (established at time of commissioning) within 0.3 mm. The Task Group recommends adherence to this tolerance value.

V.B.1.b. x-alignment of source. The position of the source in the x-direction is checked against the MLC position. For this test the MLC tongue and groove (T&G) effect is utilized. This effect is caused by the T&G design of the leaves that prevents a direct path for radiation to pass through when adjacent leaves are closed. A consequence of this design is a difference in the fluence output if two adjacent leaves open in sequence versus a simultaneous opening.

The T&G effect is minimized if the MLC is focused on the source. The latter fact can be used to test the source to MLC alignment. The vendor uses the MVCT detector array to collect output profiles with all even-numbered MLC leaves opened and then with all odd-numbered MLC leaves opened. This delivery sequence will maximize the T&G effect. To test the x-alignment of the source, the odd-numbered leaf profiles and even-numbered leaf profiles are added and divided by an output profile that is collected with all MLC leaves open. This normalized T&G profile should be symmetric about the center if the source is properly aligned with the MLC. Figure 9 shows normalized T&G data. An “out-of-focus” value is calculated based on the right-left asymmetry of the profile. For the purpose of calculating the out-of-focus value, the T&G profile is divided into two sides. For both sides, the average T&G signal and the standard deviation of the T&G signal is calculated. The smaller of the two average T&G signals is divided by the larger average T&G signal to calculate a ratio a that expresses the symmetry of the absolute signal. To express the symmetry of the standard deviations, two sums are calculated by separately adding each

standard deviation to the overall mean T&G signal, i.e., mean signal over both sides. The smaller of the two sums is divided by the larger sum to calculate a parameter b . The vendor’s out-of-focus value is based on the following formula:

$$\% \text{ out-of-focus} = 100\% \times (1 - (a + b)/2). \quad (1)$$

An empirical relationship between this value and the numerical source lateral offset has been established by the vendor. The vendor specifies a maximum out-of-focus tolerance of 2%, which corresponds to a lateral source position offset of 0.34 mm. The Task Group recommends that this test be performed in cooperation with the vendor to facilitate data collection and analysis. However, a film-based T&G procedure has been described in the literature and it can be used to independently verify the symmetry in the T&G profile.⁸ The Task Group recommends adopting the vendor’s tolerance for the x-alignment of the source.

V.B.1.c. y-jaw divergence/beam centering. The alignment of the y-jaw with the beam plane must be checked to assure that the central transverse axis of the treatment beam intersects the rotational axis perpendicularly, i.e., points straight down in a lateral view when the gantry is at 0° and that the beam diverges symmetrically around the plane of the gantry

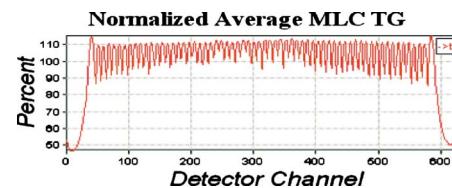


FIG. 9. The normalized tongue and groove data collected with the on-board detector array. An out-of-focus value of 1.05% was calculated from these data.

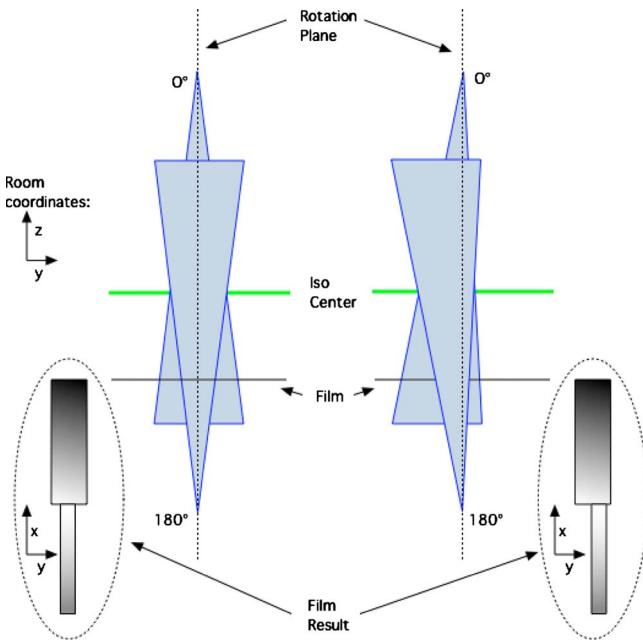


FIG. 10. Schematic of test setup for the y-divergence test. Schematic film results are shown as well. In the picture on the right hand side, the beam does not diverge symmetrically to the axis of rotation. This situation would require an adjustment of the jaw encoders.

rotation. This alignment needs to be checked if any component is replaced or moved that can affect this alignment. It is recommended to check the y-jaw/beam centering annually.

The following test procedure is acceptable to check the y-jaw divergence. A film is positioned horizontally between solid water plates (depth of 2 cm) and is positioned below the isocenter that is defined by the stationary green lasers. The film should be positioned as far as possible from the source to maximize the sensitivity of the test. Typically, the achievable distance is about 23–25 cm below isocenter. The collimation is set to define a nominal clinical field and the gantry is positioned at 0°. The MLC field is defined so that only leaves on one side of the central axis are open during exposure. The film is irradiated with the beam pointing straight down. The gantry is rotated 180° and a second irradiation is done using the same treatment slice width and MLC pattern. Figure 10 illustrates this test procedure.

A developed film of an acceptable y-divergence test is shown in Fig. 11. To test that the beam divergence is centered on the plane of gantry rotation, the center of both fields is measured. Analysis of the film involves overlaying profiles A1 and B1 of the two fields. The center of each beam is

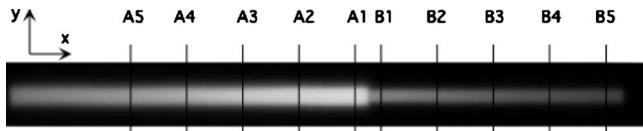


FIG. 11. Film exposure testing the alignment of the beam axial axis with the plane of rotation. For numerical analysis of the y-jaw to gantry rotation plane alignment (Sec. V.B.1.d), the y-profiles are measured at several off-axis distances that cover the length of the shorter of the two beams.

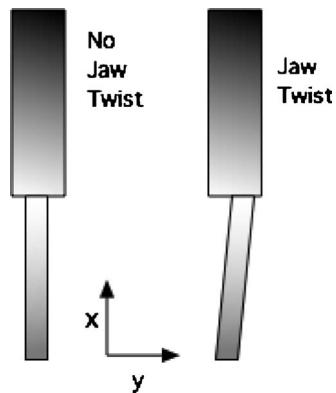


FIG. 12. Illustrations of jaw twist film results.

defined by the center of full width at half maximum (FWHM) for each beam profile (A1 and B1). A difference between the two field centers can be translated to a beam divergence at isocenter via similar triangles, i.e., divergence at isocenter=the measured difference between fields on the film multiplied by [85 cm/(2×d)], where d is the distance from the isocenter that the film was located at. For example, with a film located 25 cm below isocenter, a 0.3 mm difference between the beam centers on the film would translate into a beam divergence at isocenter of 0.51 mm [i.e., $0.3 \text{ mm} \times (85/50)$].

The divergence of the beam axis from perpendicular at isocenter should be 0.5 mm or less per the vendor's specification. The Task Group recommends adherence to this tolerance value.

V.B.1.d. y-jaw/gantry rotation plane alignment. It should be tested that the y-jaw is parallel to the plane of rotation. This needs to be checked on an annual basis and anytime that this alignment can be compromised. The film results from the y-jaw divergence/beam centering test can be used in this analysis. Figure 12 shows sketches of acceptable and unacceptable film results.

In this instance the film profile is interrogated at several points along both fields (Positions A5–A1 and B1–B5 in Fig. 11). The y-position of the profile center is defined as the midpoint between 50% intensity penumbral position. This position is noted in both x and y for the thick and thin profiles and recorded separately. The results are plotted and the slope of the resultant straight line is ascertained. Note that the physical jaw twist equals half the angle between the fields as measured on the film. The physical jaw twist should be less than 0.5°. This is the vendor specified tolerance and the Task Group recommends adherence to this tolerance value. This tolerance ensures that the dose distribution at an off-axis distance of 10 cm has a spatial accuracy of 1 mm.

V.B.1.e. Treatment field centering. All clinical treatment fields must share a common center. This alignment should be checked if any component is replaced or moved in a way that can effect this alignment. It is recommended to check the field centering annually.

To test the field centering, a film can be placed perpendicularly to the beam axis at an 85 cm source-to-film dis-



FIG. 13. Film for test of clinical beam axial centering.

tance under a stationary vertical field. The use of solid water build-up (1–2 cm) is recommended. The control sinogram is set so that MLC leaves 11–18, 29–36, and 47–54 remain open. The y-jaws are set to the nominal width of 2.5 cm and the film is irradiated. The MLC is then set to open leaves 2–9, 20–28, 38–45, and 56–63 and movable y-jaws are set to one of the other clinical beam widths. Please refer to the MLC discussion in Sec. III for the MLC leaf numbering convention.

The film is irradiated a second time and developed. In the example shown in Fig. 13, the calibrated field of 5.0 cm is tested against the clinical 2.5 cm field. Profiles taken across the different treatment slice widths should show an agreement of the field centers within 0.5 mm at isocenter per the vendor's recommendation. The task group recommends adherence to this tolerance value. The test should be repeated for each clinical field.

V.B.1.f. MLC alignment test. The lateral alignment of the MLC relative to the center of rotation should be tested on an annual basis or after MLC replacement. Similarly, it should be tested that the MLC is aligned parallel to the rotational plane.

A film-based test can be used to test these two parameters. A film is positioned at isocenter and two central MLC leaves (32 and 33) are opened in addition to two off-center leaves (27 and 28). The film is exposed with the gantry at 0° . The gantry is moved to 180° and only the two off-center leaves are opened. The developed film should look somewhat like Fig. 14. The two outer areas should be parallel to each other (the MLC is oriented parallel to the plane of rotation). The central area should be centered between the two outer areas (no MLC lateral offset). The difference in distance between the two outer fields from the central field is used to calculate the MLC offset. It should be pointed out that any MLC offset

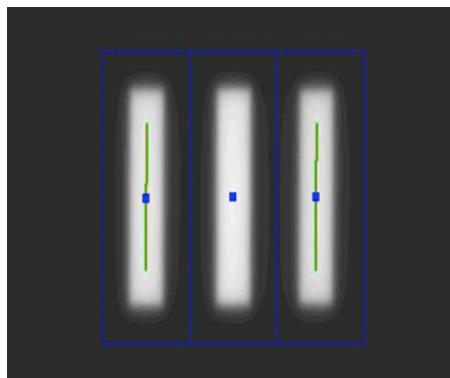


FIG. 14. MLC alignment/twist test.

and twist is magnified by a factor of 2 if the difference between the two outer field offsets from the central fields and the twist is measured using the above film procedure since misalignments are added from each of the two exposures. Hence, the MLC offset is equal to the difference between the right and left field offsets from the center divided by 2.

Per vendor specification, the MLC offset should be less than 1.5 mm at the isocenter and the MLC twist should be less than 0.5° . The Task Group recommends that the vendor's specification be adopted.

V.B.2. Beam parameters

The unique design of the TomoTherapy treatment head results in unique beam profiles. For example, the absence of a flattening filter results in cone shaped transverse beam profiles. Monte Carlo calculations of the tomotherapy beam characteristics have been described in detail by Jeraj *et al.*⁹ and Sterpin *et al.*¹⁰

For the purpose of routine quality assurance the consistency of the percentage depth dose, transverse, and longitudinal beam profiles, as well as the beam output should be monitored. Recommended frequencies and tolerances are discussed in the following sections. If any of these parameters vary beyond acceptable tolerance, adjustments of the machine parameters may be necessary. These adjustments require operation of the machine in service mode. Ideally, adjustments are performed by the field service engineer (FSE) and verified by the local medical physicist. At the physicist's discretion, output adjustments can also be performed and verified by the local physicist. Adjustment of the beam energy and/or beam profiles should be performed by the FSE and verified by the local physicist.

V.B.2.a. Beam quality. Agreement between the beam quality modeled in the planning systems and the measured beam quality should be tested. An example of a measured PDD is shown in Fig. 15. For comparison the modeled PDD is shown.

The standard tomotherapy PDD at a depth of 10 cm is reduced in comparison to that of a typical 6 MV linac beam due to the shorter SSD and the lower inherent energy that is due to the flattening filter free design of the tomotherapy units. However, the beam is filtered uniformly to remove low energy components.

Multiple techniques exist to measure a PDD curve and to monitor the beam energy consistency. For example, the consistency of the beam energy can be determined with a tissue maximum ratio (TMR) curve measured in a water-equivalent phantom with a simultaneous measurement of the dose rate at two depths or by measuring the beam attenuation with filters of different effective thickness.

In accordance with TG-142, the tolerance for beam quality variations is 1% for the PDD_{10} or TMR_{10}^{20} . The consistency of the beam quality should be tested on a monthly basis. This frequency is higher than the corresponding annual test recommended in TG-142. The reason for this increased test frequency is that targets wear more rapidly on TomoTherapy units than what one typically encounters in C-arm

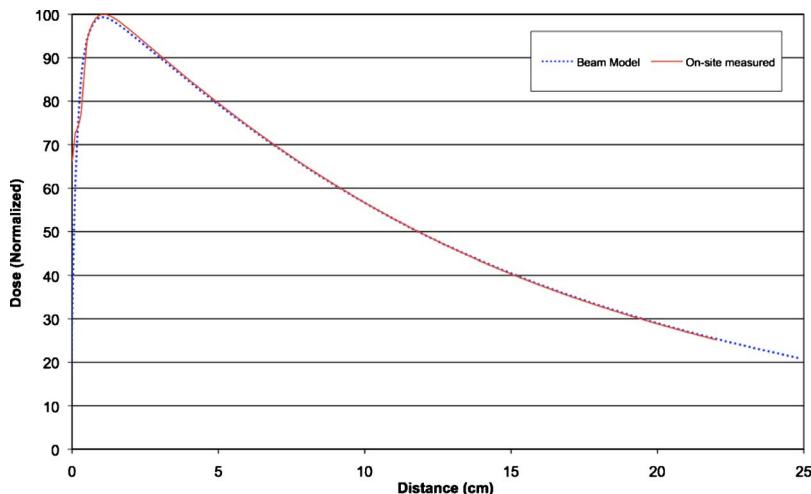


FIG. 15. Example of a PDD curve ($2.5 \times 40 \text{ cm}^2$ field) measured in water tank and the modeled PDD. Data were acquired at an SSD of 85 cm.

linacs. The beam quality is changing continuously throughout the lifetime of the target, but may exhibit significant dosimetric changes near the end. Accordingly, the user is advised to monitor the beam energy diligently and perhaps even further increase the frequency of beam quality monitoring if initial signs of target wear appear.¹¹ On an annual basis, agreement with the beam model should be verified for each commissioned treatment slice width. The beam model currently consists of PDD data in water. Hence, on an annual basis water tank data needs to be acquired for comparison with the beam data. The dimensions of water tanks are limited by the physical dimensions of the TomoTherapy bore (i.e., 85 cm). Third-party vendors have developed water tank systems that can be used in a TomoTherapy unit.

V.B.2.b. Cone (transverse) beam profiles. TomoTherapy units do not use a flattening filter and the transverse beam profiles are cone shaped. The intensity at the beam edge falls to approximately 50% of the central axis value. This is illustrated in Fig. 16. In accordance with TG-142, the consistency

of the transverse beam profile size should be monitored monthly and be compared to the beam model on an annual basis. To accommodate machines without flattening filters, a beam profile consistency tolerance of 1% is specified in TG-142 for monthly beam profile tests. This value corresponds to the average absolute difference for multiple off-axis ratio measurements that are within the core of the beam (e.g., 80% of field size). The difference is specified with respect to baseline data acquired at time of commissioning. Annually, consistency of the beam profiles should be assessed against the beam model. The beam model data are available from the vendor at the time of machine installation and commissioning. Consistency can be assessed using the monthly scoring method and tolerance values.

Cone profiles can, for example, be monitored using the on-board MVCT detector system, but data access may require assistance from the TomoTherapy service engineer. Due to variations in the detector efficiency with off-axis distance, the detector data are not used to determine the beam

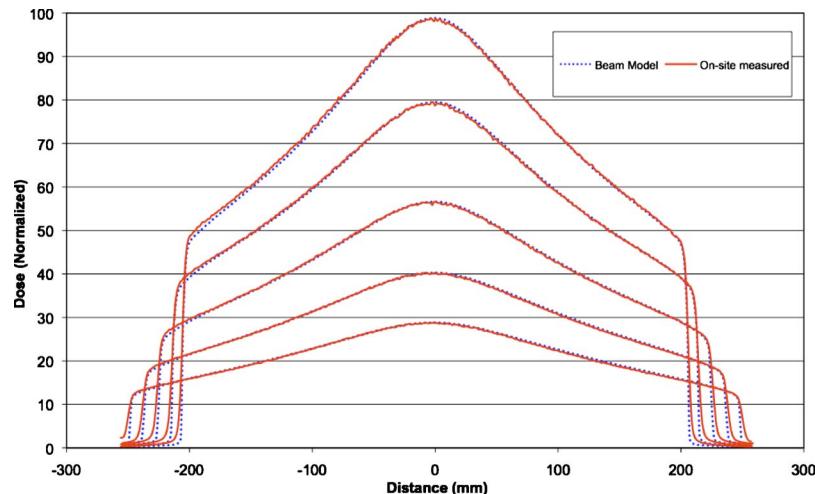


FIG. 16. Example of transverse beam profiles measured in a water tank ($2.5 \times 40 \text{ cm}^2$ field) and the respective modeled beam profiles. Data were acquired at an SSD of 85 cm and at depths of 15, 50, 100, 150, and 200 mm.

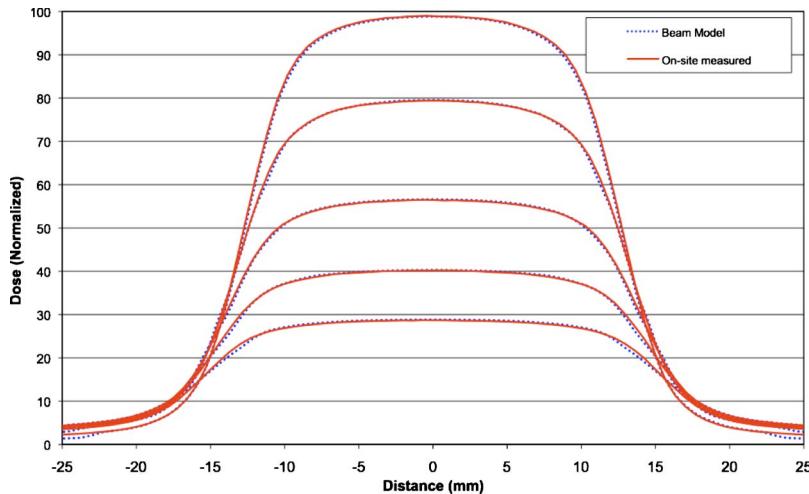


FIG. 17. Example of longitudinal beam profiles measured in a water tank and the respective modeled beam profiles. Data were acquired at an SSD of 85 cm and at depths of 15, 50, 100, 150, and 200 mm.

profile. However, changes in the beam profile result in changes of the measured detector data. Analysis of the detector data is hence a tool to test the consistency of the cone-beam profiles.^{5,12} Third-party vendors have created suitable diode arrays for cone profile measurements.¹² Finally, film can be used to monitor profile consistency. Similar to possible PDD changes at the end of the target life, changes in the cone-beam profiles have been reported with target wear.¹² On a monthly basis, the transverse beam profiles should be monitored for at least one commissioned treatment slice width. On an annual basis, the agreement of the transverse beam profiles with the beam model should be tested for all commissioned treatment slice widths. Since the beam model is currently available as beam profiles in water, water tank data should be measured on an annual basis.

Inherent to the use of the on-board detector system is the assumption that the off-axis detector response remains constant over time. This assumption is not explicitly tested. The detector is rigidly attached to the gantry such that a mechanical shift is unlikely. However, if profile changes are detected with the detector system that cannot be explained by target wear or component replacements, the response of the detector system should be verified against an independent measurement such as film or diode arrays. The annual acquisition of water tank data serves as an inherent check of the detector system consistency.

V.B.2.c. Longitudinal beam profiles. The constancy of the longitudinal beam profiles is particularly important for helical tomotherapy. The dose to the patient is the integration of the longitudinal beam profile shape with couch motion (ignoring leaf modulation) and the delivered dose will therefore change if the beam profile changes.¹³ For example, the delivered dose will change by approximately $\pm 10\%$ if the 1 cm beam profile changes in width by 10%, i.e., 1 mm. A careful monitoring of the beam's FWHM is hence recommended. While the constancy of the transverse beam profiles is also a test of the beam quality consistency, the longitudinal beam profile constancy test is primarily a slice width test and the

beam width at half maximum is recommended for monitoring. An example of modeled and on-site measured longitudinal beam profiles is shown in Fig. 17. The consistency of the longitudinal profiles should be monitored monthly for all commissioned slice widths. Several acceptable monitoring methods exist. An electrometer can be used to sample the collected charge of an ion chamber at a frequency of several Hz, while the couch is used to move the ion chamber along the longitudinal beam profile. Note that this test procedure relies on uniform couch motion. If the profile tests fail, the uniformity of the couch motion should be evaluated (Please see Sec. V B 3 b: Couch speed uniformity). Alternatively, film dosimetry can be used to monitor the longitudinal beam profiles for consistency. The profile's FWHM should not vary by more than 1%. Hence the absolute tolerance on FWHM changes is treatment slice width specific, i.e., 0.5, 0.25, and 0.1 mm, for the 5.0, 2.5, and 1.0 cm treatment slice widths, respectively. Of the three slice widths, the 1 cm treatment slice width is the most likely to fail the 1% FWHM tolerance. Note that this test is sensitive to the setup and a failed test result should prompt setup verification. If the test result continues to fail, corrective actions (such as jaw encoder adjustments) can be performed by the vendor.

Any treatment plan that is generated in the treatment planning system requires accurate jaw settings for dosimetric accuracy. Thus, the jaw setting accuracy is inherently tested with each clinical treatment plan QA as described in Sec. VII B 3 and with the rotational output test described in Sec. V B 2 d (Output constancy). While TG-142 recommends a daily check on collimator size indicator, this Task Group recommends an explicit test of the longitudinal beam profiles on a monthly basis. More frequent testing of the longitudinal beam profiles could be prompted by failures of the treatment plan QA results.

Agreement of the measured profiles with the beam model should be verified annually. Currently water tank data should be acquired annually to enable comparison with the beam model data.

V.B.2.d. Output constancy. The consistency of the output should be monitored on a daily basis. It is recommended that the output is monitored using a stationary and/or rotational procedure. The output of the TomoTherapy unit is sensitive to the machine's operating temperature and the output should only be checked when the machine is within 2 °C of its nominal operating temperature (i.e., 40 °C). This operating temperature is monitored and regulated via a water heating and cooling circuit.

If the static output is monitored on a daily basis the rotational output should be monitored on a weekly basis and vice versa. For the stationary procedure, the gantry is stationary and a treatment field can be delivered for a specified time. Since the dose rate is initially unstable, all MLC leaves should be closed for at least the first 10 s of this procedure. A rotational procedure that mimics a patient treatment, i.e., uses a rotating gantry, moving couch, and modulated leaf opening times, should be used to test for dosimetric consistency. This procedure should be generated in the TPS.

An ion chamber or a different dosimeter with similar precision can be used for these consistency tests. The daily output checks should be consistent within a 3% window. On a monthly basis, a calibrated ion chamber should be used to measure the output using static and rotational procedures. If an ion chamber is used for the daily output check, a different chamber should be used for the monthly check. Both monthly output checks should be consistent within a 2% window. These tolerances and frequencies are in accord with those recommended in TG-142.³

Both output checks should be within the tolerance window. If both outputs drift in parallel, the machine output can be adjusted to rectify the situation. A more difficult situation presents itself if both outputs drift apart and only one output is within the required window. The machine service history should be reviewed to see if the beginning of the drift coincides with machine maintenance events. For example, an MLC replacement could require a replanning of the rotational procedure due to the updated leaf latency data in the TPS (please see Sec. VIII E, "Major component replacement"). The rotational output variation data should be reviewed to see if the output variations with gantry angles changed in phase or amplitude.

Tomotherapy procedures are time-based, i.e., the beam is terminated after a specified time elapses. This technique relies on constant beam output and is therefore sensitive to dose rate fluctuations. For a detailed description of the tomotherapy dose rate monitoring system, please refer to Sec. V A 1, "Unique aspects of helical tomotherapy treatment delivery." The dose rate monitoring system is based on chamber signals from two separate transmission chambers. These signals are converted to monitor unit 1 and 2 readings for display and reporting. The two raw chamber signals have separate conversion factors such that the two monitor unit rates can be numerically identical. On a monthly basis, it should be tested that the two monitor unit rate displays are consistent to within 2%. A drift between the displayed monitor units indicates a drift in the raw count rates between the two chambers. However, to re-establish that both dose rate

interlocks have identical trigger levels, a reset of the nominal count rate based trigger level is required. A readjustment of two signal-to-MU conversion factors only affects the MU display but does not affect the actual trigger level. A re-establishment of the nominal count rate based trigger levels should be performed in cooperation with the vendor. The transmission chambers are only used to monitor the dose rates, i.e., they are used to interrupt a procedure if the dose rate is out of tolerance. They are not used to terminate the beam at the end of a procedure since the beam termination is time-based.

Output variations with gantry angle, i.e., rotational output variations should be monitored on a monthly basis. This test is similar to the output constancy versus gantry angle test recommended annually in TG-142. However, the rotational output on a tomotherapy unit is measured while the gantry continuously rotates. The increased test frequency that is recommended in this task group is based on the fact that the time-based output is sensitive to dose rate fluctuations with gantry angle. The rotational output variations are typically reproducible over several rotations with random variations (one standard variation) of the order of 1%–2%.¹⁴ No information is available regarding the long-term reproducibility of the output variation with gantry rotation.

For the rotational output variation test procedure, all MLC leaves should be open and the gantry should rotate continuously. For example, rotational output measurements can be performed with an ion chamber that is placed at the isocenter or by monitoring the monitor chamber signal as a function of gantry angle.¹⁵ The monitor chamber signal for each projection is recorded and saved as part of the patient archive (see Appendix E). To avoid beam attenuation in the treatment couch, the couch must be removed from the treatment plane, i.e., moved out of the bore, when ion chamber data are acquired.

If rotational output variation data are measured by a field service engineer as part of field service maintenance plan, the clinical physicist may review these data in lieu of a monthly measurement. The vendor's tolerance limit for the output variation with gantry angle is $\pm 2\%$ of the mean output. The tolerance for the similar TG-142 output constancy versus gantry angle test is defined relative to baseline only.³ The Task Group recommends adherence to the vendor's tolerance value. This recommendation is based on recent findings reported in the literature.^{11,14}

Since the rotational output variation is not accounted for in the treatment planning process its dosimetric effect was investigated in two recent publications. The difference in the delivered dose distribution from the planned dose distribution is smaller than the output variation since a voxel typically is irradiated from multiple gantry angles.^{11,14} Flynn *et al.*¹⁴ established a formula to calculate the acceptable amplitude of output variations as a function of the random output variations. The acceptability criterion required that the delivered dose has at least a 95% probability to be within 2% of the planned dose for all dose voxels. According to this formula the largest acceptable systematic amplitude A equals $0.34 \times (10 - \beta)$, where β is the random component of the

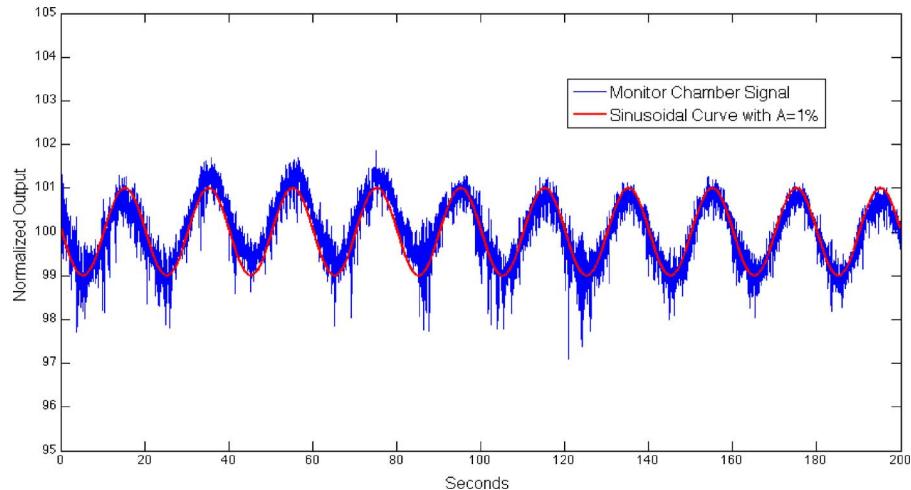


FIG. 18. Measured output variation with gantry rotation. The gantry rotation period was 20 s. A sinusoidal curve with amplitude of 1% is also shown.

output variation. Flynn *et al.*¹⁴ consequently conclude that the vendor tolerance window of 2% is more conservative than necessary. Figure 18 shows an example of measured rotation variation data. The systematic and random (one standard variation) variation of the measured data was 1%. For this case, a systematic variation with an amplitude of 3% would have fulfilled Flynn's criteria.

V.B.3. Synchrony tests

The delivery of a helical tomotherapy plan requires synchronization between the gantry rotation and table movement. Any inaccuracy or drift in these parameters over the course of a treatment would compromise treatment accuracy. The defined tests assume standard treatment scenarios, i.e., a target with longitudinal extension up to about 20 cm. When treatments involve more complex procedures (such as TBI or CSA irradiation), these tests should be modified accordingly.

V.B.3.a. Gantry angle consistency. The ability of the system to correctly identify gantry angles should be tested periodically. It is recommended that this feature be tested quarterly. The following is an example test procedure.⁶

This test involves positioning two films parallel to the rotation plane and separated on either side of the virtual isocenter by 3 cm. A delivery sequence is defined that specifies a slice width of 2.5 cm and a pitch of 0.1 for a minimum of 40 rotations. The control sinogram is set to open the middle two leaves (32 and 33) at projections centered at 0°, 120°, and 240°. Using a horizontal line marked on the films during setup, the resulting star pattern can be checked for the correct initial angles at the start of treatment and the ability to reproduce this pattern after 24 rotations. The gantry angles should be reproducible with a tolerance of 1°.

V.B.3.b. Couch speed uniformity. The ability of the system to correctly synchronize the couch position with the beam delivery needs to be tested periodically. It is recommended to test this quarterly. The following is an example test procedure. This procedure tests for uniform couch motion.⁶

A film with 1.5 cm buildup is taped to the tabletop. An irradiation is done with a static gantry in the 0° position, the

collimation set to 1 cm, all MLC leaves are opened. A couch travel distance of 20 cm for the course of the irradiation should be programmed using a couch speed that is representative of what is used clinically (e.g., 0.3–0.5 mm/s for 2.5 cm treatment slice width). The film is scanned and a profile is generated along the axis of couch travel. The relative optical density along this line should vary by less than 2%. Note that this test procedure relies on stable beam output. If this test fails, the beam output stability for static gantry procedures should be evaluated.

V.B.3.c. Couch translation/gantry rotation. The synchronization between couch translation and gantry rotation should be tested on a quarterly basis. The following describes an example test procedure.⁶

In this test, a film with 1.5 cm buildup is placed on the couch. A rotational irradiation is used with the nominal 1.0 cm beam and a pitch of 1 for 13 rotations. The control sinogram is set to open all the leaves for half a rotation on the second, seventh, and 12th rotation. The resulting film is scanned and a profile is produced along the direction of table travel. The resulting profile should show maxima 5 cm apart to within 1 mm.

V.B.4. Miscellaneous aspects

V.B.4.a. Interrupted treatment procedures. If a treatment is interrupted, the helical tomotherapy system can be used to generate a procedure to complete the treatment. The correct generation of this completion procedure should be tested monthly. This test should be performed for all commissioned slice widths on a rotating monthly schedule such that each month, one of the commissioned slice widths is scheduled for testing and each slice width will be tested every 2–3 months depending on the number of commissioned slice widths.

The following is an example test. A baseline treatment is delivered to a phantom and a coronal dose distribution is measured with film. The treatment is repeated with a new film and interrupted during the course of the treatment. A completion procedure is generated and the treatment is com-

pleted. Based on the developed films, the interrupted treatment should differ from the completed procedure by no more than 3% in its delivered dose and the overall length (FWHM) of the dose distribution in the y-direction should differ by no more than 1 mm. Since this test relies on a consistent phantom position for the interrupted and completion procedure, it is recommended to generate and deliver the completion procedure immediately after the initial treatment procedure is interrupted. It is recommended that the phantom not be moved between the deliveries of these two procedures.

V.B.4.b. Laser localization. Patients are typically positioned for treatment on the helical tomotherapy couch by aligning skin marks with wall-mounted external lasers. In theory, the use of pretreatment MVCT imaging decreases the importance of the external lasers for patient localization. In clinical practice, the use of the external lasers reduces patient rotation and aids the patient positioning process. As such, the external lasers used for helical tomotherapy units should be maintained to the same standards as used for other imaging and treatment units used in radiation oncology.

The accurate longitudinal spacing between the stationary, i.e., green, laser plane and the treatment isocenter should be tested annually using a small radiation field and a film that is marked at the virtual isocenter according to the stationary laser. The center of the radiation field should agree with the laser position to within 1 mm. The treatment field should be parallel to the laser to within 0.3° (1 mm offset at 20 cm from center). The concurrence of the virtual isocenter location and the center of the imaging plane in the x- and z-directions can be tested by imaging an object located at the intersection of the stationary lasers. This object should appear in the central MVCT pixel. Since the MVCT voxel dimensions in the “Scan”-tab are 0.8 mm in the x- and z-directions this test can test coincidence to within about ±1 mm.

The accurate movement of the movable laser with respect to the stationary laser should be tested monthly using a pre-defined plan with known red to green laser offsets. The red laser movements with respect to the green laser should be within 1 mm of the planned movement.

At initialization, the green and red lasers should coincide within 1.5 mm for non-SBRT/SRS and within 1 mm for SBRT/SRS treatments. This should be tested daily. The laser systems are independent of each other and if it is found that the two systems do not coincide upon system initialization, the physicist must investigate which of the two laser systems has changed. This test inherently tests the stability of both laser systems.

V.B.4.c. Treatment couch. Tests of the treatment couch are recommended on a monthly basis. The digital readout, couch pitch, roll, and yaw, as well as the couch sag should be tested.

The agreement between physical distances traveled and the digital readout should be tested. Over a distance of 20 cm, the agreement should be within 1 mm. Since the vertical couch position causes a longitudinal shift of the couch, the proper longitudinal position in the room coordinate system should be checked at different couch heights.

The leveling of the stationary couch should be tested and the pitch and roll should be less than 0.5°. The longitudinal couch movement should be perpendicular to the treatment plane. This can be tested by checking the couch alignment against the sagittal laser at different longitudinal couch positions. Over the distance of 20 cm, the lateral couch position should deviate by less than 1 mm. At the isocenter, the couch sag between the virtual isocenter and the treatment plane should be less than 5 mm for an unloaded couch per the vendor’s specifications.

V.B.5. Calibration

V.B.5.a. TG-51 equivalent calibration of the static beam. The development and clinical use of helical tomotherapy units has presented a challenge to the medical physics community. Helical tomotherapy units require a calibration of their dose output in the same manner and with the same accuracy as performed for conventional C-arm-gantry-based therapeutic accelerators. The recommended protocol for clinical reference dosimetry of high-energy photons in North America is the American Association of Physicists in Medicine TG-51 report.¹⁶ This protocol is based on an ionization chamber having a ⁶⁰Co absorbed-dose to water calibration factor from an Accredited Dosimetry Calibration Laboratory (ADCL), the National Institute of Standards and Technology (NIST) or the National Research Council (NRC) in Canada. The formalism used by the TG-51 protocol is the following:

$$D_w^Q = M \cdot k_Q \cdot N_{D,w}^{^{60}\text{Co}}, \quad (2)$$

where D_w^Q is the absorbed-dose to water at the point of measurement of the ionization chamber when it is absent, M is the fully corrected electrometer reading, $N_{D,w}^{^{60}\text{Co}}$ is the ⁶⁰Co absorbed-dose to water calibration coefficient, and k_Q is the beam quality conversion factor, which accounts for the change in the absorbed-dose to water calibration coefficient between the beam quality of interest Q and the ⁶⁰Co beam quality for which the absorbed-dose calibration factor was determined by the ADCL. The k_Q values to be used with the TG-51 protocol have been tabulated in TG-51 as a function of the percent depth dose specified at 10 cm and 100 cm SSD for a $10 \times 10 \text{ cm}^2$ reference field size in the clean, electron contamination-free photon beam. For several commercially available radiation therapy devices, it is not possible to measure the percent depth dose under these reference conditions. In recognition of this problem, the AAPM has formed a “Working Group on Dosimetry Calibration Protocols for Beams that are not Compliant with TG-51” to develop appropriate calibration procedures in collaboration with the International Atomic Energy Agency (IAEA).

The helical tomotherapy physical limitations do not permit a $10 \times 10 \text{ cm}^2$ field size at 100 cm SSD. However, a $5 \text{ cm} \times 10 \text{ cm}$ field size can be set at 85 cm SSD. In the longitudinal (y) direction, the maximum field dimension is 5 cm. Furthermore, there is a maximum distance of only 28 cm from isocenter to the lowest extend of couch position. This does not allow for an accurate measurement of the photon component percent depth dose at a 10 cm depth at 100 cm

SSD since there would not be sufficient phantom material for appropriate backscatter. In addition, since the helical tomotherapy unit does not have a flattening filter, depth dose data are slightly different than the depth dose data for similar nominal photon energies that have passed through a flattening filter. Since the TG-51 geometrical PDD reference conditions cannot be achieved, an alternate method of determining the helical tomotherapy beam quality is needed that will allow the use of the TG-51 tabulated k_Q values when performing a reference calibration of the helical tomotherapy unit.

The IAEA-AAPM joint committee proposed a formalism to determine the absorbed-dose to water to a static beam under specific helical tomotherapy reference conditions.¹⁷ This field is called a *machine-specific reference* (msr) field. The msr field is a static field that uses reference conditions that are achievable on a helical tomotherapy machine (i.e., a $5 \times 10 \text{ cm}^2$ field size at an SSD of 85 cm).

The Task Group recommends that this proposed formalism be followed until a formal protocol is established. The following equation, which is an extension of the TG-51 calibration protocol, details the proposed calculation of the absorbed-dose to water (the proposed formalism uses the

IAEA TRS-398 nomenclature.¹⁸ This nomenclature is adapted hence forth to facilitate comparison with the original publication of Alfonso *et al.*¹⁷):

$$D_{w,Q_{\text{msr}}}^{f_{\text{msr}}} = M_{Q_{\text{msr}}}^{f_{\text{msr}}} \cdot N_{D,w,Q_0} \cdot k_{Q,Q_0} \cdot k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}, \quad (3)$$

where Q is the beam quality [%dd(10)_x] of the conventional reference field $10 \times 10 \text{ cm}^2$ at 100 cm SSD according to TG-51 protocol; Q_{msr} is the beam quality [%dd(10)_x] of the machine-specific reference field f_{msr} ($5 \times 10 \text{ cm}^2$ field at 85 cm SSD); $M_{Q_{\text{msr}}}^{f_{\text{msr}}}$ is the corrected reading of the dosimeter for the field f_{msr} ; N_{D,w,Q_0} is the absorbed-dose to water calibration factor for a reference beam quality Q_0 (usually ${}^{60}\text{Co}$) determined by the standards laboratory (ADCL or NRC); k_{Q,Q_0} is the beam quality correction factor for beam quality Q of the conventional reference field f_{ref} ($10 \times 10 \text{ cm}^2$ at 100 cm SSD); and $k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}$ is the factor to correct for the differences between the conditions of field size, geometry, phantom material, and beam quality of the conventional reference field f_{ref} and the machine-specific reference field f_{msr} .

A key product in the equation presented above is $k_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}}$, which converts the calibration factor from calibration beam to the machine-specific reference beam, i.e.,

$$K_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}},f_{\text{ref}}} = \frac{[(L/\rho)_{\text{air}}^{\text{water}} P_{\text{wall}} P_{\text{repl}} P_{\text{cel}}]_{\text{HT(SSD=85 cm,FS=5}\times 10 \text{ cm}^2,\text{depth=10 cm)}}}{[(L/\rho)_{\text{air}}^{\text{water}} P_{\text{wall}} P_{\text{repl}} P_{\text{cel}}]_{{}^{60}\text{Co(SSD=100 cm,FS=10}\times 10 \text{ cm}^2,\text{depth=10 cm)}}}, \quad (4)$$

where $(L/\rho)_{\text{air}}^{\text{water}}$ is the ratio of the mean restricted mass collision stopping power; P_{wall} is the ionization chamber wall correction factor; P_{repl} is the fluence and gradient correction factor; and P_{cel} is a correction factor for the presence of a central electrode.

A method to determine this correction factor is described by Thomas *et al.*¹⁹ In their publication, the correction factor is called $k_{Q(\text{HT TG-51})}$, where HT stands for helical tomo-

therapy. Since the calibration correction factor k_Q is specified in TG-51 as a function of the percentage depth dose at 10 cm depth in a $10 \times 10 \text{ cm}^2$ field size at 100 cm SSD, i.e., %dd(10)_{x[HT TG-51]}, Thomas derived a conversion function for this specifier to the beam quality %dd(10)_{x[HT ref]} measured in the tomotherapy reference field (10 cm depth, 85 cm SSD, $5 \times 10 \text{ cm}^2$ field size). The relationship was plotted and a third order polynomial [Eq. (5)] was fitted to the data as seen in Fig. 19.

The polynomial as derived by Thomas *et al.* is expressed in Eq. (5),

$$\begin{aligned} \%dd(10)_{x[\text{HT TG-51}]} &= 1.35805 \cdot (\%dd_{(10)x[\text{HT ref}]})^3 \\ &\quad - 244.493 \cdot (\%dd_{(10)x[\text{HT ref}]})^2 \\ &\quad + 14672.98 \cdot \%dd_{(10)x[\text{HT ref}]} \\ &\quad - 293479.4. \end{aligned} \quad (5)$$

The maximum error in the fit of Eq. (5) is 0.3%. In order to use this relationship shown in Eq. (5), one must measure %dd(10)_{x[HT ref]} with an ionization chamber of the appropriate size. Since the helical tomotherapy photon beam is unflattened, the beam profile in the cross-plane direction is peaked and there exists only a small portion of the profile (<2 cm) where the beam may be considered uniform and

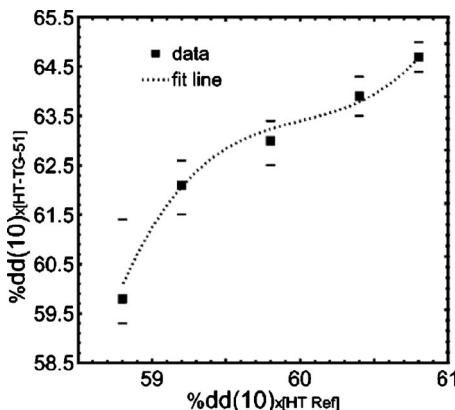


Fig. 19. The relationship between %dd(10)_{x[HT ref]} and %dd(10)_{x[HT TG-51]}. [Reproduced from Thomas *et al.* (Ref. 19)].

TABLE I. Values of k_Q for photon beams as a function of the beam quality $\%dd(10)_x$ for cylindrical ionization chambers commonly used for clinical reference dosimetry. The tabulated values can be interpolated linearly in $\%dd(10)_x$. The ionization chamber specifications are found in Table III of the TG-51 protocol. Values for the A1SL chamber are from Thomas *et al.* (Ref. 19).

Ion chamber	k_Q		
	Beam quality specifier $\%dd(10)_x$		
	58	63	66
Capintec PR-05/PR-05P	0.999	0.997	0.995
Exradin Al Shonka ^a	0.999	0.998	0.996
Exradin A12 Farmer	1	0.999	0.996
Exradin A1SL miniature Shonka	0.999	0.998	0.996
PTWN30001 0.6cc Farmer ^b	1	0.996	0.992
PTW N30002 0.6cc all Graphite	1	0.997	0.994
PTW N30004 0.6cc Graphite	1	0.998	0.995
PTW 31003 0.3cc waterproof ^c	1	0.996	0.992
WellhoferIC-10/IC-5	1	0.99	0.996

^aThe cavity radius of the A1 here is 2 mm although in the past Exradin has designated chambers with another radius as A1.

^bPTW N30001 is equivalent to the PTW N23333 it replaced.

^cPTW N31003 is equivalent to the PTW N233641 it replaced.

flat. The $\%dd(10)_{x[\text{HT ref}]}$ should only be measured with ionization chambers whose transverse diameter is smaller than the flat portion of the curve. This size requirement will ensure that the percent depth dose measurements are made in the flat portion of the beam minimizing volume averaging and reducing any error associated with centering the chamber in the beam. Conventional farmer chambers, such as those listed in Table I, whose diameter do not exceed 6.3 mm are small enough to fulfill this requirement.

The relationship shown in Fig. 19 was derived based on using an Exradin A1SL ionization chamber (Standard Imaging, Middleton, WI), but is applicable to other ionization chambers as long as the ionization chamber size limitations are met and correct percent depth dose data are measured incorporating the correct shift ($0.6r_{\text{cav}}$) to the effective point of measurement as defined by TG-51.

Another consideration in determining the helical tomotherapy unit beam quality is that any small error in the resulting $\%dd(10)_{x[\text{HT ref}]}$ will not significantly affect the k_Q value used in the calculation of the reference absorbed dose. For the range of $\%dd(10)_{x[\text{HT ref}]}$ values, i.e., 60%–64%, associated with the measured $\%dd(10)_{x[\text{HT ref}]}$ values on a helical tomotherapy unit, the k_Q values are nearly constant for the most commonly used cylindrical ionization chambers found in TG-51 and Thomas *et al.*, varying from 0.999 to 0.995, respectively.^{16,19} Any small error in the determination of $\%dd(10)_{x[\text{HT TG-51}]}$ will result in an error of typically no more than 0.1% in the final calculation of the reference absorbed dose.

The method recommended by this Task Group to determine the helical tomotherapy beam quality and the resulting

$k_{Q,Q_0} \times k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}$ product is to use the equivalent beam quality specifier technique described by Thomas *et al.*¹⁹ described above. This particular method requires the physicist to determine the beam quality specifier $\%dd(10)_{x[\text{HT ref}]}$, i.e., the percent depth dose in water at 10 cm depth at 85 cm SSD for a $5 \times 10 \text{ cm}^2$ field size and use the relationship defined by Thomas *et al.* to determine the equivalent beam quality specifier $\%dd(10)_{x[\text{HT TG-51}]}$. Once the equivalent beam specifier $\%dd(10)_{x[\text{HT TG-51}]}$ is known, the k_Q values listed in Table I and TG-51 are used to substitute the $k_{Q,Q_0} \times k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}$ product in Eq. (3). It should be noted that Table I is a reproduction of Table I from TG-51 and includes the k_Q values for the Exradin A1SL ionization chamber calculated by Thomas *et al.*^{19,20}

The calibration protocol for the helical tomotherapy unit is then similar to the procedures stated in the TG-51 protocol.

- (1) Position the ionization chamber in a water phantom such that the center electrode is at a depth of 10 cm at 85 cm SSD or SAD for a $5 \times 10 \text{ cm}^2$ field size. Allow the ionization chamber to equilibrate to the temperature of the phantom which should be at room temperature.
- (2) Record the temperature and pressure readings to determine the temperature/pressure correction, P_{TP} .
- (3) Take ionization readings per unit time at full bias to obtain M_{raw} readings.
- (4) Take ionization readings per unit time at half bias to obtain your M_{raw}^L readings to determine the ion recombination factor P_{ion} per TG-51.
- (5) Take ionization readings per unit time at the opposite polarity of the full bias reading to obtain your M_{raw}^+ readings to determine the polarity correction P_{pol} per TG-51.
- (6) Calculate the corrected ionization chamber reading per TG-51:

$$M_{Q_{\text{msr}}}^{f_{\text{msr}}} = M_{\text{raw}} \cdot P_{\text{TP}} \cdot P_{\text{ion}} \cdot P_{\text{pol}} \cdot P_{\text{elec}}. \quad (6)$$

- (7) Calculate the dose to water per unit time at a depth of 10 cm using

$$D_{w,Q_{\text{msr}}}^{f_{\text{msr}}} = M_{Q_{\text{msr}}}^{f_{\text{msr}}} \cdot N_{D,w,Q_0} \cdot k_{Q,Q_0} \cdot k_{Q,\text{msr}}^{f_{\text{msr}},\text{ref}}. \quad (7)$$

- (8) Calculate the dose to water per unit time at d_{max} using the clinical $\%dd(10)$ for SSD setup or the clinical TMR(10) for SAD setup.

One can be assisted by the worksheet in Appendix A for calculation of the static output of the helical tomotherapy machine. The worksheet is based on worksheet A of the TG-51 protocol.¹⁶

Although the static output calibration is done in a delivery mode that is not used for the treatment of patients, it forms a valuable part of the machine QA. This mode excludes all treatment dynamics and allows the determination of a single but fundamental machine characteristic. In addition, the static output calibration satisfies most state regulations that require the physicist to calibrate their machine once a year using an established calibration protocol. The methodology

described above is a simple extension of the TG-51 protocol and as such should satisfy the annual calibration requirement within the state regulations.

V.B.5.b. Output calibration (rotational procedure). Since patients are not treated with a stationary unmodulated beam, but rather with a rotating beam the output of the helical tomotherapy unit should be verified under these conditions. The IAEA/AAPM formalism mentioned earlier has addressed this issue for helical tomotherapy machines.¹⁷ In addition to static-field dosimetry it allows a second calibration route that is based on the delivery of composite fields. The formalism suggests that the physicist will develop a *plan-class specific reference* (pcsr) field and perform the measurements within this field to determine the output of the machine as it rotates about the calibration phantom. This pcsr field according to the IAEA/AAPM formalism “is as close as possible to a final clinical delivery scheme, but delivers a homogeneous absorbed dose to an extended and geometrically simple target volume.”

The pcsr field should be designed to provide a uniform dose over a region exceeding the dimensions of the reference detector. While the IAEA/AAPM formalism does not specify the particulars of the pcsr field, the recommendation of this task group is to generate a treatment plan that delivers a uniform dose of 2 Gy to a target of 8 cm diameter and 10 cm length in a 30 cm diameter water-equivalent phantom that has a minimum length of 15 cm. The vendor supplied Virtual Water™ phantom fulfills these requirements. It is recommended to use a 5 cm treatment slice width and a pitch of 0.287. For a detailed discussion of the treatment planning parameters and a discussion of phantom-based treatment plans the reader is referred to Sec. VII. The cylindrical water-equivalent phantom is imaged using a CT scanner and a treatment plan to deliver a homogeneous dose to the pcsr field is developed. The phantom should be scanned without the ionization chamber present. After the plan has been calculated, the volume that will be occupied by the active chamber volume is identified in the CT image and the average calculated dose to this volume is used for comparison with the measurements.

The phantom is placed on the treatment couch with the appropriate ionization chamber located in the center of the pcsr field. Ionization measurements (accumulating charge for the time interval to deliver the plan) are collected while delivering the plan with the homogeneous dose distribution.

The absorbed dose in a pcsr field can be calculated using the following equation, which is an extension of Eq. (3).

$$D_{w,Q_{\text{pcsr}}}^{f_{\text{pcsr}}} = M_{Q_{\text{pcsr}}}^{f_{\text{pcsr}}} \cdot N_{D,w,Q_o} \cdot k_{Q,Q_o} \cdot k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}} \cdot k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}, \quad (8)$$

where $M_{Q_{\text{msr}}}^{f_{\text{pcsr}}}$ is the corrected reading of the dosimeter in the field f_{pcsr} ; $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ is the factor to correct for the differences between the conditions of field size, geometry, phantom material, and beam quality of the machine-specific reference field f_{msr} and the plan-class specific reference field f_{pcsr} . $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ is equal to 1.003 for most commonly used ionization chambers. (In the IAEA/AAPM formalism, a $k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}}$ value of 0.997 is listed for helical tomotherapy msr field

sizes of 5×10 cm². For helical tomotherapy, pcsr field deliveries with 5, 2.5, and 1 cm field $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ values of 1.000, 1.000, and 0.997 are listed for a NE2611 chamber.¹⁷ This allows the calculation of a $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ value of 1.003 for 5 cm and 2.5 cm pcsr field deliveries. However, the reported $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ factors have a significant standard uncertainty of 0.8%.¹⁷ Revised $k_{Q_{\text{pcsr}},Q}^{f_{\text{pcsr}}/f_{\text{ref}}}$ factors may be published in the future and appropriate adjustment to the $k_{Q_{\text{pcsr}},Q_{\text{msr}}}^{f_{\text{pcsr}}/f_{\text{msr}}}$ factor may be required at that time.)

The physicist should follow the same procedure as outlined for the static beam output calibration to determine the beam quality for the machine-specific reference field, %dd(10)_{x[HT TG-51]} and using Thomas *et al.*’s relationship determine the beam quality of the conventional reference field %dd(10)_{x[HT ref]}. Knowing the beam quality, one can determine the $k_{Q,Q_0} \times k_{Q_{\text{msr}},Q}^{f_{\text{msr}}/f_{\text{ref}}}$ product for the specific chamber used in the calibration. The corrected meter reading for the pcsr field $M_{Q_{\text{pcsr}}}^{f_{\text{pcsr}}}$ should be determined as outlined in the worksheet in Appendix A. The worksheet in Appendix A can be used to assist in the calculation of the absorbed dose to the plan-class specific reference field $D_{w,Q_{\text{pcsr}}}^{f_{\text{pcsr}}}$ per Eq. (8). The absorbed-dose to water for the pcsr field is delivered in the same mode that is used to deliver patient treatments. The absorbed dose determined under the pcsr conditions can be compared to the value calculated by the tomotherapy planning software. If differences between the calculated and measured dose are identified that are in excess of 1%, it is recommended by this task group to make adjustments to the machine output.

The static calibration procedure described in Sec. V B 5 a should form part of the calibration procedure, but its use is limited since the expected output under static conditions cannot be compared to an expected value from the planning system. The calibration of the tomotherapy unit via pcsr fields is hence the relevant calibration route.¹⁷

V.B.5.c. Independent verification of calibration. It is recommended that an independent verification of the tomotherapy calibration be performed prior to the initial patient treatment and that it is repeated on an annual basis. The Radiological Physics Center in Houston (rpc.mdanderson.org/RPC/home.htm) offers a mail-in TLD monitoring service that can be used for an independent verification by NCI clinical trials participants. Other facilities are advised to contact one of the for-fee remote auditing services such as Radiation Dosimetry Services (www.mdanderson.org/education-and-research/resources-for-professionals/scientific-resources/core-facilities-and-services/radiation-dosimetry-services/index.html). Local regulation may also require an independent verification of machine calibration.

VI. TREATMENT IMAGING FOR HELICAL TOMOTHERAPY

VI.A. Introduction

In addition to its ability to deliver IMRT, the TomoTherapy system also has the ability to obtain images of the

patient in the treatment position prior to each treatment. These images are acquired to check and correct, if necessary, the patient's position for treatment. Inaccurate patient positioning will result in a geographic misplacement of the dose distribution.

The AAPM TG-142 report includes recommendations on serial and cone-beam CT for image guidance.³ Periodic tests of geometric accuracy, image quality, and imaging dose are recommended in TG-142. The intent of Sec. VI A 1 is to describe respective quality assurance procedures associated with the imaging aspect of the TomoTherapy unit.

VI.A.1. Unique aspects of megavoltage CT imaging

The radiation beam that is used for imaging on the TomoTherapy unit is generated by the same linear accelerator that is used to generate the treatment beam. Therefore, the beam energy is in the megavoltage range and the image modality is referred to as MVCT imaging. For MVCT imaging, the accelerator is adjusted such that the nominal energy of the incident electron beam is 3.5 MeV.⁹ The detector used in the TomoTherapy system is an arc-shaped CT xenon detector that has been described previously.^{21–23} The standard image matrix size is 512×512 pixels and the field-of-view has a diameter of 40 cm. A filtered back-projection algorithm is used for image reconstruction.²³

On the user interface, the operator is tasked with the selection of the scan length and the slice thickness. Three pitch values (1, 2, and 3), are pre-programmed; these are referred to as fine, normal, and coarse, respectively. The standard y-jaw setting for the imaging mode is 4 mm and the pre-programmed pitch values correspond to a nominal slice thickness of 2, 4, and 6 mm. The rotational period during the image acquisition is fixed at 10 s. Using a half-scan reconstruction technique, this translates to an acquisition rate of 1 slice per 5 s. The imaging dose depends on the selected pitch and the thickness of the imaged anatomy, but it is typically in the range of 1–3 cGy.²⁴ The total scan time depends on the number of selected slices.

The TomoTherapy operator station includes image registration tools for manual or automatic rigid-body registration. The automatic registration tools are typically faster than manual image registration, but it is important that automatically registered images are checked for accuracy by an experienced user.

The dimensions of the kVCT and MVCT image voxels are different in size. The kVCT image, which has a variable field-of-view, is typically down-sampled to a 256×256 matrix upon import to the TPS while the MVCT image has a 512×512 matrix size with a 40 cm field-of-view. During automatic image registration, a nearest neighbor approach is used for image interpolation.

A registration accuracy on the order of one-half voxel dimension can be expected for phantom MVCT to kVCT image registrations under these ideal conditions.^{25,26} The larger of the two voxel dimensions, kVCT or MVCT, is the limiting one. In the y-direction, the MVCT voxel size varies

with the imaging pitch, and the superior-inferior registration precision reduces with an increase in the MVCT slice thickness.²⁶

VI.B. Periodic quality assurance

VI.B.1. Spatial/geometry tests

The primary purpose of MVCT imaging is image guidance. Accordingly, the geometric accuracy of the reconstructed images and the accuracy and consistency of the image registration procedure should be tested. Appropriate phantom-based test procedures are described below.

It should be pointed out that the image registration precision will depend on the available image content, i.e., it could depend on the test phantom itself. For example, a high contrast object that is easy to identify in both images (e.g., a metal ball of 1–2 mm diameter) can be registered more precisely than a phantom that varies little in the superior-inferior direction. Similarly, the scan range and parameters influence the available information and this can affect the registration precision.^{26,27} It should further be understood that registering patient images can be more subjective depending on the anatomical site because anatomical changes in the patient can add a level of complexity and subjectivity that is absent from rigid phantom alignments. The clinical registration precision can be determined using actual patient images, clinical operators, and clinical alignment techniques.²⁸

VI.B.1.a. Geometric distortions. The accurate reconstruction of an object in the MVCT image in terms of dimension and orientation can be tested with a rigid phantom of known dimensions and orientation. The recommended test frequency is monthly. The vendor supplied cylindrical Virtual WaterTM phantom or a phantom of similar size can be used.

Distances between embedded objects in the x-, y-, and z-directions, and the orientation of the phantom as they appear in the MVCT image can be compared to the physical distances and orientation of the phantom. The use of small fiducial markers that are embedded or attached to the phantom will increase the precision of this test particularly in the longitudinal direction where the phantom exterior surfaces are parallel to the imaging plane and are hence subject to volume averaging effects. Spatial information from the MVCT image can be deduced using the cursor position read-out function available in the software. The use of a “fine” scan, i.e., a nominal slice thickness of 2 mm, is recommended for this scan. On the MVCT image, the orientation of the phantom should be correct. The MVCT images themselves should be free of unacceptable reconstruction artifacts. A minimum scan length of 20 cm is recommended for this test to approximate a typical scan length that is used in clinical routine. The dimension of the embedded objects or distances between fiducial markers as measured in the MVCT image should be within 2 and 1 mm of the physical distances for non-SRS/SBRT and SRS/SBRT treatments, respectively. The recommended test frequency and tolerances are in accord with those recommended in TG-142.

The accurate reconstruction of the MVCT image in terms of dimension and orientation should also be tested after sys-

tem maintenance work that can affect the hardware or software components that relate to the imaging system.

VI.B.1.b. Imaging/treatment/laser coordinate coincidence. The coincidence between the treatment and imaging coordinate system should be tested for any IGRT system. The meaning of this test changes somewhat for systems that use the treatment beam for image acquisition such as the tomotherapy MVCT system. While the beam source is identical for MVCT-based systems, the image acquisition, reconstruction, and registration involves hardware and software components that could induce discrepancies in the coordinate coincidence. It is therefore recommended to perform, on an annual basis and after software upgrades, a phantom-based end-to-end test of the image registration and treatment chain. For this test, a phantom will undergo the same chain of events that a patient would undergo. The phantom is imaged, a plan is generated in the TPS, MVCT imaging is used to check the phantom alignment, and finally the phantom is treated. The dose distribution within the phantom is tested for accuracy to establish image and treatment coordinate coincidence.

The phantom needs to contain either a film-based dosimeter or some other means of extracting a dose distribution for comparison with the dose distribution calculated in the treatment planning software. For example, ion chamber or diode arrays allow a direct measurement of the dose distribution in the phantom. Similarly, the vendor supplied Virtual Water™ phantom allows the placement of a film in the coronal or sagittal plane, and this phantom can be used for this test. In this case, the delivered dose distribution should be registered relative to the phantom. This registration can be performed within the TomoTherapy DQA panel with the aid of the “General” registration tool available in the DQA analysis panel. This registration tool allows a film registration that is based on any two points that can be identified on the film and in the CT image. Alternatively, the dose plane can be exported from the treatment planning system and the registration can be performed using third-party software. This test assesses the combined accuracy of the image registration and dose delivery process. A similar test is described in the literature by Soisson *et al.*²⁹ The tolerance should accommodate geographic uncertainties in the image registration and dose calculation. If each geographic uncertainty is assumed to be on the order of a voxel dimension or less, the tolerance of this test can be calculated by summing the two uncertainties in quadrature. Recommended tolerances for the treatment and imaging coordinate coincidence is 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatment machines. The imaging parameters and dose calculation grids may need to be chosen accordingly.

The annual test checks coincidence of the treatment and imaging system coordinates. A simultaneous test of the green laser system coincidence with the imaging system allows the establishment of the green laser system as a reference for daily and monthly consistency tests. This coincidence can be verified by checking that, post image registration, the green laser position on the phantom is in agreement with the intended position as indicated in the treatment planning sys-

tem. When this test is performed, it must be kept in mind that the couch height may sag if a phantom is aligned at the virtual isocenter and is then moved to the treatment plane. Typically, the couch sag is on the order of 3 mm if vendor supplied cylindrical Virtual Water™ phantom is positioned on top of the couch. To avoid this offset, the phantom location with respect to the green laser should be checked at the treatment plane. Recommended tolerances for this test are 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatment machines.

The use of the green laser system as a surrogate is convenient since its operation is independent of the TomoTherapy machine operation and its position is thus not affected by the machine software or hardware upgrades.

On a daily basis, it is recommended to test the accurate location of the reconstructed image with respect to the green laser system to test the accurate location of the image coordinates with respect to the treatment coordinate. For this test, an object, i.e., a phantom with a high contrast object, is aligned with the red or green laser system and is scanned. The location of the object in the reconstructed MVCT image should agree with the actual location of this object with respect to the stationary green laser system. The tolerance for this test is 2 mm for non-SRS/SBRT and 1 mm for SRS/SBRT treatments. The use of the fine MVCT scan mode is recommended. A daily test of the treatment and imaging coordinate system coincidence with the given tolerances is in accord with recommendations made in TG-142.

Since accurate MVCT to kVCT image registration relies on accurate MVCT image localization, the above coincidence can be verified during the image registration test described in Sec. VI B 1 c.

VI.B.1.c. Image registration and alignment (position/repositioning). It is recommended to test the accuracy of the image registration and alignment process on a daily basis with a position/reposition test. The creation of a “phantom” patient plan can be used to test multiple aspects of the system. For example, a phantom that is intentionally and reproducibly misaligned prior to MVCT imaging can be scanned and registered to monitor the functionality and consistency of the image guidance process. A visual inspection of the image for image artifacts can be done at the same time. The image registration process should be reproducible to within 1 mm for phantoms that contain a high contrast object. Use of the fine scan option is recommended. The post registration positioning process should also be executed and actual couch and red laser shifts should match the intended shifts within 1 mm. The vendor supplied cylindrical Virtual Water™ phantom can be used for this test. The final, postregistration and alignment, positioning of the phantom should be accurate with respect to the green laser to within 1 mm. A daily position/repositioning test with identical tolerances is recommended in TG-142. An example phantom plan that tests, among other aspects, the consistency of the image registration and alignment process is described in Appendix D.

VI.B.2. Image quality tests

Image quality and dosimetry tests are recommended to quantify the initial performance of the system and to monitor this performance periodically. Quantitative tests at the time of machine acceptance allow the user to judge the performance of their system relative to recommended values. Periodic monitoring allows the user to quantify degradations in imaging parameters.

Image degradation could indicate suboptimal performance of the beam collimation, MVCT detector system, or variations in the MVCT beam with target wear. The accuracy of the primary y-jaws in defining the MVCT slice width in the longitudinal direction can influence the patient dose. If the fan beam is wider than intended, unnecessary dose will be delivered to the patient. The appearance of ring artifacts in the image points to a malfunction in the detector system. The Hounsfield unit (HU) to electron density conversion can also vary with target wear.

The image noise, uniformity, spatial resolution, contrast, and the MVCT dose are recommended for monitoring. The CT number reproducibility and image uniformity are essential if the MVCT images are used for dose calculations. Accordingly, the monthly MVCT QA protocol will vary with the intended MVCT use. Monthly tests of the image quality are in accord with TG-142 recommendations.

VI.B.2.a. Random uncertainty in pixel value (noise). To test image noise, an image of a water or water-equivalent uniform phantom can be used. The noise can be assessed by calculating the standard deviation σ_{CT} of the HUs in a region-of-interest (ROI). Noise is expressed relative to the linear attenuation coefficient of water μ_{water} and is corrected for the contrast scale (CS) of the scanner.²² Hence, the

$$\text{Noise} = \sigma_{CT} \times CS \times 100/\mu_{water} \quad (9)$$

where

$$CS = (\mu_{polycarbonate} - \mu_{water}) / (\text{HU}_{polycarbonate} - \text{HU}_{water}). \quad (10)$$

Using the above methodology noise values of 3.7–3.8 have been published for MVCT images.³⁰ This corresponds to a standard deviation of about 35–36 HU in a homogeneous water bath. When selecting the region-of-interest, the user should avoid areas of known image artifacts such as the “button” artifact that is frequently seen in the center of MVCT images. The button artifact is a region of enhanced density that is about 10 mm in diameter. It is an artifact of the rapidly changing detector response in the central region of the detector array.

It is recommended to determine the noise in the MVCT image using a cylindrical uniform phantom with a diameter of at least 20 cm. The vendor supplied cylindrical Virtual WaterTM phantom contains a uniform section that can be used to determine the image noise. It is recommended to monitor the noise level on a monthly basis. The vendor does not issue a recommendation for acceptable noise levels and the acceptability of the measured noise level is at the user’s discretion. Typical noise levels in the central region of the MVCT image

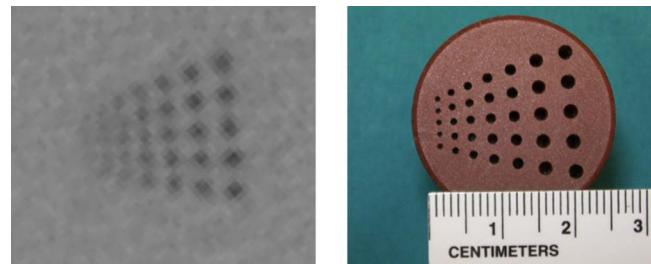


FIG. 20. MVCT image of the high contrast resolution plug that is shown on the left. The largest hole is 2 mm in diameter and the diameter is reduced in 0.2 mm steps for the smaller holes, i.e., the smallest hole has a diameter of 0.8 mm.

are around 50–70 HU (one standard deviation) while lower values (i.e., 25–35 HU) can be expected in the periphery of the image.

VI.B.2.b. Image uniformity. The uniformity can be assessed by measuring the average HU in smaller ROIs (about 5 mm in radius) that are located in the center and periphery of the phantom. The largest difference between any peripheral HU and the central HU is determined.

It is recommended to determine the uniformity in the MVCT image using a cylindrical uniform phantom with a diameter of at least 20 cm. The vendor supplied cylindrical Virtual WaterTM phantom contains a uniform section that can be used to determine the image uniformity. It is recommended to monitor the image uniformity on a monthly basis.

If the MVCT image is used for dose calculation, the largest HU difference between the peripheral and the central ROIs should be less than 25 HU. A 25 HU difference in water would translate to a 2.5% variation in the calculated density of water.

VI.B.2.c. Spatial resolution. The spatial resolution can be measured with a high contrast hole pair test pattern. TomoTherapy provides a resolution plug that can be used for this test. This plug can be inserted into the vendor supplied cylindrical Virtual WaterTM phantom. Alternatively, the resolution insert of an AAPM CT Performance Phantom (Cardinal Health, Hicksville, NY) or any similar spatial resolution insert can be used for this test. A monthly check of the MVCT image resolution should be performed. Figure 20 shows an MVCT image of a high contrast resolution test plug.

Visual inspection of a hole pattern indicated that MVCT images that are reconstructed with the typical 512×512 pixel matrix allow the resolution of a 1.25 mm high contrast object.³⁰ The vendor specifies a minimum resolution of a 1.6 mm high contrast object.

VI.B.2.d. Contrast. The low contrast visibility can be measured by inserting various density test plugs supplied by the vendor in the vendor supplied cylindrical Virtual WaterTM phantom. On a monthly basis, the visibility of the identical test plugs can be checked. This test relies on the operator and is subjective in nature. However, a significant loss in contrast resolution will be detectable. Figure 21 shows an MVCT scan of the Virtual WaterTM phantom that is loaded with test plugs of varying densities.

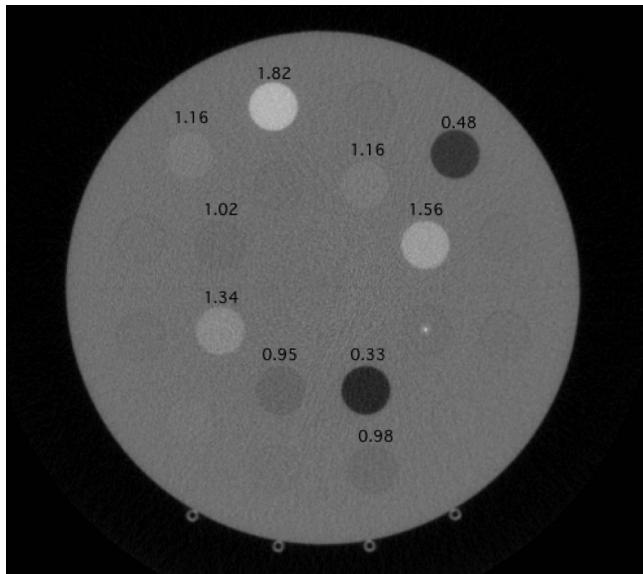


FIG. 21. MVCT image of the Virtual Water™ phantom loaded with various test plugs for a contrast and spatial resolution test. The numbers state some of the nominal plug densities in g/cm^3 .

VI.B.2.e. CT number to density calibration. The relationship of MVCT number to electron or mass density is different from that observed in kVCT scanners. This is due to the difference in physical interaction probabilities in the two beams. In the megavoltage energy range, Compton interactions are dominant even in high Z materials. Consequently, the MVCT number to physical density calibration table is expected to reflect a linear relationship.

TomoTherapy has a commercial software package called “PLANNED ADAPTIVE” that facilitates the use of MVCT images for retrospective dose calculations to evaluate the dose distribution in the anatomy of the day. If MVCT images are used in this manner, a MVCT to density calibration must be commissioned and the reproducibility of the HU calibration should be monitored on a monthly basis. Similarly, if MVCT images are used for treatment planning, an accurate HU calibration must be used.

To commission the use of MVCT images for dose calculations, a commercial CT number calibration phantom can be used. The vendor supplied cylindrical Virtual Water™ phantom contains Virtual Water™ density plugs that can be exchanged with different density plugs for this purpose. A set of density plugs ranging from lung to bonelike densities is available from TomoTherapy. A MVCT scan of the calibration phantom is obtained and a MVCT number to density table can be established. The TomoTherapy TPS expects HU calibrations in terms of mass density rather than the more common relative electron density. These tables are called image value-to-density calibration tables (IVDTs) in the TomoTherapy TPS. An IVDT editor is available to commission and edit the IVDTs. After the IVDT is commissioned, its accuracy can be tested by recalculating the dose distribution of a phantom plan in the MVCT image of the phantom. Any rigid phantom, e.g., the vendor supplied cylindrical Virtual Water™ phantom can be used for this test. The original

kVCT-based dose distribution should agree with the MVCT-based dose distribution. The PLANNED ADAPTIVE software facilitates a dose volume histogram comparison. The original and recalculated DVH should agree to within 2%.

If MVCT images are used for dose calculations, the reproducibility of this calibration curve should be monitored on a monthly basis with a subset of density plugs that cover lung, bone, and waterlike densities. The vendor supplied cylindrical Virtual Water™ phantom loaded with the appropriate density plugs can be used for this test. Any uncertainty in the HU calibration translates into dosimetric uncertainties in the MVCT-based dose calculation. The dosimetric impact of HU variations depends on what part of the calibration curve is affected. A shift in the water-equivalent HU has a larger impact than a shift in the bone equivalent HU since a typical patient image contains more water-equivalent density material than bonelike materials. Calibration curves that differed by 20 HU near water-equivalent densities and by up to 50 and 80 HU in lunglike and bonelike densities resulted in dosimetric differences of typically 2% or less for tomotherapy treatment plans.³¹ Monthly HU calibration tests should test that the HU for water-equivalent materials varies by less than 30 HU and that lung and bonelike materials result in HUs that are within 50 HU of the nominal value established at time of machine acceptance.

VI.B.3. MVCT dosimetry

A multiple slice average dose (MSAD) measurement can be performed to measure the dose in phantom and to check the consistency of the imaging dose over time. Measurements are obtained with a calibrated ionization chamber that is located at a point of interest in a phantom, such as the vendor supplied Virtual Water™ phantom described in Sec. II. The scan ranges should cover the complete phantom. The dose measured at the ionization chamber location includes dose that is accumulated while the sensitive chamber volume is imaged as well as scatter dose accumulated when the neighboring slices are imaged. A simple cylindrical phantom or test plug that accommodates a calibrated ionization chamber such as a Farmer or an A1SL chamber can be used. The chamber specific TG-51 calibration factor can be used to convert the charge to dose. No adjustments for the image beam quality or irradiation conditions is recommended since the MVCT dose does not need to be measured with the same accuracy as the treatment dose.

The imaging dose will depend on the selected imaging mode and phantom but for the vendor supplied cylindrical Virtual Water™ phantom that is imaged in the “NORMAL” mode, a MSAD dose of 1–3 cGy can be expected.²⁴ Since the imaging beam is in the megavoltage range and the image is acquired in a helical fashion, the imaging dose is fairly uniform and the position of the ion chamber within the phantom is not critical. The same position should, however, be used for the consistency tests. It is recommended to monitor the imaging dose on a quarterly basis. While TG-142 recommends an annual measurement of the imaging dose a more frequent measurement is recommended for tomotherapy ma-

chines since MVCT images tend to be acquired on a frequent, i.e., daily, basis for each patient. Unexplained increases in the MVCT dose should be investigated.

VI.B.4. Image export for analysis

The analysis of MVCT images in terms of Hounsfield units cannot be done conveniently with the standard TomoTherapy software. For example, the TomoTherapy software has no tools to select a ROI for the calculation of mean HU and their standard deviation. To facilitate the analysis of MVCT images, it is therefore recommended to export the MVCT image from the TomoTherapy database and use third-party software for analysis. Using the DICOM export feature in the TomoTherapy software, it is possible to send MVCT images to a DICOM receiver. The Image-Guided Therapy QA Center (ITC) at Washington University in St. Louis supplies a convenient and free-of-charge DICOM receiver software package (DICOMPiler) (<http://itc.wustl.edu/DICOMPiler/index.htm>) that can be installed on a PC. Once exported, any image analysis software package [e.g., IMAGEJ from the National Institute of Health (NIH) (<http://rsb.info.nih.gov/ij/>)] can be used to analyze the HU distribution in a region-of-interest. Alternatively, DICOM export to a third-party treatment planning system can be investigated since appropriate image analysis tools may be available within these systems.

VII. TREATMENT PLANNING FOR HELICAL TOMOTHERAPY

VII.A. Introduction

The AAPM TG-53 report describes the QA guidelines for clinical 3D conformal radiotherapy treatment planning.³² Not all of the issued guidelines apply to helical tomotherapy IMRT treatment planning, however, many aspects of these guidelines, e.g., the geometric tests of the TPS directly apply. Other aspects, such as the dosimetric verification of the TPS, apply but have to be adjusted to account for the specific workings of the TPS. In addition, for IMRT plans it is standard to check individual patient plans for accuracy. The intent of this chapter is to describe the treatment planning QA tests and their frequencies.

VII.A.1. Unique aspects of helical tomotherapy treatment planning

Since all TomoTherapy planning systems contain a common beam model, the traditional commissioning tasks of beam data entering and beam modeling do not apply to the tomotherapy planning system. There are no tools available in the treatment planning system to view the beam data that is used by the beam model. There are, however, two MLC-specific data files that are used by the planning system. These data files contain leaf latency and leaf specific fluence output data. In addition to these MLC-specific files, each machine has a specific set of y-jaw fluence output factors. These y-jaw fluence output factors specify the fluence of the 2.5 and 1.0 cm treatment slice fields relative to the 5.0 cm treat-

ment slice field output. The fluence output for the 5 cm treatment slice width is a common value used by all TomoTherapy treatment planning systems.

After machine acceptance, the on-site physicist is left with site-specific tasks such as the generation of a kVCT scanner specific CT number to mass density calibration curve and the setup of connectivity of the helical tomotherapy TPS to external hardware. In the TomoTherapy TPS, Hounsfield units are calibrated against mass density rather than the more common relative electron density.

TomoTherapy's Hi-ART II TPS is exclusively used for planning. No other commercial TPS is available to generate treatment plans for delivery with TomoTherapy machines. There are a number of unique aspects of this TPS that are either due to the unique treatment delivery or are due to the specific working of this TPS. An understanding of these aspects is in the interest of treatment plan quality.

Due to its unique treatment delivery technique, unique planning parameters need to be chosen during the generation of a helical tomotherapy plan. For each plan, the treatment slice width, pitch, and modulation factor need to be selected.

The treatment slice width is the fan-beam width that is defined by the collimating y-jaws in the longitudinal direction at isocenter. Typically, three commissioned treatment slice widths (1.0, 2.5, and 5.0 cm) are available for selection.

The pitch value is defined as the ratio of the couch travel per gantry rotation to the treatment slice width and it is recommended to be less than 1. To increase dose homogeneity, pitch values less than 0.5 are typically used.³³ For off-axis targets, dose heterogeneities due to beam divergence and the cyclic nature of rotational beam delivery are possible. This "thread" or ripple effect increases with the treatment slice widths, pitch values, and off-axis distance.³⁴ An empirical study of this effect showed that for all treatment slice widths, the relationship between the size of the thread effect and the pitch contains minima at pitch values equal to $0.86/n$, where n is an integer.³⁴ For example, for a 2.5 cm treatment slice width and a pitch value of 0.287, the thread effect has a value of about 1% (peak-to-trough) at an off-axis distance of 5 cm. Changing the pitch value to 0.5 increases the thread effect to about 3% for the same conditions. However, the thread effect has little clinical impact for targets that are located on-axis.

If the dose per fraction is significantly higher than 2 Gy it may be necessary to reduce the pitch value to about 0.2 or less. The delivery of a higher dose requires the gantry to rotate slower and this may conflict with a required minimum gantry rotation speed of one rotation per minute. A reduction of the pitch value means that the target voxel is within the beam plane for more gantry rotations. This allows the gantry to rotate faster and enables the delivery of higher doses per fraction.

The modulation factor is defined as the longest leaf opening time divided by the average of all nonzero leaf opening times. The longest leaf opening time is significant because it determines the gantry rotation speed that is used during the delivery. The modulation factor that the user selects in the planning software is the maximum allowed modulation factor that is available to the optimization software. Often, the

final treatment plan has smaller modulation factors. The final modulation factor, called the “actual MF,” is listed on the plan printout. A higher modulation factor may improve the plan quality and higher MFs are typically used for more complex target volumes. Typically, user selected modulation factors range from 1.5 to 3.5.

Treatment slice width, pitch, and modulation factor play important roles in the quality of the plan as well as the treatment time. The selection of a larger treatment slice width reduces the treatment time but may reduce dose conformity in the superior-inferior dimension. The selection of a smaller pitch value does not necessarily increase the treatment time since the gantry rotation speed is variable and can range from 15–60 s per rotation. Starting with the TomoTherapy software release 4.0, the maximum gantry speed will change from 15 to 12 s per rotation. A smaller pitch allows a faster gantry speed since a given voxel will experience more gantry rotations and less dose per rotation needs to be delivered. However, if the gantry is rotating at its maximum speed, a smaller pitch may increase the treatment time because the leaves are then forced to stay closed for a longer fraction of time. If the gantry rotation speed is reported to be at its maximum the user may wish to increase the pitch to prevent this loss of treatment efficiency.³⁵ A reduction of the modulation factor typically increases the gantry rotation speed and reduces the treatment time. However, this is only true if the gantry is not already rotating at its fastest speed. Similarly, an increase in modulation factor may not necessarily decrease the gantry rotation speed.

Once the plan parameters are selected, the dose distribution for each beamlet that passes through the target is calculated. The number of beamlets for a given plan depends on the slice width, pitch values, target volume, and shape. The beamlet calculation can be batched. The dose calculation engine uses the convolution/superposition method.³⁶ Once this beamlet calculation step is completed, the optimization process begins. A least square optimization method is used to optimize the objective function.³³

Unlike conventional linear accelerators, helical tomotherapy treatments are terminated by time. The treatment planning system assumes a constant dose rate (about 850 cGy/min at a depth of 1.5 cm with an SSD of 85 cm and a $5 \times 40 \text{ cm}^2$ static field). During the final dose computation and creation of the leaf control sinograms, the helical tomotherapy planning system uses measured MLC leaf latency data to determine the final programmed leaf opening times. At this final dose calculation, leaf opening times shorter than 20 ms are deleted from the control sinogram since they are too small in relationship to the actual leaf transition times. The final dose calculation reflects these changes and therefore it is possible to observe slight changes between the planned and final DVHs. The plan approval should be based on this final dose distribution.

Upon import into the helical tomotherapy system, the planning CT data set is typically down-sampled to an axial grid of 256×256 voxels. However, if the imported CT data set is extraordinary large, the user can choose to down-sample the CT data set to 128×128 voxels. The CT slice

width is maintained. “Coarse,” “normal,” and “fine” calculation grids are available in the helical tomotherapy planning system. Dose calculation in fine mode results in a dose calculation grid that equals the imported CT data grid; normal and coarse modes result in dose calculations for every 2×2 or 4×4 imported CT voxels in the axial image, respectively. A coarser calculation grid may compromise the accuracy of dose volume histograms, particularly when the structures are small. Clinical significance of this may depend on the importance of the critical structures, their location relative to the PTV volumes, and the dose gradients within the structure. A finer dose calculation grid requires more computation time. The dose computation time scales directly with the number of voxels.

A collection of tomotherapy-specific treatment planning tips is located in Appendix F.

VII.B. Periodic quality assurance

Periodic geometric and dosimetric validation tests are recommended. Due to the system’s complexity and uniqueness, independent dose calculation is nontrivial. The development of an independent dose calculation algorithm was recently explored by Gibbons *et al.*,³⁷ however, more commonly a dosimetric verification of the patient plan by measurement is performed.

VII.B.1. Geometric validation tests

TG-53 supplies guidance in regard to the image data import.³² CT parameters such as pixel dimension and slice thickness should transfer correctly to the TPS. The image orientation (left-right, head-foot) must be correct. Text information about the patient orientation such as head-first-supine must transfer correctly from the CT scanner to the TPS. Image grayscale values must also transfer correctly. Most TomoTherapy users import the CT data into a third-party TPS system for contouring. The contours and CT data are then sent from this third-party system to the TomoTherapy TPS. Any test on the CT import should use the same route. CT scans of well defined phantoms, e.g., the vendor supplied cylindrical Virtual Water™ phantom, can be imported via the typical clinical workflow to the TPS to verify CT orientation, dimensions, grayscale values, and attached text data. The phantom dimension in the tomotherapy TPS should be within a kVCT voxel dimension of the physical dimension of the phantom. The accompanying structure set must transfer correctly from the third-party planning system to the TomoTherapy planning system. The location, dimension, and orientation of the structure set in relation to the kVCT images should be correct.

The geometric validation tests should be performed annually and after updates on any system that is involved in the CT acquisition and transfer process.

It should be kept in mind that the helical tomotherapy system down-samples the planning CT data set to 256×256 voxels. The associated structure set is not down-sampled upon import to the TomoTherapy system.

VII.B.2. Dosimetric validation tests

While the dosimetric commissioning tests contained in TG-53 may not directly apply to the testing of the tomotherapy system, the overall goal, i.e., testing of the dosimetric accuracy, applies to the tomotherapy TPS. Phantom based end-to-end tests are well suited to perform dosimetric verification tests. In these tests, phantoms are treated like patients in the sense that they undergo the same imaging, contouring, planning, and plan delivery steps that patients would undergo.

For dosimetric verifications, phantoms must be used that allow the measurement of dose with calibrated ionization chambers. Please refer to Sec. V B 5 for a discussion of acceptable ion chambers and specific correction factors for rotational tomotherapy deliveries. The standard cylindrical Virtual Water™ test phantom that is supplied with each treatment unit is well suited for the dosimetric verification tests. In this phantom, thimble ionization chambers (the vendor supplied cylindrical Virtual Water™ phantom is designed to accommodate A1SL chambers that are commercially available from Standard Imaging Inc., of Middleton, WI) can be placed at multiple locations.

Plans designed to treat on-axis and off-axis cylindrical targets should be generated for each commissioned slice width. A normal dose calculation grid should be used for the dose calculation. Targets should have volumes that are significantly larger than the sensitive volume of the ionization chamber. At a minimum, two targets, one centered at the center of rotation as indicated by the stationary green lasers and one off-axis target, should be treated in one plan or two separate plans. The AAPM Task Group Report 119 on “IMRT commissioning: Multiple institution planning and dosimetry comparisons” has produced a set of test plans and the physicist may want to review this document for guidance.³⁸

There is no fundamental difference between the plans generated for the dosimetric verification and the plan generated for the pCSR-field calibration in Sec. V B 5 b and for the largest commissioned slice width the same plan can be used for both purposes.

Multiple point dose measurements should be performed in high and low dose regions. Dose gradient regions can be verified with multiple point dose measurements or planar dosimeters such as film or detector arrays. The acceptability criteria for dosimetric verifications are debated in the community. TG-53 lists dosimetric criteria but clarifies that these

criteria are “collective expectation” values rather than requirements.³² For 3D TPS systems, Van Dyk³⁹ listed acceptability criteria of 3% of the reference dose for high and low dose regions with low dose gradients and a 3 mm spatial agreement in high dose gradient regions. These values do not apply to areas of dose build-up or build-down. The recent TG-119 report provides helpful benchmark data that can be consulted for comparison when commissioning IMRT systems. In the TG-119 Report, a 3%/3mm gamma criteria were used for the evaluation of planar dose distributions.

Acceptability criteria for IMRT plans are currently formulated by the International Commission on Radiation Units and Measurements (ICRU) and will be published in a forthcoming ICRU report. Until the publication of this report, the Task Group recommends the use of 3%/3mm criteria for the dosimetric evaluation of the tomotherapy system. For the generated tomotherapy plans, point dose measurements should agree with the calculated dose to within 3% of the prescription dose or satisfy a 3 mm distance to agreement criterion. To evaluate the dosimetric pass rates the benchmark data provided by TG-119 can be consulted.

Ideally, a set of non-homogeneous phantoms should be available for testing prior to the start of patient treatment. Furthermore the verification of the calculated dose in regions other than unit density tissue is desirable. Several commercial phantoms exist for this purpose. However, in-house phantoms can be assembled to serve this purpose.

The dosimetric verification of the TPS should be performed after TPS software maintenance and annually.

VII.B.3. Clinical treatment plan QA

Once the planning system is used clinically each patient plan needs to be double checked for accuracy. Since no commercial solution for independent recalculation of helical tomotherapy dose distribution exists, current practice is to calculate each individual plan in a phantom geometry such that it can be dosimetrically verified by measurement. This current practice may evolve over time and alternative test procedures may be developed to replace the current one.

In the helical tomotherapy literature, dose recalculation of the treatment plan into a phantom geometry is called a DQA procedure. Tools to facilitate the DQA planning and analysis are integrated in the TomoTherapy planning software package. The DQA process requires that a CT scan of the phantom is imported into the tomotherapy planning system. After the calculation of the dose distribution in the phantom, point

TABLE II. Recommendations and tolerance limits for daily quality assurance procedures.

Daily test	Purpose	Tolerance limit	Report section
Output—Rotational or static	Consistency	3%	V.B.2.d
Image/laser coordinate coincidence	Accuracy	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.b
Image registration/alignment	Accuracy	1 mm	VI.B.1.c
Red laser initialization	red=green laser	1.5–1 mm (non-SRS/SBRT-SRS/SBRT)	V.B.4.b

doses and planar dose distributions can be compared to measurements. A planar dose distribution can be exported from the tomotherapy system and this feature can be used for comparison with diode or ionization chamber arrays. Van Esch *et al.*⁴⁰ reported the use of an ionization chamber array for the dosimetric verification of tomotherapy plans. The use of a device that incorporates two orthogonal diode arrays for tomotherapy IMRT QA is reported by Guerts *et al.*⁴¹

It should be understood that the DQA plan verification does not test all aspects of the calculated treatment plan in the patient anatomy. For example, an incorrect mass density table could be applied during the patient plan calculation. This error will not be detected in a DQA procedure. Similarly, the correct replacement of the CT couch with the tomotherapy couch in the patient plan is not tested in the DQA process.

Most users currently use the vendor supplied cylindrical Virtual WaterTM phantom for the patient plan verification and this is an acceptable verification procedure. In this process, a single point dose is measured with an ionization chamber and a single 2D dose distribution is measured with film. The measured ionization chamber points should be within 3% of the dose calculated with the TPS. If the measured ionization chamber point differs by more than 3% but less than 5%, it is recommended that the physicist investigate the discrepancy. At the discretion of the physicist and attending physician,

treatment can be continued. If the discrepancy exceeds 5%, a thorough investigation is recommended prior to patient treatment. During the process of generating a DQA plan, the requested phantom position can be changed in the TPS and care should be taken to position the phantom such that the ionization chamber point is in a high dose and low dose gradient region. An ionization chamber measurement in such a region minimizes the problems associated with dose variations over the effective volume of the chamber. However, even larger low gradient dose regions are produced by the superposition of smaller fields and the user should be aware of uncertainties associated with small field dosimetry such as the potential lack of electronic equilibrium.

Analysis of the film plane is more revealing if the expected dose map contains both high and low dose regions. For planar dosimetry, a rectangle that encompasses the area within 5 mm from the phantom edge should be analyzed for a gamma coefficient.⁴² It is the experience of the TG-148 Task Group that tomotherapy DQA plans that are calculated on a normal dose grid have typical gamma pass rate of at least 90% when a 3% dose difference/3 mm distance to agreement gamma criterion is used. The 3% dose difference is based on the prescription dose. If film dosimetry is used for the gamma analysis, the film dose can be scaled to match the ionization chamber reading in the target dose. While the TPS software facilitates the calculation of a gamma index, it

TABLE III. Recommendations and tolerance limits for monthly quality assurance procedures.

Monthly test	Purpose	Tolerance limit	Report section
Beam parameters			
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Monitor chamber constancy	Constancy between monitor chambers	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference in field core	V.B.2.b
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
Alignment and Misc.			
Interrupted procedure	Agreement with uninterrupted Proc.	3%	V.B.4.a
Red laser movement	Correct movement	1 mm	V.B.4.b
Treatment couch	Digital readout versus actual movement	1 mm	V.B.4.c
Treatment couch	Level	0.5°	V.B.4.c
Treatment couch	Longitudinal motion alignment	1 mm	V.B.4.c
Treatment couch	Sag	5 mm	V.B.4.c
MVCT			
Geometric distortions	Dimension, orientation	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.a
Noise	Monitor image quality	Consistency with baseline	VI.B.2.a
Uniformity	Monitor image quality	Consistency with baseline	VI.B.2.b
Spatial resolution	Monitor image quality	1.6 mm object	VI.B.2.c
Contrast	Monitor image quality	Consistency with baseline	VI.B.2.d
<i>(if MVCT is used for dose calc.)</i>			
Uniformity	Monitor image quality	25 HU	VI.B.2.b
HU (water test plug)	Monitor HU accuracy	within ±HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within ±HU 50 of baseline	VI.B.2.e

TABLE IV. Recommendations and tolerance limits for quarterly quality assurance procedures.

Quarterly test	Purpose	Tolerance limit	Report section
Synchronicity			
Gantry angle	Correct and consistent	1°	V.B.3.a
Couch speed uniformity	Uniform	2% dose nonuniformity	V.B.3.b
Couch translation per gantry rotation	Synchrony	1 mm per 5 cm	V.B.3.c
MVCT			
Dose	Monitor image dose	Consistency with baseline	VI.B.3

does not currently allow the selection of a region of interest for analysis. Hence, the evaluation of the pass criteria requires export and analysis of the measured and calculated dose distributions with third-party analysis programs. At the discretion of the on-site physicist(s), a visual evaluation of the calculated gamma distribution may suffice.

If DQA results are outside the tolerance level, the clinical physicist needs to investigate. Initially, the phantom setup should be verified along with the correct extraction of the calculated point dose from the TPS. It should also be investigated if the ionization chamber measurement is in or near a high-gradient region. While this scenario should be avoided,

TABLE V. Recommendations and tolerance limits for annual quality assurance procedures.

Annual test	Purpose	Tolerance limit	Report section
Mechanical alignments			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
y-jaw/gantry rotation plane alignment	y-jaw alignment with axis of rotation	0.5°	V.B.1.d
Treatment beam field centering	Common center	0.5 mm at iso	V.B.1.e
MLC lateral offset	MLC alignment with center of rotation	1.5 mm at iso	V.B.1.f
MLC twist	Alignment with beam plane	0.5°	V.B.1.f
Beam parameters			
Beam quality (each slice width)	Agreement with model	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile (each slice width)	Agreement with model	1% average difference in field core	V.B.2.b
Longitudinal profiles (each slice width)	Agreement with model	1% of slice width at FWHM	V.B.2.c
TG-51 calibration	Calibration	1%	V.B.5
Misc.			
Axial green laser (distance and twist)	Nominal distance to iso	1 mm/0.3°	V.B.4.b
Sagittal/coronal green laser	Alignment with axis of rotation	±1 mm	V.B.4.b
MVCT			
Imaging/treatment/laser coordinate coincidence	accurate location of dose	2–1 mm (non-SRS/SBRT-SRS/SBRT)	VI.B.1.b
Treatment planning system			
<i>CT data import</i>			
Dimension of object in TPS	Agreement with physical dimension	1 kVCT voxel	IV.B.2
CT voxel dimensions	Correct transfer	Pass/fail	IV.B.2
CT orientation	Correct transfer	Pass/fail	IV.B.2
CT gray scale values	Correct transfer	Pass/fail	IV.B.2
Associated text info	Correct transfer	Pass/fail	IV.B.2
<i>Structure set import</i>			
Dimension of structure	Agreement with contouring software	1 kVCT voxel	IV.B.2
Location of structure	Agreement with contouring software	Pass/fail	IV.B.2
Orientation of structure	Agreement with contouring software	Pass/fail	IV.B.2
<i>Dosimetric verification</i>			
Point dose in low gradient area	Agreement with TPS	Within 3%	IV.B.3
Point dose in high gradient	Agreement with TPS	3%/3 mm	IV.B.3

TABLE VI. Recommendations and tolerance limits for quality assurance procedures post major component replacement.

After major component replacement test	Purpose	Tolerance limit	Report section
Magnetron/SSM			
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference in field core	V.B.2.b
Longitudinal profile	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
<i>(if MVCT is used for dose calc.)</i>			
HU (water test plug)	Monitor HU accuracy	within \pm HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within \pm HU 50 of baseline	VI.B.2.e
Linac/target			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
Beam quality	Consistency with baseline	1% PDD ₁₀ or TMR ₁₀ ²⁰	V.B.2.a
Transverse profile	Consistency with baseline	1% average difference	V.B.2.b
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
<i>(if MVCT is used for dose calc.)</i>			
HU (water test plug)	Monitor HU accuracy	within \pm HU 30 of baseline	VI.B.2.e
HU (lung/bone test plug)	Monitor HU accuracy	within \pm HU 50 of baseline	VI.B.2.e
y-jaw (actuators/encoders)			
y-jaw centering	Source to y-jaw alignment	0.3 mm at source	V.B.1.a
y-jaw divergence/beam centering	Source alignment with axis of rotation	0.5 mm at iso	V.B.1.c
y-jaw/gantry rotation plane alignment	y-jaw alignment with axis of rotation	0.5°	V.B.1.d
Treatment beam field centering	Common center	0.5 mm at iso	V.B.1.e
Longitudinal profiles (each slice width)	Consistency with baseline	1% of slice width at FWHM	V.B.2.c
Output—Static (IC)	Consistency	2%	V.B.2.d
Output—Rotational (IC)	Consistency with TPS	2%	V.B.2.d
Rotation output variation	Amplitude of variation	2%	V.B.2.d
DQA/phantom plan	Agreement with TPS	3%	VII.B.5
MLC			
x-alignment of source	Source to MLC alignment	0.34 mm at source	V.B.1.b
MLC lateral offset	MLC alignment with center of rotation	1.5 mm at iso	V.B.1.f
MLC twist	Alignment with beam plane	0.5°	V.B.1.f
DQA/phantom plan	Agreement with TPS	3%	VII.B.5

a small target volume may result in the chamber being placed in or near such a high gradient. If the target is considerably off-axis and the plan was generated with a large pitch value or slice width, the measurement point may be in an inhomogeneous area due to the thread effect. Volume averaging and distance to agreement techniques can be used judiciously when DQA discrepancies are investigated.

A drift in the machine output can lead to unacceptable DQA results. A repeat of a previous or a standard DQA plan can be useful for this analysis. An analysis of the daily out-

put checks could also be helpful. An adjustment of the machine output may be required. It is recommended that the physicist has a standard IMRT plan available for each treatment slice width. Phantom plans or previous DQA plans for representative clinical scenarios can be used for this purpose. These plans would have similarities in gantry speed, leaf opening times, etc., and a repeat of these plans may help to determine if the measured dose discrepancy is specific to a plan or uniform for all plans.

The use of short leaf opening times has been associated

with possible DQA discrepancies.³⁵ Shorter leaf opening times occur if plans use low pitch values. Planning with a higher pitch value (around 0.287 for a prescription dose of 2 Gy) will reduce this delivery uncertainty.

VII.C. MVCT-based treatment planning

Metallic implants cause fewer image artifacts in MVCT images compared to standard kVCT images. MVCT-based treatment planning can hence be of advantage for patients that have artificial implants and in whom regular kVCT artifacts hinder treatment planning.⁴³

If MVCT images are used for treatment planning purposes, it is recommended that an up-to-date MVCT to mass density table be measured immediately before or after the patient planning image is acquired. This recommendation is based on the observation that the MVCT Hounsfield numbers are susceptible to changes in the imaging beam that are secondary to target wear and other factors that are still under investigation. It is also recommended to obtain a scan of the DQA phantom at the same time. This latter scan should be used in the DQA process of the MVCT-based treatment plan. The measured MVCT density table should be applied to the patient and DQA phantom MVCT images. Furthermore, it is recommended to contour areas of high density such as metallic hip implants and to prohibit beam entrance through these areas. This is done to avoid uncertainties in the beam attenuation calculations associated with high-density materials. These uncertainties have two sources: (1) The fluence attenuation tables have data up to a maximum density of 4 g/cm³ and for higher densities the TPS defaults to using this maximum density and (2) the IVDT tables for MVCT images will need to be extended to high-density materials.

VIII. SUMMARY AND RECOMMENDATIONS

In this chapter, the QA aspects discussed in the previous chapters are summarized and arranged according to their recommended frequencies. Recommendations on what to QA after machine service work are also listed in the chapter for several service scenarios.

VIII.A. Daily

On a daily basis, the beam output should be monitored. The output consistency should be measured under static and/or rotational conditions. If the static output is monitored on a daily basis, the rotational output should be monitored on a weekly basis and vice versa. The correct initialization of the laser system should be checked. After the image registration, the automatic couch and red laser adjustment should be tested daily. It should be checked visually that the MVCT quality is consistent with that accepted at time of commissioning and that there are no gross artifacts in the image. It should be checked that the image registration process is operating consistently. An example procedure that combines several tests in one procedure is outlined in Appendix D. Table II summarizes the recommendations for daily QA.

Standard safety tests are not included in this list. They should be performed per recommendations detailed in TG-142.³

VIII.B. Monthly

Monthly tests cover beam parameter consistency tests, MVCT tests and miscellaneous aspects. Table III summarizes the recommended tests and their tolerance limits. Standard safety tests such as interlock testing are not covered in the table but should be performed per recommendations detailed in TG-142.³

VIII.C. Quarterly

On a quarterly basis, the gantry angle and the uniformity of the couch movement should be tested. The synchrony between couch translations and gantry rotations should also be tested at this interval. The MVCT dosimetry should be done quarterly. Table IV summarizes the recommended tests and their tolerance limits.

VIII.D. Annual

Annual tests contain mechanical alignment, beam parameters, and miscellaneous test items. MVCT registration and an end-to-end test of the registration process should be performed as well as several treatment planning system tests. Table V summarizes the recommended tests and their tolerance limits.

VIII.E. Major component replacement

The replacement of major components necessitates QA tests. These tests obviously depend on the particular service issues. Recommended post service tests are discussed for several scenarios. Table VI summarizes the recommended QA test for four service scenarios.

Magnetron/solid state modulator (SSM): A replacement of the magnetron or SSM can change beam parameters such as output and beam energy. It is recommended that the user tests beam output, energy, and longitudinal as well as lateral profiles. The beam parameters only need to be tested for one slice width. It is the intent of these tests to check that the parameters are consistent with the baseline values. A repeat of the monthly QA procedures of these beam parameters should be sufficient to establish consistency with nominal values. If MVCT images are used for dose calculations, the monthly QA test for HU accuracy should be performed. Post service, a DQA or phantom plan should be checked and verified for agreement with calculations. This last step also forces the user to exercise all functions (imaging registration and treatment) that are used for regular treatments. This tests that the system is fully operational.

Linac or target: A replacement of the target requires a movement of the Linac during the process. The source alignment (Sects. V B 1 a, V B 1 b, and V B 1 c) needs to be tested post-target/linac replacement. In addition, all tests that are recommended post magnetron/SSM replacement should be performed post-target/linac alignment.

Y-jaw: Work on the y-jaws, actuators, or encoder necessitates a verification of the y-jaw alignment and longitudinal beam profiles. The jaw centering, divergence, and alignment with the rotation plane should be checked in addition to the treatment field centering. Longitudinal beam profiles should be collected and checked for agreement with the reference beam data. In addition to a beam output check, DQA or phantom plans should be checked for each commissioned slice width and verified for agreement with calculations.

MLC: Replacement of the MLC requires MLC alignment tests to be performed. The MLC lateral offset as well as the MLC twist should be tested. The vendor includes MLC-

specific leaf latency data in the treatment planning system. It is not possible to adjust the leaf latency for a given MLC. Instead, the vendor will measure and update these data in the TPS after a MLC replacement. These data are used at the time of "Final Dose" calculation and therefore are only applied to plans that are generated subsequently. Existing plans are not altered. It is therefore recommended to repeat several DQA plans for existing patients to ensure that these are within acceptable tolerance. Plans with short leaf opening times may be more sensitive and should be included in the group of plans that is selected for this test. If DQA plans are out of tolerance the user may have to replan selected cases.

APPENDIX A: WORKSHEET A: HELICAL TOMOTHERAPY PHOTON BEAM CALIBRATION**1. Site data**

Institution:

Physicist:

Date:

Accelerator:

Model & serial number:

2. Instrumentation**a. Chamber model:**

Serial number:

Cavity inner radius (r_{cav}):

cm

Waterproof: yes no If no, is waterproofing \leq 1 mm PMMA or thin latex?: yes no **b. Electrometer model:**

Serial number:

i. P_{elec} , electrom. corr. factor:

C/C or C/rdg

c. Calibration factor N_{D,W,Q_o} :

Gy/C (or Gy/rdg)

Date of report (not to exceed 2 years):

3. Measurement Conditions (choose step a. or step b.)**a. Static Beam Output** (5 cm x 10 cm, measurement at 10 cm depth water equivalent)i. Distance (SSD or SAD): _____ cm SSD or SAD ii. Field size: _____ cm^2 on surface (SSD setup): at detector (SAD setup):

iii. Irradiation time: _____ min

b. Rotational Beam Output (8 cm diameter x 10 cm long homogeneous dose volume
within a 30 cm diameter water equivalent phantom)

i. Axial collimation: _____ cm

4. Beam Quality

Measure beam quality specifier %dd(10)_{x(HT ref)} [FS=5 cm × 10 cm, 85 cm SSD, % depth-dose at 10 cm depth for curve shifted upstream by $0.6r_{cav}$]

Field size 5 cm x 10 cm on surface, SSD = 85 cm: yes no

a. %dd(10)_{x(HT ref)} : _____

Using the following equation or Figure 19 to determine %dd(10)_{x(HT TG-51)} :

$$\begin{aligned} \%dd(10)_{x[HT\ TG-51]} &= 1.35805 \cdot (\%dd_{(10)x[HT\ ref]})^3 \\ &\quad - 244.493 \cdot (\%dd_{(10)x[HT\ ref]})^2 \\ &\quad + 14672.98 \cdot \%dd_{(10)x[HT\ ref]} \\ &\quad - 293479.4 \end{aligned}$$

b. %dd(10)_{x(HT TG-51)}: _____

5. Determination of $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$

Chamber model used to get $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$: _____

a. $k_{Q,Q_0} \times k_{Q_{msr},Q}^{f_{msr}, f_{ref}}$ [Table 1]: _____

6. Temperature/pressure Correction

a. Temperature: _____ °C

b. Pressure: _____ kPa $\left[= \text{mmHg} \frac{101.33}{760} \right]$

c. P_{TP} : _____ $\left[P_{TP} = \left(\frac{273.2 + 6a}{295.2} \right) \left(\frac{101.33}{6b} \right) \right]$

7. Polarity correction

M_{raw}^+ : _____ C or rdg

M_{raw}^- : _____ C or rdg

a. M_{raw} (for polarity of calibration): _____ C or rdg

b. P_{pol} : _____ $\left[P_{pol} = \left| \frac{(M_{raw}^+ - M_{raw}^-)}{2M_{raw}} \right| \right]$

8. P_{ion} measurementsOperating voltage = V_H : _____ VLower voltage V_L : _____ V M_{raw}^H : _____ C or rdg M_{raw}^L : _____ C or rdg

a. $P_{ion}(V_H)$: _____

$$P_{ion}(V_H) = \left(1 - \frac{V_H}{V_L} \right) \left/ \left(\frac{M_{raw}^H}{M_{raw}^L} - \frac{V_H}{V_L} \right) \right.$$

If $P_{ion} > 1.05$, another ion chamber should be used.**9. Corrected ion. ch. rdg. M for msr or pcsr field:**

$$M_{corr} = P_{ion} P_{TP} P_{elec} P_{Pol} M_{raw} = [8a \cdot 6c \cdot 2b \cdot i \cdot 7b \cdot 7a] = _____$$

10. Dose to water at 10 cm depth for Static Beam Output:

a. $D_{w,Q_{msr}}^{f_{msr}} = M_{Q_{msr}}^{f_{msr}} \cdot N_{D,w,Q_0} \cdot [k_{Q,Q_0}^{f_{msr}, f_{ref}}] = [9 \cdot 2c \cdot 5a] = _____$ Gy

b. Dose/ min at 10 cm depth: _____ Gy/min [10a/3a.iii]

c. Clinical % $dd(10)$ for SSD setup / 100: _____

or clinical TMR(10) for SAD setup: _____

Dose / min at d_{max} : _____ Gy/min [10b/10c]**11. Correction factor between conventional reference field and plan-case specific reference field**

$$k_{Q_{pcsr}, Q_{msr}}^{f_{pcsr}, f_{msr}} : 1.003$$

12. Dose to pcsr field for Rotational Beam Output:

$$D_{w,Q_{pcsr}}^{f_{pcsr}} = M_{Q_{pcsr}}^{f_{pcsr}} \cdot N_{D,w,Q_0} \cdot [k_{Q,Q_0}^{f_{msr}, f_{ref}}] \cdot k_{Q_{pcsr}, Q_{msr}}^{f_{pcsr}, f_{msr}} = [9 \cdot 2c \cdot 5a \cdot 11] = _____$$
 Gy

APPENDIX B: NOTE ON CONTROL XML FILES AND CONTROL SINOGRAMS

Typically, the machine receives operating instructions via XML files that are generated at the end of the treatment planning process. To pass instructions to the machine independently of the treatment planning system requires that the user generate an XML file. Tools to generate XML files are included in the operator station software. These files contain, among others, instructions on gantry position, table movements, and MLC opening patterns. The vendor supplies a number of XML files and the associated binary MLC control files (control sinograms) that can be used to run some of the procedures detailed in this report. If the user wants to generate their own XML files, it is recommended to select an existing XML file and modify it according to the user's intentions. These files can be viewed, modified, and saved using the operator station software. Details of how to develop XML files can be found in the TomoTherapy documentation (Calibration Data Tool Guide, Version 3.X).

Embedded in the XML file is a reference to a binary file referred to as the control sinogram which controls the timing of the binary MLC leaves during treatment delivery. The control sinogram is a binary file with 64 columns. Each column contains a value ranging from 0.0 to 1.0. These values are normalized opening times for each leaf. Leaf opening times must be supplied for each leaf and projection. The sinogram files must therefore have a minimum number of rows that is equal to the number of delivered projections. The duration of each projection is defined elsewhere in the XML file.

APPENDIX C: RADIATION SAFETY

IMRT techniques have raised unique room-shielding concerns that are mainly due to increased workloads. In addition to room shielding, leakage concerns have been raised for some systems since the increased workload may affect the whole body doses that the patient receives.⁴⁴

Shielding and leakage concerns specific to helical tomotherapy have been addressed in the literature.⁴⁵⁻⁴⁹ The continuous rotation of the gantry complicates the traditional usage factor that accounts for the particular beam direction employed. Additionally, due to the exclusive IMRT treatment mode, the workload is significantly larger than with traditional accelerators. Workloads of 10^6 MU per week are often assumed for shielding calculations, which is about an order of magnitude greater than the workload for non-IMRT accelerators.⁴⁶ However, since helical tomotherapy was designed exclusively as an IMRT machine, extra shielding was designed into the accelerator head. This extra shielding is assembled around the linac to (i) protect the patient from unwanted exposure and to (ii) reduce linac leakage. In addition, a beam stop was added to the machine that provides over two orders of magnitude of primary beam attenuation. Continuous gantry rotation also serves to decrease the contribution of primary beam exposure since it limits the time any point is exposed to the primary beam. There is actually more exposure due to backscattered leakage radiation than

due to direct primary radiation at 2 m from the isocenter. Due to differences in energy between primary and leakage radiation and different effective source positions, that ratio may change as a function of shielding wall distance and thickness. A final but significant advantage for room-shielding designs is that helical tomotherapy units only have a single nominal 6 MV beam energy.

Patient scatter is approximately the same as with all external beam radiation therapy since the patient integral dose is approximately the same regardless of the modality. The effect of the unique tomotherapy design is that backscattered leakage radiation dominates shielding concerns. Tomotherapy provides a site-planning guide which lists a polar plot of leakage levels versus distance and angle from the isocenter to assist in shielding design.

In general, helical tomotherapy units can safely be installed in most bunkers with standard-density concrete walls 3.5 to 4.0 ft thick. Of course, each proposed bunker must be extensively analyzed. Furthermore, goal exposure levels do vary according to the site specifics. To verify shielding requirements post install, access to an integrating survey meter is helpful.

Exposure due to scattered radiation at the door is similar to that of conventional machines. Radiation at the door consists mostly of scattered leakage radiation. As such, it is of much lower energy. McGinley⁵⁰ has calculated such scattered photon radiation to be less than 0.3 MeV. Therefore, a 1/4 in. lead liner in a wood door is usually more than sufficient for shielding. Exact entrance exposure is dependent on maze length and width and overall room size and geometry.

TomoTherapy, Inc. will soon offer a new product, "TomoDirect." This will allow the gantry to operate in a static gantry mode while the couch translates and MLC leaves modulate. This will decrease beam-on time for some treatments more suitable for nonrotating delivery. It is not yet known how TomoDirect will affect shielding requirements. Most likely, required shielding will only decrease because TomoDirect was designed to decrease beam-on time.

The unique features of the tomotherapy unit may conflict with certain local regulations such as regulations on field flatness and symmetry. Local regulations should be interrogated for possible conflicts. Regulatory exemptions may have to be applied for.

APPENDIX D: EXAMPLE OF DAILY TEST PROCEDURES

With the gantry at a static position the beam output can be tested. The rotational output (or integral dose) can be tested with a phantom patient plan. This procedure is generated in the TPS. During the plan generation, the movable red lasers can be intentionally offset from the alignment marks. The offsets should be similar to what is typically encountered in the clinic. A daily MVCT scan, registration, and alignment of this phantom then serves to test the laser functionality, image registration, and automatic couch alignment procedure. The final phantom position can be checked against the green laser system by marking the expected green laser projection on the

phantom. If the phantom is always placed in the same location on the couch (e.g., phantom position can be marked on couch), the consistency of the initial table readout is also tested. After alignment, the delivery of the correct dose can be verified, i.e., the rotational output can be tested. All tests can be done with the vendor supplied cylindrical Virtual WaterTM phantom. However, some users have designed phantoms specifically for daily QA of TomoTherapy units.⁷

APPENDIX E: PATIENT ARCHIVES

The user can generate an archive of a patient plan at any time using the patient archiving tool integrated in the planning station or operator station software. This patient archive contains a wealth of information: Planning parameters, kVCT and MVCT images, planned MLC sinograms, recorded detector data sinograms, recorded monitor chamber signal, and more. Some of this information is stored in binary format in separate files that are part of the archive. Each patient archive contains an XML file that is labeled with the patient's name. This XML file contains numerical information (e.g., registration offsets) and provides the file names for the MVCT or detector sinogram files. The patient archive can then be searched for this file. A third-party XML viewer is recommended to view the XML file and third-party software, e.g., MATLAB (The MathWorks, Inc., Natick, MA), can be used to read, display, and analyze image or sinogram files. Detector data can also be extracted immediately after a procedure is completed using a tomotherapy quality assurance tool that is commercially available from the vendor.

APPENDIX F: TREATMENT PLANNING TIPS

Like other IMRT TPS, the helical tomotherapy planning system is driven by dose-based objectives, their associated penalties, and ROI-based weighting factors. For tumor or target volumes, minimum and maximum dose values and their respective penalties are used in addition to a DVH-based prescription point. Sensitive structure objectives are described by a maximum dose, a DVH-based constraint, and their respective penalties. However, it is important to recognize that in the helical tomotherapy TPS, the DVH-based prescription for one selected target structure is a hard constraint, which means that it is always met. The optimized treatment plan is scaled after each iteration to satisfy this DVH-based prescription dose.

The treatment planning system prompts the user to divide regions of interest into two groups: (i) Tumors and (ii) sensitive structures. If ROIs in the same group overlap, the voxels contained in the overlap region can only be assigned to one or the other structure for the purpose of plan optimization and dose volume histogram calculations. The overlap priority setting governs to which structure the voxel belongs. It is therefore possible that in the case of overlapping structures, the DVH statistics may not completely reflect the volume of interest. It is important that all involved parties understand this. However, in future software releases, the use

of overlap priorities may change and the user needs to be aware how these priority settings are used in their current software release.

There are two sets of lasers used in helical tomotherapy planning and delivery. Fixed green lasers define a virtual isocenter that is nominally 70 cm away from the gantry (treatment and imaging beam) isocenter. A movable red laser system is used for patient positioning. During the treatment planning process, the red lasers can be requested to point toward the patient's setup marks. The physical movement of the red lasers in the treatment room is restricted to a maximum distance of about 20 cm from the green laser system at isocenter. The exact value depends on the particular laser placement in the room and is site-specific. During treatment planning, it is possible to request larger movements of the red laser system. However, these requests result in a hardware error interrupt (i.e., a nondeliverable procedure) once these plans are selected for treatment. This scenario can be avoided if a smaller laser separation is selected. The selected distance should allow for possible further red laser movements after image registration. The axial laser settings are most susceptible to this issue and the position of the axial green laser with respect to the patient can be adjusted in the planning system to alleviate this problem.

During treatment the patient is moved in the longitudinal (i.e., y) direction through the rotating fan-beam plane. The fan beam is used for treatment as soon as the superior target edge enters the beam plane and the treatment is completed only after the inferior target edge leaves the beam plane. Consequently, an area equivalent to the longitudinal dimension of the fan beam is exposed superior and inferior to the target volume. It is recommended that the treatment planning CT volume extends superior and inferiorly beyond the target volume by a length sufficient to include any irradiated volume. Taking beam divergence into account this is typically satisfied if the CT volume extends by a distance larger than two treatment slice widths.

^{a)}Conflict of interest: Dr. Gustavo Olivera is an employee of TomoTherapy, Inc. and has a financial interest in TomoTherapy, Inc. Dr. Olivera served as an industry consultant to this task group. Dr. John Balog owns TomoTherapy stock. Dr. Katja Langen holds a research agreement with TomoTherapy, Inc.

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24

American College of Radiology

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The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2009 (Resolution 8)*

ACR PRACTICE GUIDELINE FOR RADIATION ONCOLOGY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action

based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Radiation oncology, together with surgical and medical oncology, is one of the 3 primary disciplines involved in cancer treatment. Radiation therapy with either curative or palliative intent is used to treat up to 60% of all cancer patients [1]. Radiation therapy uses ionizing radiation, delivered with either external beam therapy or radioisotopes, to destroy or inhibit the reproductive ability of neoplastic cells or to cause programmed cell self-destruction (apoptosis). It is also occasionally used to inhibit the growth of non-neoplastic tissues in certain benign diseases.

Separate guidelines and standards define the appropriate use of external beam therapy, brachytherapy, and therapies using radioisotopes, sealed isotopes, and unsealed isotopes. This guideline addresses the overall role of the radiation oncologist, medical physicist, and other specialized personnel involved in the delivery of radiation therapy.

The use of radiation therapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education. Because the practice of radiation oncology occurs in a variety of clinical environments, the judgment of a qualified radiation oncologist should be used to apply these guidelines to individual practices.

A literature search was performed and reviewed to identify published articles regarding guidelines and

standards in radiation oncology. Selected articles are found in the suggested reading section.

II. PROCESS OF RADIATION THERAPY

The clinical use of ionizing radiation is a complex process involving trained personnel who carry out a variety of interrelated activities.

A. Clinical Evaluation

The initial evaluation of the patient includes obtaining a history, performing a physical examination, reviewing pertinent diagnostic studies and reports, and communicating with the referring physician and other appropriate physicians involved in the patient's care. The extent of the tumor must be determined and recorded for staging; this will facilitate treatment decisions, determine prognosis, and allow a comparison of treatment results. Consideration should be given to performing pain assessment when clinically appropriate.

B. Establishing Treatment Goals

The goal of treatment (curative, palliative, adjuvant, or to establish local tumor control) should be defined as clearly as possible. Treatment options with their relative merits and risks should be discussed with the patient. If the treatment plan requires combining radiation therapy with surgery, chemotherapy, or other systemic therapies, the anticipated interactions between the modalities should be discussed with the patient. A summary of the consultation should be communicated to the referring physician and to other physicians involved in the care of the patient [2].

C. Informed Consent

Prior to simulation and treatment, informed consent must be obtained and documented. The anticipated side effects and potential complications, the availability of alternative treatment options, and the risks and benefits of forgoing treatment, should be discussed with the patient. The radiation oncologist should ensure that language and cultural barriers do not prevent the patient from gaining the understanding of his/her disease and treatment plan necessary to provide informed consent [3].

D. Patient Education

To help patients retain the information that the radiation oncologist imparts to them at the time of the consultation visit, additional reinforcement of patient education may be considered. Techniques may include subsequent visits between the patient and the radiation oncologist or nurse, and/or the use of printed materials or electronic presentations.

E. Simulation of Treatment

Simulation is the process of establishing and documenting the appropriate volume to be treated and identifying the normal structures within or adjacent to this volume. During simulation, optimal patient positioning is determined. Treatment positioning devices are used or fabricated as needed to aid in optimal positioning and reproducibility. Patient anatomic data are acquired, often with computed tomography (CT) imaging (treatment-planning CT scan) or other modalities (i.e., magnetic resonance imaging (MRI), positron emission tomography (PET), ultrasound). For some situations, simpler 2-dimensional simulation techniques may be appropriate. Beam entry sites and other points helpful in patient positioning and field localization are identified on the patient. All field setups should be documented by properly labeled photographs and/or diagrams and, when appropriate, by standard radiographs or digitally reconstructed radiographs (DRRs).

After treatment planning has been completed, a simulation-per-plan procedure may be appropriate. This procedure involves duplicating the intended treatment setup either on a conventional simulator or on the treatment unit itself. Images of each intended treatment portal and of associated treatment parameters are obtained and are compared to planning images generated from the treatment planning system to confirm accuracy and reproducibility of treatment setup and delivery.

F. Treatment Planning

The cognitive process of treatment planning requires the radiation oncologist to have knowledge of the natural history of the tumor to be treated and to determine the tumor site, its extent, and its relationship with adjacent normal tissues. This process is based on consideration of the history, physical examination, endoscopy, diagnostic imaging, findings at surgery, pathological findings, and response to previous therapies.

When ionizing radiation is to be used, the radiation oncologist must select beam characteristics and/or radionuclide sources, method of delivery, doses, and coordination with other treatments. Multimodality treatments should be coordinated in collaboration with medical and surgical oncologists and other specialists. The radiation oncologist determines the dose to be delivered to the tumor, limiting doses to critical structures, and the fractionation desired. Using these parameters, the radiation oncologist directs the medical physicist and dosimetrist in the design of potential treatment programs or develops them personally. This process uses the patient data obtained during the initial simulation procedure. Beam-specific physical data are used with source data and other physical characteristics measured by the physicist to calculate the dose to a

specific point within the patient or to calculate the dose distribution within a region of interest.

The radiation oncologist, in consultation with the medical physicist and dosimetrist, selects the treatment plan. The radiation oncologist prescribes the radiation treatment course. The prescription should include: volume (site) to be treated, description of portals (anteroposterior [AP], posteroanterior [PA], lateral, etc.), radiation modality, energy, dose per fraction, number of fractions per day, number of fractions per week, total number of fractions, total tumor dose, and prescription point or isodose volume. The prescription shall be signed by the radiation oncologist prior to the initiation of radiation therapy or approved electronically. The graphical isodose plan, when warranted, should be signed within 1 week of initiation of treatment.

Daily treatments are carried out by the radiation therapist following the prescription and treatment plan of the radiation oncologist. It is essential that all treatment parameters be described in detail and orders be signed by the responsible radiation oncologist. Likewise, any changes in the planned treatment by the radiation oncologist requiring adjustment in immobilization, new calculations, or even a new treatment plan must be documented on the record and signed or initialed by the radiation oncologist.

G. Fabrication of Treatment Aids

Devices to aid in positioning and immobilizing the patient, normal tissue shielding, compensating filters, etc. are designed to improve treatment accuracy and reduce treatment toxicity. They should be used where clinically appropriate.

H. Physics

The medical physicist, dosimetrist, and radiation oncologist perform the calculations necessary to determine the appropriate dose to be delivered by the treatment equipment. This requires knowledge of the physical properties of the treatment units, whether external beam or radioactive implants. These calculations must be checked by an independent person or method before the first treatment if the total number of fractions is 5 or fewer, or otherwise before the third fraction.

I. External Beam Treatment

External beam radiation therapy is usually delivered in single daily doses for several weeks or in multiple increments daily over the same period (hyperfractionation) or over shorter times (accelerated fractionation). Fractionation schemes in which the intended dose is delivered over a shorter time period than

used in standard fractionation using larger-than-usual fraction sizes (hypofractionation) may be appropriate in some clinical situations.

Intensity modulated radiation therapy (IMRT) may be used as a form of external beam RT in some cases. If so, consideration should be given to the [ACR–ASTRO Practice Guideline for Intensity-Modulated Radiation Therapy \(IMRT\)](#) [4]. In some cases, image-guided radiation therapy (IGRT) may also be clinically indicated, and centers that use it should refer to the [ACR–ASTRO Practice Guideline for Image-Guided Radiation Therapy \(IGRT\)](#) [5].

To permit proper delivery of therapy, portal or isocenter verification images produced by each treatment beam unit with the patient in the treatment position are compared with the treatment planning images to verify that the treatment beams and fields planned at simulation are well matched. A set of initial portal or isocenter verification images should be obtained. A set of patient positioning or target localization images should be taken at least every 5 to 10 treatments and for any new fields. Dosimeters may be used *in vivo* to measure and record actual doses at specific anatomic sites.

J. Patient Evaluation During Treatment

The radiation oncologist monitors the patient's progress, checks entries in the treatment chart, and discusses the plan of therapy and any changes with appropriate team members. Re-evaluation examinations of the patient should be performed at least weekly, or more often when warranted. Pertinent laboratory and imaging studies are periodically ordered and reviewed. The patient and/or referring physician should be informed of the progress of treatment whenever deemed appropriate. At completion of irradiation, the radiation oncologist should assess the tumor response and acute side effects.

K. Follow-Up Evaluation

After treatment periodic assessments by the radiation oncologist of tumor response and sequelae of treatment are recommended as clinically indicated. They should be communicated to appropriate other physicians. Early detection of post-treatment tumor progression may permit additional, potentially beneficial treatment. Early detection and treatment of radiation-induced sequelae may avoid serious problems later.

L. Brachytherapy

Brachytherapy may be used for many sites and may be delivered with either low-dose-rate or high-dose rate techniques. The ACR has practice guidelines relating to low-dose-rate brachytherapy, low-dose-rate brachy-

therapy for prostate cancer, and high-dose-rate brachytherapy [6-8].

M. Stereotactic Radiosurgery

Stereotactic radiosurgery may be used for some intracranial lesions and lesions elsewhere in the body. ACR has guidelines relating to stereotactic radiosurgery and stereotactic body radiation therapy [9,10].

N. Other Treatment Modalities

Other treatment modalities are sometimes combined with external photon beams or brachytherapy to enhance the antitumor effects and decrease the effects on surrounding normal tissues. Examples include hyperthermia, photodynamic therapy, and the use of unsealed-source radioisotopes [11].

O. External Beam Sources

The radiation oncologist may have at his/her disposal external beam treatment equipment that provides beams other than conventional photon and electron beams (e.g., proton beams). The general principles discussed above apply to the use of unconventional beam sources, but special expertise on the part of the radiation oncologist as well as the physics and therapy staff will be required for safe use of this treatment equipment.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualifications and Certification

1. The medical director of the radiation oncology center or service should be a radiation oncologist who is credentialed as indicated below.
2. Radiation oncologists (staff)
 - a. Certification in Radiology by the American Board of Radiology (ABR) of a physician who confines his/her professional practice to radiation oncology or certification in Radiation Oncology or Therapeutic Radiology by the ABR, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec may be considered proof of adequate physician qualifications.
or
 - b. Satisfactory completion of a radiation oncology residency program approved by the American Council of Graduate Medicine Education (ACGME), the Royal College of Physicians and Surgeons of Canada

(RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).

The continuing education of a radiation oncologist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

3. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The appropriate subfield of medical physics for this guideline is Therapeutic Medical Physics. (Previous medical physics certification categories including Radiological Physics and Therapeutic Radiological Physics are also acceptable.)

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 16g, adopted in 2006 – Revised 2012, Resolution 42)

4. Radiation therapists and simulation staff

Radiation therapists and simulation staff should fulfill state licensing requirements, and treating radiation therapists should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy. Simulation staff should have ARRT certification in either radiation therapy or diagnostic imaging.

5. Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

6. Patient support staff

Individuals involved in the nursing care of patients should have appropriate nursing

credentials and appropriate experience in the care of radiation therapy patients.

B. Availability

1. A radiation oncologist should be available for direct care and quality review on a daily basis. The radiation oncologist, facility, and support staff should be available to initiate urgent treatment within a medically appropriate response time on a 24-hour basis or refer to a facility that is available to treat on a 24-hour basis. When unavailable, the radiation oncologist is responsible for arranging appropriate coverage. A radiation oncologist's availability should be consistent with state and federal requirements.
2. The medical physicist must be available when necessary for consultation with the radiation oncologist and to provide advice or direction to technical staff when a patient's treatments are being planned or patients are being treated. The center should have written policies specifying any special procedures (e.g., high-dose-rate brachytherapy [6] or stereotactic radiosurgery [9]) that require the presence of the medical physicist. When a physicist is not immediately available on site during routine patient treatment, clinical needs should be met by using documented procedures. Authority to perform specific clinical physics duties shall be established by the medical physicist for each member of the physics staff in accordance with his or her competence. The radiation oncologist should be informed of the clinical activities authorized for each member. Refer to the [ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy](#) for minimal requirements for physics support.

IV. EQUIPMENT SPECIFICATIONS

High-energy photon and electron beams, a computer-based treatment-planning system, simulation, dosimetry with direct participation of the medical physicist, brachytherapy, stereotactic radiosurgery, radioisotope therapy, and the ability to fabricate treatment aids must be available to patients in all facilities, either on site or through arrangements with another center.

A. Radiation oncology equipment, either on site or available through arrangements with another center, should include:

1. Megavoltage radiation therapy equipment for external beam therapy.
2. Electron beam or X-ray equipment for treating skin lesions or superficial lesions.
3. Simulator capable of duplicating the setups of any megavoltage unit and producing either standard radiographs or digitally reconstructed radiographs (DRRs) of the fields to be treated. A dedicated CT simulator may be substituted for a conventional simulator.
4. Appropriate brachytherapy equipment for intracavitary and interstitial treatment (or arrangements for referral to appropriate facilities).
5. Appropriate equipment for stereotactic radiosurgery procedures (or arrangements for referral to appropriate facilities).
6. Computerized dosimetry equipment capable of providing external beam isodose curves as well as brachytherapy isodose curves and 3-dimensional (3D) radiation treatment planning.
7. Physics calibration devices for all equipment.
8. Beam-shaping devices.
9. Immobilization devices.

B. Maintenance and Repair

Regular maintenance and repair of equipment are mandatory. The medical physicist is responsible for documenting maintenance and repair. It is recommended that the medical physicist maintain up-to-date statistics regarding treatment unit uptime.

The center should have procedures in place to provide treatment for patients in case of extended treatment interruption due to equipment repair, maintenance, or replacement.

V. PATIENT AND PERSONNEL SAFETY

A. Patient protection measures should include:

1. Charting systems for prescription, definition, and delivery of treatment parameters, and daily dose recording and summation, including appropriate forms for brachytherapy and radiosurgery procedures, as needed.
2. A physics program for calibrating equipment that ensures accurate dose delivery to the patient, including external beam therapy, brachytherapy, and radiosurgery (see [ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy](#) [12]).
3. A system for independent checking by another person or method before the first treatment if the total number of fractions is 5 or fewer, or otherwise before the third fraction.

4. A system for independent checking of initial dose for single or 2-fraction treatments (intraoperative, stereotactic, hemibody, etc.) before any treatment is given.
5. A system for the radiation oncologist and medical physicist to check independently all brachytherapy parameters to be used in each procedure (source, isotope and activity, dose rate, source position, total dose prescribed and time, etc.).
6. A program to prevent mechanical injury by the machine or accessory equipment.
7. Visual and audio contact with the patient while under treatment.

B. Personnel safety measures should include:

1. A radiation exposure-monitoring program, as required by the Nuclear Regulatory Commission or appropriate state agencies.
2. Systematic inspection of interlock systems.
3. Appropriate room shielding.
4. Routine leak testing of all sealed sources, as required by regulatory agencies.
5. Appropriate safety equipment for use of sealed sources.

VI. EDUCATIONAL PROGRAM

Continuing medical education programs should include the radiation oncologists and the physics, dosimetry, nursing, and radiation therapy staffs. The programs must cover the safe operation of facility equipment as appropriate to the individual's responsibility, and the treatment techniques and new developments in radiation oncology. In addition, each licensed staff member will undertake and document continuing professional education as required by his/her licensing authority.

VII. QUALITY IMPROVEMENT

The medical director of radiation oncology is responsible for instituting and supervising the continuing quality improvement (CQI) program. It will be the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

The director will select appropriate personnel to constitute a CQI Committee, which will meet on a regular basis. The review will be documented as the committee's minutes. Problems recognized will be addressed, and any special studies or further in-depth analysis required will be outlined and undertaken. CQI records should be maintained in a manner that will, to the extent permitted by state and federal law, protect the confidentiality and undiscoverability of these records.

The following items should be included:

A. Chart Review

A designated chart reviewer will audit an appropriate number of charts opened each month after an adequate time has passed to allow completion and closure of these charts. A chart screen must be performed and may include:

1. Diagnosis.
2. Stage of disease.
3. Pertinent histopathologic report.
4. Pertinent history and physical findings of disease.
5. Signed and dated graphical treatment plan (if done) and prescription at beginning of treatment and any prescription changes.
6. Planned total dose, numbers of fractions, dose/fraction, and fractions/day.
7. Method of delivery.
8. Treatment site or treatment volume, with diagrams and/or photographs of fields.
9. Fields documented by port films or electronic portal images.
10. Dosimetry calculations.
11. Summary or a completion-of-therapy note.
12. Follow-up plan.
13. Documentation that the treatment record was checked weekly during treatment.
14. Documented periodic examination of the patient by the radiation oncologist, including patient progress and tolerance.
15. Documented informed consent.

Charts failing to pass any one of the indicators chosen for review will be documented and the report referred to the CQI Committee staff for review and corrective action, as warranted.

B. Review of regular physics quality improvement program report.

C. Review of all cases in which there is a variation from the prescription of greater than 10% of the intended total dose. This review includes any chart in which mathematical corrections of 10% or more are made on the second check of dose calculations.

D. If a new treatment modality or technique is started in a facility (e.g., high-dose-rate brachytherapy, stereotactic radiosurgery), the procedures, results, problems, complications, etc. should be reviewed by the CQI Committee in a timely fashion consistent with patient safety.

E. Review of any chart in which an incident report is filed or in which there is a report of an accident or injury to a patient.

F. Review of unplanned interruptions during treatment; unusual or severe, early or late complications of treatment; and unexpected deaths.

G. Review of outcome studies from the cancer committee, tumor registry, or any other section, department, or committee of an associated hospital that includes radiation oncology patients.

H. Individual Physician Peer Review

If there is a hospital-wide or similar broad-ranging peer-review program that includes evaluation of appropriateness of actions by radiation oncologists, this evaluation should be reviewed by the CQI Committee and may be used as its physician peer review. If no such higher-level program exists, or if a separate intradepartmental review is desired, a facility physician peer-review program will be put in place.

It is recognized that the peer-review process for the radiation oncologist in solo practice presents a unique and difficult situation; however, the practitioner should institute a documented peer-review mechanism for reviewing the appropriateness of given treatment.

I. Patient Outcome

Radiation oncologists should attempt to follow up, at appropriate intervals, all patients treated with curative intent and document the outcome of therapy, including results of treatment (tumor control, survival) and significant sequelae. Patients who are treated with palliative intent may also require close follow-up. For patients who are not followed by the radiation oncologist, the name of the physician who will be responsible for the patient's ongoing care should be documented.

J. Appropriate patient radiation records should be kept in the radiation oncology department or facility, consistent with state and local requirements.

K. Patient-Related Outcome Data

Facilities should collect data for an annual summary, including:

1. Number of new patients.
2. Number of consultations.
3. Number of patients treated.
4. Treatment intent: curative, palliative, and local control.

5. Number of simulations, external treatments, and/or brachytherapy procedures performed.

Facilities should also strive to collect data on:

1. Anatomic site and stage (American Joint Committee on Cancer [AJC], International Federation of Gynecology and Obstetrics [FIGO], etc.) of tumors treated.
2. Stage-related survival and local control.
3. Complications and complication rate.

These functions can be accomplished by maintaining a tumor registry.

L. Patient Satisfaction and Quality-of-Life Audits

Throughout the year the facility may endeavor to perform audits of patient attitudes, observations, and recommendations.

M. Other General Information That Helps to Assure Quality

The following items are recommended; however, constraints of the practice setting are recognized.

1. New patient review conferences: documented review of plans of management for new patients by attending staff to the greatest degree possible.
2. Portal verification review: documented and dated review of appropriate initial and periodic (at least every 5 to 10 treatments) portal films or electronic portal images by the radiation oncologist.
3. Chart review: documented initial and periodic review of all records of patients under treatment to assess completeness and to monitor patient progress.

VIII. DOCUMENTATION

Documentation should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [2].

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web page (<http://www.acr.org/guidelines>) by the Guidelines and Standards Committee of the Commission on Radiation Oncology.

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Development Chronology for this Guideline

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Revised 2004 (Resolution 18)

Amended 2006 (Resolution 16g, 36)

Revised 2009 (Resolution 8)

25

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**Colorado Department
of Public Health
and Environment**

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

State Board of Health

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 1: GENERAL PROVISIONS

Last amended 03/16/11, effective 04/30/2011

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

STATE BOARD OF HEALTH

RADIATION CONTROL - GENERAL PROVISIONS

6 CCR 1007-1 Part 01

PART 1: GENERAL PROVISIONS

1.1 Purpose and Scope.

1.1.1 Authority.

1.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(k), 25-1.5-101(1)(l), and 25-11-104, CRS.

1.1.2 Basis and Purpose.

1.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

1.1.3 Scope.

1.1.3.1 This part includes provisions generally applicable throughout all parts of these radiation control regulations.

1.1.4 Applicability

1.1.4.1 Except as otherwise specifically provided herein, these regulations apply to all persons who receive, possess, own, acquire, use, process, store, transfer, or dispose any source of radiation.

1.1.4.2 Nothing in these regulations shall apply to any person to the extent such person is subject to regulation not relinquished by the U.S. Nuclear Regulatory Commission.¹

¹ Regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 (January 1, 2010) of the Commission's regulations.

1.1.5 Published Material Incorporated By Reference.

1.1.5.1 Published material incorporated in Part 1 by reference is available in accord with Section 1.4.

1.2 Definitions.

1.2.1 Definitions of general applicability to the *Rules and Regulations Pertaining to Radiation Control* promulgated by the Department pursuant to provisions of sections 25-1-108, 25-1.5-101(1)(k), 25-1.5-101(1)(l), and 25-11-104, CRS, are set forth in section 1.2.2 and shall be liberally construed to protect the public health by controlling excess radiation.

1.2.2 As used in these regulations, each term below has the definition set forth. A cross-reference is provided for each common abbreviation. Any additional definition used only in a single part of these regulations is found in that part.

“A₁” means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix 17A or may be derived in accordance with the procedures prescribed in Appendix 17A.

“A₂” means the maximum activity of radioactive material, other than special form, low specific activity (LSA) and surface contaminated object (SCO) material, permitted in a Type A package. This value is either listed in Appendix 17A or may be derived in accordance with the procedures prescribed in Appendix 17A.

“AAPM” means the American Association of Physicists in Medicine.

“Absorbed dose” (D) means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

“Absorbed dose rate” means absorbed dose per unit time.

“Accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “linear accelerator” or “particle accelerator” is an equivalent term.

“Accelerator-produced radioactive material” means any material made radioactive by an accelerator.

“Accessible surface” means the external surface of the radiation machine enclosure or housing provided by the manufacturer.

“Accident” means any unintended event (including an operating error, equipment failure or other mishap) that could:

- (1) Result in a dose in excess of regulatory limits on site or for the public; or
- (2) Have consequences or potential consequences which cannot be ignored from the point of view of protection or safety (such as an actual or potential substantial degradation of the level of protection or safety of the facility or release of radioactive material in sufficient quantity to warrant consideration of protective actions).

“Act” means Title 25, Article 11, Colorado Revised Statutes (CRS), as amended.

“Action levels”. See “action limits”.

“Action limits” means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken. Action limits or levels are also sometimes called control limits or levels.

“Activity” means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

“Acute” means radiation dose(s) or chemical exposure(s) occurring within a short period of time (24 hours or less).

“Address of use” means the facility designated on the license or registration where radioactive material is permitted to be received, produced, prepared, used, processed, or stored or where a radiation machine is permitted to be installed, operated, repaired or stored.

“Adult” means an individual 18 or more years of age.

“Agreement State” means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

“Air kerma” (K) means the kinetic energy released in the mass of a small volume of air by ionizing radiation (see kerma). Air kerma is measured in joules per kilogram (J/kg). For diagnostic x-rays, air kerma is the same as the absorbed dose measured in gray (Gy) delivered to the volume of air in the absence of scatter.

“Air kerma rate” (AKR) means the air kerma per unit time.

“Air-purifying respirator” means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

“Airborne radioactive material” means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

“Airborne radioactivity area” means a room, enclosure, or area in which airborne radioactive material exists in a concentration:

- (1) In excess of the derived air concentration (DAC) specified in Appendix 4B, Table 4B1; or
- (2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC hours.

“Airline respirator” . See “supplied-air respirator” .

“Alert” means an event may occur, is in progress, or has occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect any individual(s) offsite.

“ALI” . See “annual limit on intake” .

“Annual limit on intake” (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference human that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Part 4, Appendix 4B, Table 4B1, Columns 1 and 2.

“Annually” means either:

- (1) At intervals not to exceed 1 year; or
- (2) Once per year, at about the same time each year (plus or minus 1 month).

"ANSI" means the American National Standards Institute.

"Applicant" means any person who applies for a Department license, registration, certification or other acceptance, approval or permit.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, producing, preparing, processing, using, or storing radioactive material or installing, operating, repairing, or storing a radiation machine.

"As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Assigned protection factor" (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

"Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied air respirators (SAR) and self-contained breathing apparatus (SCBA) units.

"Authorized medical physicist" (AMP) means an individual who meets the Appendix 7B requirements that are applicable to a type of use of radioactive material licensed under Part 7 and has current Department approval to perform medical physics activities.

"Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the Appendix 7C requirements that are applicable to a type of use of radioactive material licensed under Part 7 and has current Department approval to perform nuclear pharmacy activities.

"Authorized user" (AU) means an individual who meets State training and experience requirements and has Department approval for a use of radioactive material.

"Background radiation" means radiation from:

- (1) Extraterrestrial sources;
- (2) Naturally occurring radioactive material (which has not been technologically enhanced), including radon (except as a decay product of source or special nuclear material); and
- (3) Global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that are not under the control of the licensee or registrant.

Background radiation does not include sources of radiation from radioactive materials regulated by NRC.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration per second (dps) or transformation per second (s^{-1}).

"Becquerel per cubic meter", 1 Bq/m³ (0.027 pCi/L), means a unit of radioactivity representing one disintegration per second per cubic meter.

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, *in-vivo* counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Brachytherapy" means a method of radiation therapy in which sealed, plated, embedded, activated, or electronic sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitory, intraluminal or interstitial application.

"Business day" means any day of the year, exclusive of Saturdays, Sundays, and State of Colorado holidays.

"Byproduct material" means:

- (1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;
- (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes (underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition);
- (3) Any material produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity, that:
 - (a) Is a discrete source of radium-226; or
 - (b) Has been made radioactive by use of a particle accelerator; or
- (4) Any discrete source of naturally occurring radioactive material, other than source material, that:
 - (a) Is extracted, or converted after extraction, for use for a commercial, medical, or research activity; and
 - (b) Is determined by NRC to pose a threat to the public health and safety or the common defense and security similar to the threat posed by a discrete source of radium-226.

"Calendar quarter" . See "quarter" .

"Calibration" means the determination of:

- (1) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
- (2) The strength of a source of radiation relative to a standard.

"CCR" means the Colorado Code of Regulations.

"CFR" means Code of Federal Regulations.

"Chelating agent" means a substance that through binding allows efficient elimination of radionuclide contamination from the human body (decorporation), for example, amine polycarboxylic acids, hydroxy carboxylic acids, and polycarboxylic acids.

"Chiropractor" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice chiropractic health care.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for class D, days, of less than 10 days, for class W, weeks, from 10 to 100 days, and for class Y, years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Classified material" means radioactive materials that are one or more of the following types:

- (1) "Type 2 byproduct material" as byproduct material is defined in 42 U.S.C. sec. 2014 (e) (2);
- (2) Naturally occurring (NORM) or technologically enhanced naturally occurring radioactive material (TENORM);
- (3) Non-11 e (2) material; or
- (4) Ore.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity that might adversely affect the natural environment of a site; this term does not include changes desirable for the temporary use of the land for public recreational uses, limited borings to determine site characteristics as necessary for environmental assessment or other pre-construction monitoring to establish background information related to the suitability of a site, or to the protection of environmental values.

"Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum W_T \times H_{T,50}$).

"Computer-readable medium" means that the Department's computer can transfer the information from the medium into its memory.

"Constraint" (dose constraint) means a value above which specified action is required.

"Contact hour" means an hour of training received through direct instruction.

“Continuing education” is lifelong learning to ensure that new information and knowledge is put into practice.

“Continuing education unit” (CEU) means one documentable contact hour.

“Controlled area” means an area, outside of a restricted area but inside the site boundary, access to which can be limited for any reason and/or the occupancy and activity of those within is subject to supervision.

“Cost estimate” means a document containing the total costs that would be incurred if an independent contractor were hired to perform decommissioning of the facility and disposal of radioactive materials at the facility, and associated administrative indirect and legal costs to the Department in conducting decommissioning oversight.

“Critical group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

“CRS” means the Colorado Revised Statutes.

“Cumulative air kerma” means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

“Curie” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} transformations per second (s^{-1}).

“Cyclotron” means a particle accelerator in which a magnetic field bends the path of charged particles. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

“DAC”. See “derived air concentration” .

“Declared pregnant woman” means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

“Decommission” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

- (1) Release of the property for unrestricted use and termination of the license; or
- (2) Release of the property under restricted conditions and termination of the license.

“Decommissioning funding plan” means a written document that contains a cost estimate for decommissioning and a description of the method for assuring funds for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

“Decommissioning plan” means a written document that includes the licensee’s planned procedures and activities for decommissioning of the facility or site.

“Deep dose equivalent” (H_D), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

“Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

“Dentist” means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

“Department” means the Colorado Department of Public Health and Environment.

“Depleted uranium” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“Derived air concentration” (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Part 4, Appendix 4B, Table 4B1, Column 3.

“Derived air concentration-hour” (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

“Detector”. See “radiation detector” .

“Diagnostic imaging system” means an assemblage of components for the generation, emission, and reception of machine-produced x-rays and the transformation, storage and visual display of the resultant image.

“Direct supervision” means the supervisor is present in the facility and immediately available to observe, correct, assist and direct the supervisee throughout the performance of a procedure, as needed, but is not always required to be present in the room. For purposes of these regulations, “on-site supervision” is an equivalent term.

“Discrete source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for a commercial, medical, or research activity.

“Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end of service life renders it unsuitable for use. Examples of this type of respirator are a disposable half mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

“Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

“DOE” means the U.S. Department of Energy.

“Dose” is a generic term that means absorbed dose, dose equivalent, effective dose, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, “radiation dose” is an equivalent term.

“Dose commitment” means the total radiation dose to a part of the body that will result from retention of radioactive material in the body. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

“Dose equivalent” (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

“Dose limits” means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, “limits” is an equivalent term.

“Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

“DOT” means the U.S. Department of Transportation.

“Drill” means a supervised, hands-on instruction period intended to test, develop or maintain a specific emergency response capability. A drill may be a component of an exercise.

“Effective dose equivalent” (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T \times H_T$).

“Embryo/fetus” means the developing human organism from conception until the time of birth.

“Emergency” means an event requiring prompt action to mitigate a threat to the health and safety of workers and the public or a threat of damage to the environment.

“Emergency planning zone” means a geographic area surrounding a specific facility for which special planning and preparedness efforts are carried out to ensure that prompt and effective protective actions can reduce or minimize the impact of releases of radioactive material to public health and safety or to the environment.

“Enriched uranium” means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

“Entrance exposure rate” means the exposure free-in-air per unit time.

“Entrance point” or “access point” means any location through which an individual could gain access to a radiation area, source of radiation or licensed or registered radioactive material, including an entry or exit portal of sufficient size to permit human entry, irrespective of its intended use.

“Evacuation” means the urgent removal of people from an area to avoid or reduce high-level, short-term exposure.

“Event” means a situation reasonably discrete in time, location and consequences.

“Examination” means performing a procedure, including selection of exposure settings, positioning the x-ray system and the patient, and initiating and terminating the exposure.

“Exercise” means a multi-faceted activity that tests the plans, procedures, adequacy of training, resources, and integrated capability of an emergency response system.

“Explosive material” means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

“Exposure” means being exposed to ionizing radiation or to radioactive material.

“Exposure” means the quotient of dQ by dm where “dQ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “dm” are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg).²

2 When not underlined as above, or indicated as “exposure” (X), the term “exposure” has a more general meaning in these regulations.

“Exposure rate” means the exposure per unit of time.

“External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

“Extremity” means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

“Facility” means the location within one building (or vehicle, or under one roof, or at one address) and under the same administrative control (multiple locations or addresses at a site or part of a site are considered together if so approved by the Department) at which:

- (1) The possession, use, processing or storage of radioactive material is or was authorized;
- (2) A radiation machine is or was installed, operated, repaired and/or stored; and/or
- (3) A source of radiation is located.

“FDA” means the United States Food and Drug Administration.

“Filtering facepiece” (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

“Final radiation survey” means the survey of the facility or site after decommissioning activities have been completed during which the determination is made by the licensee that the facility or site meets the Department’s release criteria.

“Financial surety” or “financial warranty” means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

“Fissile material” means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition.

“Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

“Fit test” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

“General emergency” means an accident has occurred or is in progress which involves actual or imminent catastrophic reduction of facility safety systems with potential for loss of containment or confinement integrity or release of radioactive material that can be reasonably expected to exceed offsite protective action guides.³

3 A definition of “general emergency” is provided for reference and completeness. It is unlikely that any Colorado licensee would need to plan for a general emergency.

“General supervision” means the procedure is under the supervisor’s overall direction and control but the supervisor’s presence is not required during the performance of the procedure.

“Generally applicable environmental radiation standards” means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

“Gray” (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose resulting from deposition of 1 joule (J) of energy in 1 kilogram of material (100 rad).

“Hazardous waste” means any waste designated as hazardous by Department regulations in 6 CCR 1007-1-3.

“Healing arts” means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition. For purposes of Parts 2, 6 and 24, “healing arts” includes animals other than humans.

“Helmet” (respiratory) means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

“High radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

“Hood” (respiratory) means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

“Human use” means the internal or external administration of radiation or radioactive material to human beings.

“ICRP” means the International Commission on Radiological Protection.

“Immediate” means within not more than fifteen minutes or as otherwise specified in writing by the licensee and approved by the Department.

“Incident” means any unintended event involving radiation for which the public dose is a fraction of regulatory limits and safety provisions are sufficient, but further degradation of safety systems could lead to an accident condition.

“Individual” means any human being. “Natural person” is an equivalent term.

“Individual monitoring” means the assessment of:

(1) Dose equivalent by the use of:

- (a) Individual monitoring devices; or
- (b) Survey data; or

(2) Committed effective dose equivalent by:

- (a) Bioassay; or
- (b) Determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition of DAC-hours).

“Individual monitoring device” mean a device designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, “personnel dosimeter” and “dosimeter” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal (lapel) air sampling devices.

“Inhalation class” . See “class” .

“Inspection” means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, license conditions and other requirements of the Department.

“Interlock” means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

“Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

“Irradiation” means the exposure of a living being or matter to ionizing radiation.

“Kerma” (K [italicized]) means kinetic energy released in a unit mass, determined by the quotient $K = dE_{tr} / dm$, where dE_{tr} is the sum of the initial kinetic energies of all the charged ionizing particles (such as electrons) liberated (transferred, E_{tr}) by uncharged ionizing particles (such as neutrons and photons) in air of mass dm . Kerma is measured in joules per kilogram (J/kg).

“Kilo electron volt” (keV) means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

“Kilovolt” (kV) is a unit (a thousand volts) used to measure the nominal accelerating potential of charged particles used to create an x-ray beam.

“Kinetic energy” means the energy of motion of an object, which is completely described by magnitude alone and has no direction.

“Lens dose equivalent” (LDE) means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

“License” means a license issued by the Department in accordance with the regulations adopted by the Department.⁴

4 The term “license”, “licensed material” or “licensee” is taken to have an equivalent meaning when these regulations apply to a license issued by another Agreement State or NRC.

“Licensed material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.⁴

“Licensee” means any person who is:

- (1) Licensed by the Department⁴ in accordance with these regulations and the Act;
- (2) Responsible for decommissioning by being:
 - (a) Registered with the Department;
 - (b) Subject to a record of possession of a radiation source or device under general license, for example, pursuant to 3.6.4.3(13); or
 - (c) Otherwise legally obligated to conduct decommissioning activities in accordance with these regulations and the Act; or
- (3) Responsible under 10 CFR 71 (January 1, 2010) as certificate holder, or applicant for a certificate of compliance, or under Part 17, for demonstrating that package design, fabrication, assembly and testing requirements are met with respect to a package before the time a package approval is issued. “Limits”. See “dose limits” .

“Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

“Lost or missing licensed source of radiation” means a licensed or registered source of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

“Lung class” . See “class” .

“mA” means milliampere.

“Major processor” means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and Type B quantities are defined in Part 17 of these regulations.

“Mammographer” means a registered radiologic technologist who has specialized training to perform mammography examinations.

“Management” means the chief executive officer, or other individual having the authority to manage, direct, or administer the licensee’s activities, or delegate(s) of such individual.

“mAs” means milliampere second.

“Medical institution” means an organization in which two or more medical disciplines are practiced.

“Medical physicist” means an individual trained and experienced in a medical physics specialty.

“Medical use” means the intentional internal or external administration of radioactive material or radiation to humans or animals in the practice of the healing arts, including administration of radioactive materials to patients or human or animal research subjects under the supervision of an authorized user and operation of radiation machines for healing arts purposes.

“Member of the public” means an individual, except when that individual is receiving an occupational dose.

“MeV” means one mega electron volt, or one million electron volts. One MeV is the amount of energy acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. One MeV is equivalent to 1.60×10^{-16} joules.

“Minor” means an individual less than 18 years of age.

“Misadministration” means an event that results in a dose or dosage administered to the wrong individual, or by the wrong mode of radiation delivery, or that differs from the prescribed dose or dosage, as stated in 7.21, 24.6, or an equivalent section of these regulations. “Reportable medical event” is an equivalent term.

“Monitoring” means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, “radiation monitoring” and “radiation protection monitoring” are equivalent terms.

“MQSA” means Mammography Quality Standards Act.

“NARM” . See “naturally occurring or accelerator-produced radioactive material” (NARM).

“Nationally tracked source” means a sealed source containing a quantity equal to or greater than a Category 2 level of any radioactive material listed in Appendix 4G. Category 1 nationally tracked sources are those containing radioactive material in a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

In this context, a sealed source:

- (1) Means radioactive material that is sealed in a capsule or closely bonded, in a solid form, and is not exempt from regulatory control; and
- (2) Does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

“Natural radioactivity” means radioactivity of naturally occurring nuclides.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

"Natural uranium" means uranium containing the naturally occurring distribution of the uranium isotopes 234, 235 and 238 (approximately 0.711 weight percent uranium-235 and the remainder by weight essentially uranium 238) that is neither enriched nor depleted in the isotope uranium 235.

"Naturally occurring or accelerator produced radioactive material" (NARM) means any radioactive material that is not source or special nuclear material or byproduct material types (1) or (2).

"Naturally occurring radioactive material" (NORM) means any radioactive material that is not byproduct, source, or special nuclear material, produced in an accelerator, or by-products of fossil-fuel combustion, including bottom ash, fly ash, and flue-gas emission by-products.

"NCRP" means the National Council on Radiation Protection and Measurements.

"Negative-pressure respirator (tight-fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"NIST" means the National Institute of Standards and Technology.

"Non-11 e (2) material" means byproduct material that is not type 2 byproduct material or ore. "Non-11 e (2) byproduct material" does not include depleted or enriched uranium as defined by Colorado or federal statute or rule.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

"NORM". See "naturally occurring radioactive material" (NORM).

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material".

"NRC". See "Nuclear Regulatory Commission".

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or a duly authorized representative.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation whether or not the sources of radiation are in the possession of the licensee, registrant or other person.

Occupational dose does not include doses received:

- (1) From background radiation;
- (2) From any medical administration the individual has received;

- (3) From exposure to individuals administered radioactive material and released in accordance with 7.26 of these regulations;
- (4) From voluntary participation in medical research programs; or
- (5) As a member of the public.

"Offsite response organization" means the non-licensee offsite organizations that may be needed to respond to an emergency, including, but not limited to, local fire, police, ambulance and hospital services.

"Operator" means an individual adequately trained in accordance with these regulations in the purpose and experienced in the practice of performing a radiographic examination and/or using a device containing radioactive material.

"Ore" means naturally occurring uranium-bearing, thorium-bearing, or radium-bearing material in its natural form, to be processed for its uranium or thorium content, prior to chemical processing including but not limited to roasting, beneficiating, or refining, and specifically includes material that has been physically processed, such as by crushing, grinding, screening, or sorting.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator" . See "accelerator" .

"Patient" means an individual human being or an animal to whom radioactive materials or machine produced radiation is delivered for healing arts examination, diagnosis or treatment.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing. "Natural person" means an individual human being.

"Personal supervision" means the supervisor is in attendance in the room with the supervisee during the performance of the procedure. For purposes of these regulations, "physical supervision" or "immediate supervision" or "individual supervision" is an equivalent term.

"Personnel monitoring equipment" . See "individual monitoring device" .

"PET" means positron emission tomography. See "positron emission tomography radionuclide production facility" .

"Phantom" means an object designed such that the interaction of ionizing radiation with the object is suitable for the evaluation of the particular characteristics of the radiation-producing system or anatomic region under consideration.

"Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice pharmacy.

"Physician" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

"Positive-pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"Positron Emission Tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

"Powered air-purifying respirator" (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the facepiece.

"Practitioner of the healing arts" means any person upon whom the U.S. Food and Drug Administration has conferred the authority to administer prescription drugs.

"Pressure-demand respirator" means a positive-pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"Principal activity" means an activity authorized by the license which is essential to achieving the purpose(s) for which the license was issued or amended.

Not included as principal activities are:

- (1) Radioactive material storage while no licensed material is accessed for use or disposal; and
- (2) Activity incidental to decontamination or decommissioning.

"Projected dose" means a future dose calculated for a specified time period on the basis of estimated or measured initial concentrations of radionuclides or exposure rates and in the absence of protective actions.

"Protective action" means an action taken by members of the public to protect themselves from radiation from an accident involving radioactive material. Protective action may include sheltering, evacuation, relocation, control of access, administration of a radioprotective drug, decontamination of persons, decontamination of land or property, or control of food or water.

"Protective action guide" means a projected dose from an accidental release of radioactive material at which protective action is to be considered.

"Protective apron" means an apron made of radiation-attenuating material(s) used to reduce exposure to radiation.

"Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.

Public dose does not include occupational dose or doses received from:

- (1) Background radiation;
- (2) Any medical administration the individual has received;

- (3) Exposure to individuals administered radioactive material and released in accordance with Section 7.26 of these regulations; or
- (4) Voluntary participation in medical research programs.

“Pyrophoric liquid” means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water reactive materials.

“Qualified expert” (QE) means an individual who meets the requirements of Appendix 2B or 2C and has current Department approval in a designated specialty to evaluate radiation shielding design and recommend radiation safety procedures.

“Qualified inspector” (QI) means an individual who meets the requirements of Appendix 2I and has current Department approval in a designated specialty to perform evaluations of radiation machines, facilities, service providers and operators for compliance with these regulations.

“Qualified trainer” (QT) means an individual whose training and experience adequately prepares the individual to carry out specified training assignments.

“Qualitative fit test” (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

“Quality assurance” (QA) comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

“Quality Assurance Officer” means the individual responsible for the development, maintenance and oversight (including corrective action) of the quality assurance program.

“Quality control” (QC) comprises those quality assurance actions that relate to control of the physical characteristics and quality of the material or component to predetermined requirements, including the steps taken by an organization to measure performance, compare performance with standards, and act on any differences.

“Quality factor” (Q) means the modifying factor, listed in Appendix 1A, Table 1A-1 or Table 1A-2, that is used to derive dose equivalent from absorbed dose.

“Quantitative fit test” (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

“Quarter” means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day of the year is omitted or duplicated in consecutive quarters. See also “year” .

“Rad” means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

“Radiation” means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these

regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

“Radiation area” means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

“Radiation detector” means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“Radiation dose” . See “dose” .

“Radiation machine” means any device capable of producing radiation except those devices with radioactive material as the only source of radiation. Radiation machine includes any accelerator and/or x-ray system, subsystem or equipment.

“Radiation safety officer” (RSO) means an individual who has demonstrated sufficient knowledge to apply radiation protection regulations appropriately and who has been assigned such responsibility by the licensee or registrant.

“Radioactive material” means any solid, liquid, or gas which emits radiation spontaneously.

“Radioactivity” means the transformation of unstable atomic nuclei by the emission of radiation.

“Radiobioassay” . See “bioassay” .

“Reference man” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in International Commission on Radiological Protection (ICRP) Publication 23, “Report of the Task Group on Reference Man,” 1975.

“Registered medical physicist” (RMP) means an individual who meets the applicable requirements of Appendix 2B and has current Department approval to perform medical physics activities in a designated specialty.

“Registrant” means any person who is registered with the Department and is legally obligated to register with the Department pursuant to these regulations and the Act.

“Registration” means registration with the Department in accordance with the regulations adopted by the Department.

“Regulations of the DOT” means the regulations in 49 CFR Parts 100-189 and Parts 390-397 (October 1, 2009).

“Regulations of the NRC” means the regulations in 10 CFR Parts 1-50 and Parts 51-199 (January 1, 2010).

“Relocation” means the removal or, after a plume has passed, continued exclusion of people from contaminated areas to avoid chronic radiation dose.

“Rem” means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

“Reportable medical event” means an event that results in a dose or dosage administered to the wrong individual, or by the wrong mode of radiation delivery, or that differs from the prescribed dose or dosage, as stated in 7.21, 24.6, or an equivalent section of these regulations.

“Misadministration” is an equivalent term.

“Research and development” means:

- (1) Theoretical analysis, exploration, or experimentation; or
- (2) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

“Residual radioactivity” means radioactivity in structures, materiel, soils, groundwater, and other media at a site resulting from activities under the licensee’s control.

- (1) This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation.
- (2) It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part 4.

“Respiratory protective equipment” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive materials.

“Restricted area” means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

“Restricted use” means that a limit or control has been placed on future use of the facility and the facility is no longer under the control of the licensee, registrant, or holder of the record of possession. See also “unrestricted use” .

“Roentgen” means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air. See “exposure” .

“Sanitary sewerage” means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

“Sealed source” means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

“Sealed source and device registry” (SSD) means the national registry, maintained by the NRC, which contains the registration certificates that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

“Self-contained breathing apparatus” (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

“Shallow dose equivalent” (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

“Sheltering” means the use of a structure for radiation protection from an airborne plume containing radioactive material.

“SI” means the abbreviation for the International System of Units.

“Sievert” means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

“Site” means the area within the boundary of a location under the control of a person using or storing radioactive material or at which a source of radiation is located.

“Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee, registrant or person who controls a site.

“Site area emergency” means an event may occur, is in progress, or has occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

“Source material” means uranium or thorium, or any combination thereof, in any physical or chemical form, including ore that contains by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.

“Source material milling” means any activity that results in the production of radioactive material that meets byproduct material definition (2).

“Source of radiation” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

“Special form radioactive material” means radioactive material that satisfies the following conditions:

- (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
- (2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
- (3) All test requirements specified by the NRC that are applicable and in effect at the time are met by the special form encapsulation design and/or construction.

“Special nuclear material” means:

- (1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the NRC, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

- (2) Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope ^{235}U in quantities not exceeding 350 grams of contained ^{235}U ; ^{233}U in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula--for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula: [175 (grams contained ^{235}U)/350] + [50 (grams contained ^{233}U)/200] + [50 (grams Pu)/200] \leq 1.

"Specific activity of a material", for a material in which the radionuclide is essentially uniformly distributed, means the radioactivity per unit mass of the material.

"Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide.

"Spent nuclear fuel" or "spent fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

"State" means the State of Colorado. If it is clear from the context that the term is being used in general, "state" means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

"Structured educational program" means an accredited educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Technologically enhanced naturally occurring radioactive material" (TENORM) means naturally occurring radioactive material whose radionuclide concentrations are increased by or as a result of past or present human practices. "TENORM" does not include:

- (1) Background radiation or the natural radioactivity of rocks or soils;
- (2) "Byproduct material" or "source material", as defined by Colorado statute or rule; or
- (3) Enriched or depleted uranium as defined by Colorado or federal statute or rule.

"Test" means the process of verifying compliance with an applicable regulation.

"These regulations" mean all parts of the State of Colorado "Rules and Regulations Pertaining to Radiation Control," 6 CCR 1007-1.

"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

"Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

"Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose in accordance with Part 4.

"Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly, or indirectly through one or more intermediate steps, and that all comparisons have been documented.

"Transuranic" means radionuclides with atomic numbers greater than 92.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93 438, October 11, 1974, 88 Stat. 1233 at 1237 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Unirradiated uranium" means uranium containing not more than 2×10^3 Bq (54 nanocurie) of plutonium per gram of uranium-235, not more than 9×10^6 Bq (243 microcurie) of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium 236 per gram of uranium-235.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Unrestricted use" means that the facility or area may be used by individuals for any purpose without limit or control of the licensee, registrant, or holder of the record of possession. See also "restricted use".

"Uranium" . See depleted uranium, enriched uranium, or natural uranium.

"User seal check" (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamylacetate check.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in

excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.⁵

5 At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

“Veterinarian” means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice veterinary medicine.

“Volumetric dental imaging system” means an x-ray machine that produces, for oral and maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-dimensional tomographic data sets. A dental x-ray machine only capable of producing a two dimensional image is not considered to be a volumetric dental imaging system.

“Waste” means low-level radioactive waste that is acceptable for disposal in a land disposal facility and, for purposes of this definition, that is not classified as high level radioactive waste, spent nuclear fuel, or byproduct material meeting definition (2), (3) or (4).

“Waste handling licensee” means a person licensed to receive and store radioactive waste prior to disposal and/or a person licensed to dispose of radioactive waste.

“Week” means 7 consecutive days starting on Sunday.

“Weighting factor” (w_T) for an organ or tissue (T) means the proportion, listed in Appendix 1B, of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly.

“Whole body” means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

“Worker” means an individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant.

“Working level” (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^{-5} MeV of potential alpha particle energy. The short lived radon daughters are: for radon-222: polonium-218, lead-214, bismuth-214, and polonium 214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

“Working level month” (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month).

“X-ray equipment” means an x-ray system, subsystem, or component thereof.

- (1) “Mobile or portable x-ray equipment” means x-ray equipment that is designed to be transported from place to place.
 - (a) Mobile x-ray equipment is often mounted in a vehicle or on a permanent base with wheels and/or casters for moving while completely assembled.
 - (b) Portable x-ray equipment includes x-ray equipment that is designed to be hand-carried and hand-held during use.
- (2) “Stationary x-ray equipment” means x-ray equipment that is installed in a fixed location.

“X-ray imaging system” or “x-ray system” means an assemblage of components for the controlled production of x rays.

- (1) At a minimum, an x-ray imaging system includes an x-ray high-voltage generator, an x-ray exposure control, a tube housing assembly, a beam-limiting device, and necessary supporting structures.
- (2) Additional components such as the image receptor(s) that function with the system are considered integral parts of the system.

“Year” means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a transition from one licensee or registrant to another occurs during a year, each licensee or registrant shall assure that no day is omitted or duplicated in consecutive years. See also “quarter”.

COMMUNICATIONS AND REFERENCED MATERIALS

1.3 Communications.

- 1.3.1 All communications and reports concerning parts of these regulations, and applications filed thereunder, should be addressed to the Department.

1.4 Referenced Materials.

- 1.4.1 Parts of these regulations incorporate by reference (as identified within a particular section) materials originally published elsewhere. These regulations do not include amendments to or editions of incorporated materials published later than the effective date of the particular section.
- 1.4.2 Materials incorporated by reference will be available to the public for inspection during regular business hours or for copying at reasonable charge at the offices of the Hazardous Materials and Waste Management Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, CO 80246-1530.
- 1.4.3 The addresses of the Federal Agencies and Organizations originally issuing the referenced materials are available on the Division website at <http://www.cdphe.state.co.us/hm/index.htm> .
- 1.4.4 In accordance with Section 24 4 103(12.5)(c)(ii)(C), CRS, copies of any material that has been incorporated by reference have been provided to the State Publications Depository Library and Distribution Center and are available for interlibrary loan. The incorporated materials may be examined at any state publications depository library.

EXEMPTION FROM THE REGULATORY REQUIREMENTS

1.5 Exemptions.

- 1.5.1 The Department may, upon application or upon its own initiative, grant such exemption or exception from a requirement of these regulations as it determines is authorized by law and will not result in undue hazard to public health and safety or property.
- 1.5.2 Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

- 1.5.2.1 Prime contractors performing work for the U.S. Department of Energy at U.S. Government owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
- 1.5.2.2 Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;
- 1.5.2.3 Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a U. S. Government owned vehicle or vessel; and
- 1.5.2.4 Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine that:
 - (1) The exemption of the prime contractor or subcontractor is authorized by law; and
 - (2) Under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

GENERAL REGULATORY REQUIREMENTS

1.6 Records.

- 1.6.1 Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation.
- 1.6.2 Additional record requirements are specified elsewhere in these regulations.

1.7 Inspections.

- 1.7.1 Each licensee and registrant shall afford the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used, stored and/or located.
- 1.7.2 Each licensee and registrant shall make available to the Department for inspection, at all reasonable times, records maintained pursuant to these regulations.

1.8 Tests.

- 1.8.1 Each licensee and registrant shall perform upon instructions from the Department, or shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:
 - 1.8.1.1 Sources of radiation;
 - 1.8.1.2 Facilities wherein sources of radiation are used, stored and/or located;
 - 1.8.1.3 Radiation detection and monitoring instruments; and
 - 1.8.1.4 Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

ADDITIONAL REGULATORY REQUIREMENTS

1.9 Additional Requirements.

- 1.9.1 The Department may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations, as it deems appropriate or necessary to minimize danger to public health and safety or property.

ENFORCEMENT REQUIREMENTS

1.10 Violations.

- 1.10.1 An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder.
- 1.10.2 Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.
- 1.10.3 Additionally, any person who violates any provision of the Act or any regulation may be subject to a civil penalty as provided for in Part 13 or these regulations.
- 1.10.4 Submittal of false information shall be sufficient basis for rejecting or revoking any Department license, registration, certification or other acceptance, approval or permit.

1.11 Impounding.

- 1.11.1 Sources of radiation shall be subject to impounding pursuant to the Act.

1.12 Prohibited Uses.

- 1.12.1 A radiation producing machine or radioactive material shall not be used except in accord with these regulations.

SEVERABILITY

1.13 Severability.

- 1.13.1 Each provision of these regulations is severable, and if any provision or the application of the provision to any circumstance is held invalid, the application of such provision to other circumstances, and the remainder of these regulations shall not be affected thereby.

PART 1, APPENDIX 1A: QUALITY FACTORS

1A.1 Table 1A-1 lists the quality factors for converting absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

TABLE 1A-1: QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

1A.2 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, 0.01 Sv (1 rem) of neutron radiation of unknown energies may be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 1A-2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 1A-2: MEAN QUALITY FACTORS (Q) AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron energy (MeV)	Quality factor ⁶ (Q)	Fluence per unit dose equivalent ⁷ (neutrons cm ⁻² rem ⁻¹)	Fluence per unit dose equivalent ⁷ (neutrons cm ⁻² Sv ⁻¹)
2.5×10^{-8} (thermal)	2	980×10^6	980×10^8
1×10^{-7}	2	980×10^6	980×10^8
1×10^{-6}	2	810×10^6	810×10^8
1×10^{-5}	2	810×10^6	810×10^8
1×10^{-4}	2	840×10^6	840×10^8
1×10^{-3}	2	980×10^6	980×10^8
1×10^{-2}	2.5	1010×10^6	1010×10^8
1×10^{-1}	7.5	170×10^6	170×10^8
5×10^{-1}	11	39×10^6	39×10^8
1	11	27×10^6	27×10^8
2.5	9	29×10^6	29×10^8
5	8	23×10^6	23×10^8

7	7	$24 \times t; 10^6$	$24 \times t; 10^8$
10	6.5	$24 \times t; 10^6$	$24 \times t; 10^8$
14	7.5	$17 \times t; 10^6$	$17 \times t; 10^8$
20	8	$16 \times t; 10^6$	$16 \times t; 10^8$
40	7	$14 \times t; 10^6$	$14 \times t; 10^8$
60	5.5	$16 \times t; 10^6$	$16 \times t; 10^8$
100	4	$20 \times t; 10^6$	$20 \times t; 10^8$
200	3.5	$19 \times t; 10^6$	$19 \times t; 10^8$
300	3.5	$16 \times t; 10^6$	$16 \times t; 10^8$
400	3.5	$14 \times t; 10^6$	$14 \times t; 10^8$

6 Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

7 Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

PART 1, APPENDIX 1B: ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder ⁸	0.30
Whole Body ⁹	1.00

8 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

9 For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $wT = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case by case basis until such time as specific guidance is issued.



**Colorado Department
of Public Health
and Environment**

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

Last amended 06/16/10, effective 07/30/2010

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 2:

REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

2.1 Purpose and Scope.

2.1.1 Authority

2.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

2.1.2 Basis and Purpose.

2.1.2.1 A statement of basis and purpose of these regulations accompanies this part and changes to this part. A copy may be obtained from the Department.

2.1.3 Scope.

2.1.3.1 This part provides for:

- (1) Registration of facilities;
- (2) Certification of radiation machines;
- (3) Registration of persons providing radiation machine services including assembly, installation, maintenance and repair;
- (4) Registration of qualified inspectors and qualified experts; and
- (5) Approval of mammographers and other operators.

2.1.4 Applicability.

2.1.4.1 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted.

2.1.4.2 The provisions of this part are in addition to (and not in substitution for) other applicable provisions in Parts 1, 4, 5, 6, 7, 8, 9, 10, 24 and other parts of these regulations.

2.1.5 Published Material Incorporated by Reference.

2.1.5.1 Published material incorporated in Part 2 by reference is available in accord with 1.4.

2.2 Definitions.

2.2.1 Definitions of general applicability to these regulations are in Part 1, section 1.2.

2.2.2 As used in Part 2, each term below has the definition set forth.

“ARRT” means the American Registry of Radiologic Technologists.

“ARRT(R)”. See “radiologic technologist”.

“ASRT” means the American Society of Radiologic Technologists.

“Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into a radiation machine system or subsystem.

“Calibration” means to adjust and/or determine the:

- (1) Response or reading of an instrument relative to a series of conventionally true values; or
- (2) Strength of a radiation source relative to a standard or conventionally true value.

“Certification Evaluation” (CE) means the evaluation of a radiation machine at a facility by a qualified inspector or the Department for the purpose of ascertaining the performance of the radiation machine system and/or facility in order to determine conformance with these regulations.

“Direct supervision” means the supervisor is present in the facility and immediately available to furnish assistance and direction to the supervisee throughout the performance of a procedure.

- (1) The direct supervisor is not required to be present in the room when the procedure is performed.
- (2) Direct supervision during the performance of a mammography examination means that the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination.

“Examination” means performing a procedure, including selection of exposure settings, positioning the x-ray system and the patient, and initiating and terminating the exposure.

“Facility” means, for purposes of Part 2, the location within one building (or vehicle, or under one roof, or at one address) and under the same administrative control, at which a radiation machine is or was installed, operated and/or located.

“FDA” means the United States Food and Drug Administration.

“Intercomparison” means the direct comparison, in accord with 2.4.4.4, of two instruments designed to measure the same physical quantity.

“Limited-scope operator” means an individual who has taken and passed a required test and has approval by the Department pursuant to 2.6.1 to operate x-ray systems and to conduct specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum.

“LSO” means limited-scope x-ray machine operator, abbreviated by the ASRT as LXMO, limited

x-ray machine operator.

"MQSA" means Mammography Quality Standards Act.

"NIST" means the National Institute of Standards and Technology.

"Operator" means an individual adequately trained in accordance with these regulations in the purpose and experienced in the practice of performing a radiographic examination.

"Performance adjustment" means the adjustment or repair of a function (not including the setting of operator-selectable functions, such as time, mA and/or kVp for an individual exposure) of an x-ray machine or imaging system that is required to bring the machine into compliance with these regulations and the specifications.

"Provisional qualified inspector" (PQI) means an individual who meets the applicable requirements of Appendix 2I and has current Department approval in a designated specialty to perform, under the general supervision of a qualified inspector, evaluations of radiation machines, facilities, and operators for compliance with these regulations.

"QE(R)" means a qualified expert medical physicist designated for radiographic imaging.

"QE(S)" means a qualified expert physicist designated in other than the healing arts.

"QE(T)" means a qualified expert medical physicist designated for radiation therapy.

"Qualified expert" (QE) means an individual who as provided in 2.4.3 meets the applicable requirements of Appendix 2B or 2C and has current Department approval in a designated specialty to evaluate radiation shielding design and recommend radiation safety practices.

"Qualified inspector" (QI) means an individual who as provided in 2.4.4 meets the applicable requirements of Appendix 2I and has current Department approval in a designated specialty to perform evaluations of radiation machines, facilities, service providers and operators for compliance with these regulations.

"Qualified mammographer" means a mammographer who as provided in 2.4.5.4 meets the applicable requirements of Appendix 2M and has current Department approval.

"Qualified trainer" (QT) means an individual whose training and experience adequately prepares the individual to carry out specified training assignments as illustrated in Appendix 2J.

"Radiologic technologist" means an individual who is currently registered in radiologic technology with the American Registry of Radiologic Technologists, designated ARRT(R).

"Registered medical physicist" (RMP) means an individual who meets the applicable requirements of Appendix 2B and has current Department approval to perform medical physics activities in a designated specialty, including to design shielding, measure ionizing radiation, and oversee radiation protection, quality assurance and clinical medical physics for radiation therapy, computed tomography, mammography and/or other healing arts facilities.

"Service company" means a person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services.

"Service technician" means an individual who is employed by a service company to perform

radiation machine servicing or services.

“Shielding design” means physical specifications, such as room layout, floor plan, construction materials, and equipment configuration, to demonstrate compliance with the radiation limits set forth in Part 4 of these regulations.

EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

2.3 Exemptions.

- 2.3.1 Electronic equipment that is not designed primarily to produce radiation is exempt from the registration and notification requirements of Part 2, provided that the dose equivalent rate averaged over an area of 10 cm² does not exceed 5 µSv (0.5 mrem) per hour at 5 cm from any accessible surface of such equipment.
- 2.3.2 Radiation machines while in transit or storage incident thereto are exempt from the requirements of Part 2.
- 2.3.3 Domestic television receivers, computer monitors, and similar devices are exempt from the requirements of Part 2.
- 2.3.4 A radiation machine that is out of service yet kept at a facility is exempt from the registration and certification evaluation requirements of Part 2 if the Department has received documentation, on Form R-61, “Disposition of a Radiation Machine”, signed by a service technician, or equivalent signed form, that the radiation machine has been made physically inoperable by inactivating or dismantling the electrical circuitry such that the radiation machine is not capable of producing radiation.
- 2.3.5 An electron microscope or electron microprobe is exempt from Part 2 provided that:
 - 2.3.5.1 A survey shows compliance with 2.3.1; or
 - 2.3.5.2 The device is not capable of exceeding an operating voltage of 50,000 electron volts.
- 2.3.6 The legal owner of electronic equipment which meets the requirements of 2.3.1 but which is not specifically exempted under 2.3.2, 2.3.3, and 2.3.4 shall maintain for the lifetime of the equipment radiation measurement results or certification from the manufacturer or a qualified expert indicating that the equipment complies with the exposure rates specified in 2.3.1.

REQUIREMENTS FOR DEPARTMENT APPROVAL AND/OR REGISTRATION

2.4 State of Colorado Authorization or Approval Recognized by the Department is Required for Each Category Designated in This Section.

- 2.4.1 Registration of a Facility.
 - 2.4.1.1 Each person possessing or in the process of coming into the possession of a radiation machine facility shall:
 - (1) Be registered with the Department;
 - (2) Apply for registration of such facility with the Department prior to using a radiation producing machine at the facility;

- (3) Complete and submit an application for registration on Department Form R-4, and include all of the information required by the form and any accompanying instructions, together with the required fee(s);
- (a) Designate a radiation safety officer who meets the applicable requirements of Appendix 2A to be responsible for overall radiation protection for the facility;
 - (b) Attest that a policy is in place for keeping up to date a written or electronic list of all operators who have demonstrated adequate radiation safety training and experience, as prescribed by 2.6.1 and the applicable appendices of parts of these regulations; and
 - (c) Attest that a written shielding design, if required, has been:
 - (i) Completed, or will have been completed, in accordance with 6.3.2 and Appendices 6A, 6B and 6C of these regulations, prior to any radiation machine installation; and
 - (ii) Placed and retained on file at the facility for the life of the facility.

- 2.4.1.2 As prescribed by 6.3.3.3 for a healing arts screening program, complete and submit Form R-300, "Application for Registration - Healing Arts Screening", including all of the information required by Appendix 6F and/or Form R-300 and any accompanying instructions, together with the required fee(s).
- 2.4.1.3 In addition to the other requirements of 2.4, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB).
- 2.4.1.4 If radioactive materials are also present at the facility, the requirements of Part 2 apply as appropriate to coordination with the equivalent licensee or application for a license.

2.4.2 Registration as a Service Company.

- 2.4.2.1 Each person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State, shall be registered with the Department prior to furnishing or offering to furnish any such service.
- 2.4.2.2 Application for registration shall be completed on Form R-60, "Application for Registration - Radiation Machine Servicing and Services," and shall contain all of the information required by the Department as indicated on the form and all accompanying instructions, together with the required fee(s).

2.4.2.3 Each person applying for registration under 2.4.2 shall identify and provide:

- (1) The specific services for which registration is being requested, including but not limited to:
 - (a) Engaging (or offering to engage) in selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, trading out, or disposing of radiation machines and associated radiation machine components; and

- (b) Servicing of radiation machines and associated radiation machine components; and
 - (c) Performance adjustment to or calibration of radiation machines, measurement instruments, and devices; and
- (2) The name and qualifications of each service technician who will provide service, including:
- (a) Documentation of the training and experience that demonstrate, as required by Appendix 2H, sufficient competence to provide the services for which registration is being requested; and
 - (b) Certification that each service technician has been instructed in the requirements of these regulations and of the Federal Performance Standard (21 CFR Chapter I, Subchapter J, April 1, 2010), and demonstrated an understanding thereof; and
- (3) The type of personnel dosimetric monitoring supplied, frequency of reading, and replacement or exchange schedule as appropriate (see 4.17 and 4.18); and
- (4) The type of measurement instruments that will be used to determine compliance with these regulations, including:
- (a) The frequency of calibration; and
 - (b) The provider of calibration services; and
 - (c) A written commitment to meet the instrument calibration requirements specified in 2.4.4.4.

2.4.3 Registration as a Qualified Expert.

2.4.3.1 Each individual who offers the service of designing and/or evaluating shielding to meet the requirements of 6.3.2 shall be registered with the Department as a qualified expert designated QE(R), QE(S) and/or QE(T).

- (1) For a healing arts facility, each shielding design shall be completed as specified in Part 6 by a registered medical physicist who:
 - (a) Meets the criteria established in Appendix 2B; and
 - (b) Has a current Department "Notice of Registration" as a QE(R) for radiography and/or QE(T) for radiation therapy.
- (2) For other than a healing arts facility, each shielding design shall be completed by a qualified expert who:
 - (a) Meets the criteria established in either Appendix 2B for a registered medical physicist or Appendix 2C for any other physicist, designated QE(S); and
 - (b) Has a current Department "Notice of Registration" as QE(R), QE(S) and/or QE(T).

2.4.3.2 Each individual who offers the service of calibration and compliance surveys for a radiation therapy unit shall be registered with the Department as a registered medical physicist who meets the criteria in Appendix 2B and has current Department approval as a registered qualified expert for radiation therapy, designated QE(T).

2.4.3.3 The application for registration shall be submitted on Form R-68, "Application for Registration - Qualified Expert," and include all of the information required by the form and any accompanying instructions, together with the required fee(s).

2.4.4 Registration as a Qualified Inspector.

2.4.4.1 Each individual who offers the service of performing a certification evaluation of a radiation machine and/or facility evaluation shall be registered with the Department as a qualified inspector who meets the criteria established in Appendix 2I.

2.4.4.2 The application for registration shall be submitted on Form R-53, "Application for Registration - Qualified Inspector," and include all of the information required by the form and any accompanying instructions, together with the required fee(s).

2.4.4.3 Department approval as a registered medical physicist consistent with Appendix 2B is considered also to be Department approval as a qualified inspector for any facility and/or machine.

2.4.4.4 Measurements shall be made with instruments that are sufficiently sensitive to determine compliance with these regulations.

- (1) The instruments shall be maintained and used in good working order.
- (2) Notwithstanding the requirement of 4.17.2, such equipment shall be calibrated every two (2) years, or in accordance with the manufacturer's recommendation, whichever is more frequent, or after any repair that could affect the calibration.
- (3) Calibrations shall be NIST-traceable where such traceability is feasible.
- (4) In lieu of calibration, instrument accuracy may, with Department approval, be determined by (inter)comparison with a suitable and appropriately calibrated instrument.
- (5) Each (inter)comparison protocol shall be submitted to the Department for review and approval.
 - (a) The comparison shall be between an instrument that has a current calibration traceable to NIST and an instrument for which a calibration factor is to be determined.
 - (b) The comparison shall be made using the actual physical quantity to be routinely measured (for example, radiation energy/quality or visible light spectrum) and shall be compared in the same physical geometry.
- (6) Instruments used for the certification evaluation report to measure the air kerma or air kerma rate of mammography machines shall be calibrated at least once every two (2) years and each time the instrument is repaired.
 - (a) The instrument calibration shall be NIST-traceable; and

- (b) The instrument shall be calibrated with an accuracy of \pm six (6) percent (95 percent confidence level) in the mammography energy range.

2.4.5 Approval of an Operator.

2.4.5.1 X-ray Machine Operator Subject to Appendix 2D.

- (1) Consistent with and governed by 2.6.1, prior to operating an x-ray system on living humans in the State of Colorado, each individual shall meet the x-ray machine operator adequate radiation safety training and experience criteria established in Appendix 2D, in particular 2D.2.4 for a limited scope x-ray machine operator.
- (2) Application for renewal as a limited scope x-ray machine operator, accompanied by the required fee(s) and evidence of 24 hours of continuing education as prescribed in Appendix 2D and not inconsistent with 2.6.1, shall be submitted at least thirty (30) calendar days prior to the expiration of each two-year registration period.

2.4.5.2 Computed Tomography Operator Subject to Appendix 2E.

- (1) Consistent with and governed by 2.6.1, prior to operating a computed tomography system on living humans, each individual shall at minimum meet the Computed Tomography Operator adequate radiation safety training and experience criteria established in Appendix 2E.

2.4.5.3 Bone Densitometry Equipment Operator (BDEO) Subject to Appendix 2F.

- (1) Consistent with and governed by 2.6.1, prior to operating a bone densitometry x-ray system on living humans, each individual shall at minimum meet the Bone Densitometry Equipment Operator adequate radiation safety training and experience criteria established in Appendix 2F, in particular 2F.2.4.
- (2) Application for renewal, accompanied by the required fee(s) and evidence of 18 hours of continuing education as prescribed in Appendix 2F, shall be submitted at least thirty (30) calendar days prior to the expiration of each three-year registration period.

2.4.5.4 Qualified Mammographer.

- (1) Prior to performing any mammography examination in the State of Colorado, each individual operator shall be a qualified mammographer who meets the adequate radiation safety training and experience qualification criteria established in Appendix 2M.

DEPARTMENT NOTICE OF REGISTRATION

2.4.6 Requirements Applicable to Issuance and Maintenance of Department Registration.

- 2.4.6.1 Upon a determination that an applicant meets the requirements of the regulations, the Department shall issue a Notice of Registration.
- 2.4.6.2 The Department may incorporate in the Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's activities as the Department deems appropriate

or necessary.

2.4.6.3 Approval to conduct or perform activities in accordance with the registration requirements of these regulations shall be:

- (1) For a period of two (2) years, except as otherwise specified by these regulations or the Department; and
- (2) Limited to the category or categories of activities specifically designated.

2.4.6.4 The registrant shall notify the Department in writing within thirty (30) calendar days of making any change which would render inaccurate the information contained in the application for registration and/or the Notice of Registration.

- (1) Each servicing and services registrant under 2.4.2 shall notify the Department each time the registrant adds a service technician (or several service technicians at the same time) to the list of service technicians authorized to provide radiation machine service(s).
 - (a) The registrant will be assessed an acceptance review fee as required by Part 12 for each list change.
 - (b) Changes made during renewal will not be assessed an acceptance review fee.

2.4.6.5 Except as provided by 2.4.6.6, each Notice of Registration shall expire at the end of the month in the year stated therein.

2.4.6.6 In any case in which a registrant, not less than thirty (30) calendar days prior to the expiration of the registrant's authorization, has filed an application in proper form for renewal or for a new registration authorizing the same activities, such existing authorization shall not expire until final action by the Department.

2.4.6.7 The Department may not review or otherwise process a new application or application for renewal for which no remittance is received.

- (1) An application that is incomplete or not accompanied by the prescribed fee(s) will not necessarily be returned to the applicant.
- (2) All application fees are non-refundable.

2.4.6.8 The Department may deny, withdraw, limit or qualify its approval of any person to perform activities upon determining that such action is necessary in order to prevent undue hazard to health and safety, or for other reasonable cause.

2.4.7 Peremptory Registrant Obligations.

2.4.7.1 Whenever a business relationship exists between the qualified inspector and services and servicing provider, a "Notice of Registrant's Rights" Form R-65 shall be furnished to the registrant prior to beginning the service or evaluation, including:

- (1) When a qualified inspector is also authorized to perform services and servicing;
- (2) When a qualified inspector is also a qualified expert; and

- (3) When a qualified inspector, a qualified expert and/or a services and servicing provider is a member of the same corporation, partnership or other formal business relationship.
- 2.4.7.2 No person, in any advertisement, shall refer to the fact that the person is registered with the Department pursuant to the provisions of 2.4.1, 2.4.2, 2.4.3 and 2.4.4, and no person shall state or imply that the quality of conduct or performance of any activity under such registration has been approved or endorsed by the Department.

CERTIFICATION EVALUATION

2.5 Certification Evaluations.

2.5.1 Frequency of Certification Evaluations.

- 2.5.1.1 Each radiation machine registrant shall have its radiation machine(s) and facility evaluated by a Department-approved qualified inspector annually, except as provided in 2.5.1.2 through 2.5.1.5 (section 2.5.1 is summarized in Table 2-1).
 - (1) Each certification evaluation shall be capable of determining that the machine is safe for each intended use and in compliance with the specifications of the equipment manufacturer and these regulations.
 - (2) Each certification evaluation is in addition to and not intended to replace the manufacturer(s) recommended equipment service and/or repair procedures or facility quality assurance programs.
 - (3) Each certification evaluation subsequent to the initial certification evaluation shall be completed in or prior to the same calendar month as the previous certification evaluation.
 - (4) The calendar month of a certification evaluation of a machine in any month prior to the month in which it is due shall become the calendar month in which the subsequent certification is due.
 - (5) A certification evaluation conducted after the month in which it was due shall not alter or change the month in which subsequent certification evaluations are due.
- 2.5.1.2 Each non-healing-arts fixed industrial radiography, analytical, cabinet, or self-contained airport or port-of-entry inspection x-ray imaging machine or system shall be inspected at least every two (2) years.
- 2.5.1.3 Each bone densitometry, dental, podiatry or veterinary radiation machine shall be inspected at least every three (3) years, except that:
 - (1) Each radiographic x-ray machine or tomographic or computed tomographic system that is capable of a variable kilovoltage peak (kVp) or variable milliamperage (mA) or variable collimation and used in non-intraoral dentistry or podiatry shall be inspected annually.
 - (2) Each machine used in podiatry that is capable of operating at more than 30 mA shall be inspected annually.
 - (3) Each volumetric dental imaging system shall be inspected annually.

- 2.5.1.4 Each human use portable hand-held instrument used for any purpose shall be inspected annually.

TABLE 2-1: SUMMARY OF FREQUENCY OF RADIATION MACHINE INSPECTION

Category	Frequency
Each radiation machine, including under reciprocity, unless otherwise provided below:	Every year
Each non-healing-arts fixed industrial radiography or analytical, cabinet, airport or port-of-entry x ray machine or system	Every two years
Each bone densitometry, dental, podiatry or veterinary radiation machine, except as required below:	Every three years
Pursuant to 2.5.1.3(1), each radiographic x-ray machine or tomographic or computed tomographic system used with a variable setting (kVp, mA or collimation) in non-intraoral dentistry or podiatry	Every year
Pursuant to 2.5.1.3(2), each x-ray machine used in podiatry at more than 30 mA	Every year
Pursuant to 2.5.1.3(3), each volumetric dental imaging system	Every year
Pursuant to 2.5.1.4, each human use hand-held x-ray machine	Every year

- 2.5.1.5 Each new installation of a radiation machine system or replacement component that will affect or could potentially affect radiation output shall be evaluated within no more than ninety (90) calendar days of installation.
- 2.5.1.6 Each new installation of a mammography system shall be evaluated by a qualified inspector authorized in mammography prior to being used to perform any human examination.
- 2.5.1.7 Any radiation machine and/or facility not inspected in accordance with 2.5.1.1 through 2.5.1.6, or otherwise determined to be out of compliance with these regulations, shall be subject to a Department enforcement inspection and subject to the fees specified in Part 12.

2.5.2 Procedures for Certification Evaluations by Qualified Inspectors.

- 2.5.2.1 Each qualified inspector who performs a certification evaluation of a radiation machine and/or facility evaluation shall use procedures that are sufficient to determine compliance with these regulations.
- 2.5.2.2 If a radiation machine fails to meet any requirement specified by these regulations, including manufacturer's required specifications, the qualified inspector shall immediately so inform the registrant and/or RSO designated pursuant to 2.4.1.1.
- 2.5.2.3 If the radiation machine is determined to be unsafe (as provided in Part 6 and described in Appendix 6D), the qualified inspector shall affix to such radiation machine system, in a location clearly visible to the patient, an "Unsafe for Use" label authorized and issued by the Department, indicating, as applicable, that such machine is not authorized for human, animal or other use.

2.5.2.4 Reporting and Labeling Procedures.

- (1) Each qualified inspector shall certify each determination of compliance and be responsible to provide an accurate and complete Certification Evaluation Report to the registrant and to the Department on Form R-59-1, "X-ray Machine Certification Evaluation Report," in accordance with the instructions contained in that form.
 - (a) A clear and legible report may be substituted for Form R-59-1, provided that it is in the same format and provides all of the information required by Form R-59-1.
 - (b) Violations of the regulations not related to the performance of the specific radiation machine(s) shall be reported to the Department using Form R-59-2, "X-ray Facility Compliance Evaluation Report," in accordance with the instructions contained in that form.
- (2) A qualified inspector shall provide to the registrant and Department a copy of the R-59-1 or R-59-2 Report.
 - (a) The Report shall indicate full or partial compliance and any specific violation of these regulations.
 - (b) The Report shall include recommendations for corrective actions by the registrant (if applicable) to assist in achieving full compliance and/or improving radiation safety and the quality of the imaging process.
 - (c) The Report shall be received by the Department no later than fifteen (15) calendar days after the inspection date, unless otherwise authorized by the Department.
- (3) The qualified inspector shall personally affix, or personally direct the registrant exactly how and where to affix, a certification label issued by the Department in a location clearly visible to the machine operator and patient, if (and only if) and when it is determined that the requirements of these regulations, including manufacturer's required specifications, are fully met.
 - (a) For a machine that was found to be in full compliance, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the inspection date.
 - (b) For a noncompliant machine, the certification label shall be affixed no later than fifteen (15) calendar days (unless otherwise authorized by the Department) after the date that full compliance was achieved.
- (4) Each qualified inspector shall ensure that the following closeout documentation is provided to the Department to confirm that each violation was corrected as required by 2.6.3.1 and/or 2.6.4.1 within thirty (30) calendar days of the date of inspection.
 - (a) For a noncompliant machine for which full compliance has been achieved, the completed documentation (on Form R-59-1 or equivalent, signed by the qualified inspector as completed and including the number of the label that was affixed) shall be received by the Department no later than fifteen (15) calendar days after the date that compliance was

achieved.

- (b) For a noncompliant facility, the completed documentation (on Form R-59-2 or equivalent signed by the registrant as completed) shall be received by the Department no later than fifteen (15) calendar days after the date that full compliance was achieved.
- (5) Concealing, defacing or altering of Department-issued labels is prohibited.
- (6) Repeated failure to affix certification labels and/or to accomplish timely completion of certification evaluation reports as provided in this subsection shall be subject to review and audit as provided in 2.9 and also subject to the non-routine inspection fee as provided in Part 12.

2.6 Facility Registrant Responsibilities.

- 2.6.1 In any facility regulated by or requiring registration under these regulations, the registrant shall allow only individuals who are adequately trained in radiation safety and the safe and effective use of the machine to operate any radiation machine.
 - 2.6.1.1 The facility registrant shall document evaluation of the qualifications of each individual permitted to operate any radiation machine at the facility.
 - (1) Each operator shall meet all radiation safety training and experience requirements of the respective State of Colorado professional licensure board, as applicable, and any applicable requirements of this Part 2.
 - (2) Consistent with 2.4.1.1(3)(b), the registrant shall maintain a list of operators (or have a policy in place that specifies how such a list will be provided on request) who have been determined to be adequately trained in accordance with these regulations.
 - (a) For fluoroscopy equipment used in examination of a living human, a list of qualified individuals shall be maintained as required by 2.6.1.5.
 - (b) The list of all operators qualified for fluoroscopy shall be updated at least annually as part of the radiation safety program required by 4.5.
 - (3) Records of such evaluations shall:
 - (a) Include current certifications of qualification;
 - (b) Be maintained by the facility; and
 - (c) Be produced for examination upon request during any inspection conducted under the requirements of these regulations.
 - 2.6.1.2 A physician, chiropractor, dentist, podiatrist, or veterinarian who has a current active license from the appropriate State of Colorado professional licensure board is considered to have demonstrated adequate training in radiation safety and the safe and effective use of the radiation machine (consistent with 2.6.1.5) and may operate radiation machines as part of medical, chiropractic, dental, podiatric or veterinary practice, respectively.
 - 2.6.1.3 For a radiologist assistant "adequately trained" shall mean that the individual is qualified as provided in Appendix 2G.

- 2.6.1.4 For any radiographic x-ray system used on a living human (not inconsistent with 2.6.1.2, 2.6.1.3, and 2.6.1.5 through 2.6.1.14), "adequately trained" shall mean that the individual meets the requirements of Appendix 2D.
- (1) Limited-scope x-ray machine operator approval is limited to imaging procedures for x-ray examination of the skull, chest, hip/pelvis and spine/sacrum, upper extremities and lower extremities.
 - (2) A limited-scope x-ray machine operator shall not perform radiologic procedures involving the administration or utilization of contrast media, bone density or fluoroscopic equipment, mammography, computed tomography, or radiation therapy procedures.
- 2.6.1.5 For fluoroscopy equipment used in examination of a living human, "adequately trained" shall mean that, in addition to meeting all applicable requirements in 2.6.1.1 through 2.6.1.4, each healing arts facility shall make a written determination that any individual who either supervises a fluoroscopy procedure or operates a fluoroscopy imaging system has adequate training in its safe operation, including documented training in the following:
- (1) Fundamental principles of radiation protection;
 - (2) Biological effects of ionizing radiation;
 - (3) Safe operation of fluoroscopy equipment for each mode of operation to be used;
 - (4) Dose reduction techniques for fluoroscopy; and
 - (5) Applicable radiation regulations.
- 2.6.1.6 For mammography equipment used in radiography of the human breast, "adequately trained" shall mean that the individual operator meets the registration and/or other requirements of Appendix 2M.
- 2.6.1.7 For any computed tomography system used on a living human, "adequately trained" shall mean that the individual operator meets the registration and/or other requirements of Appendix 2E.
- 2.6.1.8 For any bone densitometry equipment used in examination of a living human, "adequately trained" shall mean that the individual operator meets the registration and/or other requirements of Appendix 2F.
- 2.6.1.9 For radiographic equipment used in the practice of medicine, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado State Board of Medical Examiners (in particular Rule 700, "State Board of Medical Examiners Rules and Regulations Regarding Education and Training Standards for Unlicensed Personnel Exposing Ionizing Radiation" of 3 CCR 713-16).
- 2.6.1.10 For radiographic equipment used in chiropractic, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado State Board of Chiropractic Examiners (in particular Rule 19, "Safety Training for Unlicensed Chiropractic Personnel," of 3 CCR 707-1).
- 2.6.1.11 For radiographic equipment used in dentistry, "adequately trained" shall mean that the individual operator meets all applicable requirements of the Colorado State Board of Dental Examiners (in particular Rule X, "Minimum Standards for Qualifications,

Training and Education for Unlicensed Personnel Exposing Patients to Ionizing Radiation," of 3 CCR 709-1).

2.6.1.12 For radiographic equipment used in podiatry, "adequately trained" shall mean that the individual operator meets all applicable requirements of the State of Colorado Podiatry Board (in particular Rule 700 of 3 CCR 712-9).

2.6.1.13 For radiographic equipment used in veterinary medicine, "adequately trained" shall mean that the individual operator meets all applicable requirements of the State of Colorado Board of Veterinary Medicine (in particular 4 CCR 727 1).

2.6.1.14 An individual, enrolled in an ARRT-recognized program or graduated therefrom, may operate radiation machines so long as the individual works under the direct supervision of a radiologic technologist or other qualified trainer and has documentation of having completed education and experience equal to that specified in the program.

- (1) A graduate from an ARRT-recognized program is granted ninety (90) calendar days from the date of graduation to schedule, take and pass the radiologic technology registry examination.
- (2) During the 90-day period allowed by 2.6.1.14(1), the graduate is considered to satisfy Appendix 2D.
- (3) A student or graduate who fails to pass the registry examination has not met the requirements of Appendix 2D and shall not operate any radiation machine system on a living human unless otherwise authorized by the Department.

2.6.1.15 For radiation machines used in non-healing-arts applications, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2N.

- (1) For industrial radiography, the requirements in Part 5 apply, as stated in 2N.1.
- (2) The requirements of 2N.2 apply to all non-healing-arts applications (including but not limited to analytical, forensic, morgue, and homeland security uses) not subject to Part 5.

2.6.1.16 For assembly, installation and repair of radiation machines, "adequately trained" shall mean that the individual service technician meets the requirements of Appendix 2H.

2.6.1.17 Department recognition of training as adequate pursuant to 2.6.1.3 through 2.6.1.16 shall pertain only to the areas of training and experience specifically identified in these regulations.

2.6.1.18 If and when an application to the Department is required, the application for adequate training review and approval or for an examination administered by the Department shall be:

- (1) Submitted on forms prescribed by the Department; and
- (2) Completed to contain all the information required by the form and all accompanying instructions; and
- (3) Accompanied by the application fee(s) specified in Part 12; and
- (4) Accompanied by evidence of continuing education, if and when required.

2.6.1.19 The Department may, upon application or upon its own initiative, accept as being adequate:

- (1) Documented combinations of radiation safety training and experience; or
- (2) Equivalent approval by another state or agency.

2.6.2 The facility registrant shall ensure that all required certification and compliance evaluations are performed as required by 2.5.2 in accordance with the instructions that accompany Form R-59-1, "X-ray Machine Certification Evaluation Report" and Form R-59-2, "X-ray Facility Compliance Evaluation Report."

2.6.3 For each radiation machine finding of noncompliance (Form R-59-1), the facility registrant shall:

2.6.3.1 Correct any failure of a radiation machine or imaging system to meet the requirements of these regulations or manufacturer's required specifications, within thirty (30) calendar days or as otherwise specified by the Department, in particular as identified on Form R-59-1, "X-ray Machine Certification Evaluation Report."

2.6.3.2 Not use a radiation machine that has been determined to be unsafe for use, in particular according to any of the criteria in Appendix 6D, until subsequent certification by a Department-approved qualified inspector or the Department.

2.6.3.3 Permit only a person who has provided evidence of current registration with the Department in accordance with 2.4.2 to provide radiation machine servicing or services.

2.6.3.4 Upon correction of any radiation machine item of violation, confirm to the qualified inspector that indicated repairs have been completed.

- (1) A copy of the Certification Evaluation Report, Form R-59-1, with the service repair certification signed and dated by the person providing service, shall be provided to the qualified inspector who signed the original Form R-59-1.

- (2) A copy of any service report shall be provided to the qualified inspector upon request as evidence of completed corrective action.

2.6.3.5 Upon correction of any item of violation identified on Form R-59-1, "X-ray Machine Certification Evaluation Report," retain documentation that each indicated violation has been corrected to bring the machine into compliance.

2.6.3.6 Pay the fee required by Part 12 for each certification label issued to the registrant by the qualified inspector.

2.6.4 For each finding of facility noncompliance (Form R-59-2), the registrant shall:

2.6.4.1 Correct any violation within thirty (30) calendar days of each finding of facility noncompliance (Form R-59-2) or as otherwise specified by the Department.

2.6.4.2 Provide documentation to the Department to confirm that each indicated violation has been corrected to bring the facility into compliance.

- (1) For any item identified for correction on Form R-59-2, "X-ray Facility Compliance Evaluation Report", provide a copy of the Form R-59-2 with the "Registrant's Certification of Correction" section signed and dated by the registrant or registrant's agent.

2.6.4.3 Pay any fee required by Part 12.

2.6.5 Record Retention and Reports.

2.6.5.1 The registrant shall maintain each diagnostic image in a medical record for each patient as specified by the applicable State of Colorado professional licensure board; absent an applicable board specification, record retention shall be for a period not less than ten (10) years or any period of minority or incompetency.

2.6.5.2 The registrant shall maintain for the duration of the registration, records of each shielding design, and each radiation survey required by 6.9.4.1, performed for the facility.

- (1) Upon any transfer of ownership, such shielding design(s) and survey records shall also be transferred to the new owner.

2.6.5.3 The registrant shall maintain for the duration of the registration, until a machine is retired from service, the operator and service manual(s) provided by the manufacturer, if available.

- (1) If the operator manual is not obtainable from the manufacturer, such a manual of written operating procedures shall be developed and maintained by the registrant, including:
 - (a) A description, including purpose and function, of each control panel knob, button, and meter;
 - (b) Techniques for collimation and centering of the beam to the image receptor;
 - (c) The function of all locks and detents; and
 - (d) Emergency shutdown instructions.

2.6.5.4 The registrant shall maintain for inspection for a period of three (3) years for each x-ray imaging or image processing system (six years for a facility or machine inspected only every three years) records of:

- (1) Operator certifications;
- (2) Operator training;
- (3) Service and repair reports;
- (4) Radiation machine inspection certification evaluation reports;
- (5) Facility compliance evaluation reports; and
- (6) Notices of violation.

2.7 Service Company Registrant Responsibilities.

2.7.1 No person shall certify or declare that a radiation machine or component, or the supplies used in connection with such a machine or component, is ready for its intended use, unless and until:

- 2.7.1.1 The shielding design has been completed if and as required by 6.3.2, as documented (without exception after June 30, 2010) by a comment on Form FDA 2579 or a signed and dated notification to the Department.
- 2.7.1.2 The machine and/or component (and any associated equipment and supplies), after having properly been made operational, demonstrably meet the manufacturer specifications and the requirements of these regulations; and
- 2.7.1.3 The registrant has been provided, by the vendor, assembler and/or services and servicing personnel, as required by the Federal Performance Standard (21 CFR Chapter I, Subchapter J, April 1, 2010) and these regulations, the following:
- (1) All guidance documents, including instruction manuals, manufacturer specifications and information notices, that are applicable to each newly installed radiation machine system or component; and
 - (2) A checklist of the registrant's responsibilities under these regulations, including but not limited to requirements of 2.6.3, in particular 2.6.3.4.
- 2.7.2 Any person who sells, leases, transfers, lends, assembles, installs, trades out or disposes any radiation machine, or component, which affects radiation output in this State shall notify the Department in writing within fifteen (15) calendar days of each transaction subject to this section with the following information:
- 2.7.2.1 The full name and address of each person who has received the radiation machine or component and the specific location within the facility; and
- 2.7.2.2 Specific details about the system or sub-system, including the manufacturer, model, and serial number of each radiation machine or component transferred; and
- 2.7.2.3 The date of transfer, assembly, or installation of each radiation machine or component; and
- 2.7.2.4 A completed Form FDA 2579 or a signed and dated affirmation that all instruction manuals, written instructions and regulations applicable to the newly installed radiation machine system or components have been delivered to the registrant.
- 2.7.3 A report of assembly (Form FDA 2579 or equivalent) in compliance with requirements of the Federal Performance Standard (21 CFR 1020.30(d), April 1, 2010) shall be submitted to the Department within fifteen (15) calendar days following completion of the assembly or installation.
- 2.7.3.1 The assembly or installation is considered completed when the unit has properly been made operational and is ready for its intended use.
- 2.7.3.2 Form FDA 2579 or an equivalent report suffices in lieu of any reports required in 2.7.2.
- 2.7.4 If required by the Department on a Certification Evaluation Report, Form R-59-1, a service company that performs a radiation machine repair shall:
- 2.7.4.1 Sign, as the person providing service, the service repair certification section of a copy of the original Certification Evaluation Report, Form R-59-1;
- 2.7.4.2 Provide a copy to the qualified inspector who signed the original Certification Evaluation Report, Form R-59-1, with the service repair certification signed by the person providing service; and

2.7.4.3 Provide, upon request, a copy of any additional information about the details of the repair.

RECIPROCITY

2.8 Out-of-State Radiation Machines.

2.8.1 Subject to these regulations, any person who desires to bring radiation machines into this state for temporary use is hereby granted authorization to conduct activities using these machines for a period not to exceed a total of 180 days in any calendar year, provided that:

2.8.1.1 The out-of-state registration, and/or other documents authorizing the use of radiation machines issued by the agency having jurisdiction where the out-of-state registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, does not limit the activity authorized by such document to specified installations or locations; and

2.8.1.2 The person proposing to bring such machines into Colorado shall give written notice to the Department at least fifteen (15) calendar days before such machine is to be used in the state, unless otherwise authorized by the Department as provided in 2.8.2. The notice shall be made using the Department's "X-ray Reciprocity Request" Form R-200 and shall include all information required by that form.

- (1) As part of this notice, the person requesting reciprocity shall certify that:
 - (a) A copy of all applicable parts of these regulations shall be available at each use location in State of Colorado;
 - (b) Each machine has been evaluated and determined to be in compliance with these, or equivalent, regulations; and
 - (c) The operation of each radiation machine shall be in accordance with the applicable requirements of these regulations.
- (2) In the case of a request to perform a healing arts screening program within the State, submit a completed Form R-300, "Application for Registration – Healing Arts Screening," with the reciprocity request, including all of the information required, pursuant to Part 6, Appendix 6F, by the form and any accompanying instructions.
- (3) In the case of a request to perform mammography screening within the State, a copy of the facility's mammography certificate issued by the FDA (21 CFR 900.11(a), April 1, 2010) and applicable American College of Radiology credentials shall be included with the reciprocity request.
- (4) The person requesting reciprocity shall also supply such other information as the Department may request.

2.8.1.3 The out-of-state registrant complies with all applicable regulations of the Department; and

2.8.1.4 The out-of-state registrant shall at all times during work at any work location within the State have available the pertinent documentation as required by these regulations, including:

- (1) Pertinent registration documentation;

- (2) Written authorization from the Department for in-state activities;
 - (3) Applicable sections of these regulations as certified pursuant to 2.8.1.2(1)(a);
 - (4) Documentation that each radiation machine has been evaluated in accordance with these regulations, or other state regulations which are equivalent; and that
 - (a) The machines comply with the manufacturer's required specifications;
 - (b) The evaluations are current, having been performed within one year prior to entry into the State as required in 2.5; and
 - (5) In the case of mammography-related functions, a copy of the mammography certificate issued by the FDA, applicable American College of Radiology credentials, quality control records, personnel records, and the most recent medical physicist survey.
- 2.8.2 Based upon an application that includes documentation of why it is not possible or is an undue hardship to provide fifteen (15) calendar days notice, the Department may:
- 2.8.2.1 Grant permission to proceed sooner; or
 - 2.8.2.2 Waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities pursuant to 2.8.1.
- 2.8.3 While in the State of Colorado, all radiation machines are subject to inspection and may be required to be inspected and/or certified by a qualified inspector who is registered with the Department.
- 2.8.4 The out-of-state registrant shall notify the Department within one hour after arrival at the actual work location within the State and shall notify the Department within one hour after any change of work location within the State.
- 2.8.5 If multiple individuals work concurrently at more than one work location under an approval granted pursuant to 2.8.1, each day worked per location shall be counted separately toward the limit of 180 cumulative total days per calendar year.
- 2.8.6 The Department may revoke, limit, or qualify its approval for the use of radiation machines in the State upon determining that the approval was based on false or misleading information submitted to the Department or that such action is necessary in order to prevent undue hazard to public health and safety or property.
- 2.8.7 Each person operating a radiation machine within the State under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable federal requirements.

ENFORCEMENT

2.9 Department Review of Performance.

- 2.9.1 The Department as appropriate shall:

2.9.1.1 Notify the registrant regarding inadequate action on any item of violation;

2.9.1.2 Determine a schedule for correction of each violation, specifying a date by which

compliance must be achieved;

2.9.1.3 Confirm and verify by inspection a registrant's corrective action(s) to assure compliance with these regulations; and/or

2.9.1.4 Assess a non-routine inspection fee provided in Part 12, at the programmatic hourly rate, for the inspection of a radiation machine system or facility, if:

- (1) The registrant fails to fulfill the requirements in 2.5.1; or
- (2) Any item of violation has not been corrected in accordance with the compliance schedule established in 2.9.1.2.

2.9.2 The Department shall periodically review and audit:

2.9.2.1 The adequacy of servicing and services of each registrant, for example, on a frequency consonant with the type of radiation machine, as in 2.5.1.2;

2.9.2.2 The competency of each service technician in meeting standards and requirements for adequate service company performance;

2.9.2.3 The performance of each qualified inspector, in particular:

- (1) Adequacy of inspections;
- (2) Competency in determining radiation machine system or facility compliance with these regulations; and
- (3) Completeness and accuracy of findings on Form R-59-1 or R-59-2;

2.9.2.4 The performance of each qualified expert and/or registered medical physicist, in particular:

- (1) Adequacy of shielding evaluations; and
- (2) Competency in performing activities in accordance with these regulations.

2.9.3 The Department shall notify the registrant of any failure to meet a performance standard or requirement of the regulations that is identified as a result of the review or audit.

2.9.4 The Department shall determine a schedule for actions required, specifying the date by which adequacy or competency shall be demonstrated.

2.9.5 For any failure to demonstrate adequacy or competency in accordance with the compliance schedule established in 2.9.4, the Department will assess a non-routine inspection fee at the programmatic hourly rate for Department effort to enforce compliance with a performance standard or requirement of the regulations.

2.9.6 The Department may deny, withdraw, limit or qualify its approval of any person to perform activities upon determining that such action is necessary in order to prevent undue hazard to health and safety, or for other reasonable cause.

2.9.7 A registrant that fails to comply with these regulations including 2.4.5 and 2.4.6 shall be subject to revocation as provided in 2.10.

MODIFICATION AND REVOCATION OF REGISTRATION

- 2.10 The terms and conditions of all registrations/certificates shall be subject to amendment, revision, or modification or the registration/certificate may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.

PART 2, APPENDIX 2A: RADIATION MACHINE RADIATION SAFETY OFFICER (RSO) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The applicant, licensee, or registrant shall require each individual assigned to fulfill responsibilities as Radiation Safety Officer (RSO) to be an individual who:

2A.1 Has provided evidence of current credentials acceptable to the Department that demonstrate training and experience in the safe and effective use of radiation machines and the potential radiation hazards and emergency precautions applicable to the type(s) of activity or facility for which the individual is seeking to perform RSO duties, to include:

2A.1.1 For any healing arts facility, approval by the Department as a registered medical physicist (RMP), provided in addition that the RMP has:

2A.1.1.1 For radiation therapy, as provided by 2.4.3.2 and Part 6, current registration as a QE(T);

2A.1.1.2 For computed tomography, as provided by Part 6, current registration as either a QE(R) or QE(T); or

2A.1.2 For non-healing arts facilities (such as those governed by Part 8, "Radiation Safety Requirements for Radiation Generating Machines Not Used in the Healing Arts", and Part 9, "Radiation Safety Requirements for Particle Accelerators Not Used in the Healing Arts"), has current Department approval as a QE(R), QE(S), QE(T) or as having satisfactorily completed:

2A.1.2.1 A baccalaureate or higher degree in natural or physical science, health physics, radiological sciences, nuclear medicine, nuclear engineering, or other structured educational program that included classroom training in the responsibilities of an RSO, including but not limited to:

(1) Establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with these regulations;

(2) Ensuring that individual monitoring devices are properly used by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part 3;

(3) Investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these regulations and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;

(4) Having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;

(5) Assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency

- situations or unsafe conditions;
- (6) Maintaining records as required by these regulations; and
- (7) Ensuring that personnel are adequately trained and complying with these regulations, the conditions of the certificate of registration, and the operating and safety procedures of the registrant; and
- 2A.1.2.2 Experiential training in radiation safety for the assigned type(s) of activity or facility, including emergency procedures and how to appropriately apply radiation regulations; or
- 2A.1.3 For a healing arts facility other than for radiation therapy or computed tomography, unless otherwise provided or prohibited by these regulations:
- 2A.1.3.1 Meets the applicable operator requirements of 2.6.1.2 through 2.6.1.14; and
- 2A.1.3.2 Has completed a structured educational program that includes ionizing radiation safety, for example, radiological sciences training as part of a professional course of study or a 40-hour radiation safety course; and
- 2A.1.3.3 Has completed at least two years of applicable supervised use of radiation machines; or
- 2A.1.4 For a healing arts facility other than for radiation therapy or computed tomography, or for a non-healing arts facility (such as those governed by Part 8, "Radiation Safety Requirements for Radiation Generating Machines Not Used in the Healing Arts", and Part 9, "Radiation Safety Requirements for Particle Accelerators Not Used in the Healing Arts"), has:
- 2A.1.4.1 Prior Department approval pursuant to another part of these regulations as an authorized RSO; and
- 2A.1.4.2 Sufficient radiation safety experience, for example, as a qualified radiation machine operator (at least two years unless otherwise approved by the Department), commensurate with the type(s) of activity or facility for which the individual is seeking to perform RSO duties as, or under the supervision of, a certified health physicist, certified medical physicist, experienced RSO, or radiation protection professional recognized by the Department;
- 2A.2 And has also complied with each additional requirement applicable to the assigned type(s) of activity or facility that pertains to qualification or duties of a radiation safety officer under any other part of these regulations.

PART 2, APPENDIX 2B: REGISTERED MEDICAL PHYSICIST ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Each registered medical physicist shall be an individual who:

2B.1 Has provided evidence of:

2B.1.1 Current certification in a subfield of medical physics by:

- 2B.1.1.1 The American Board of Medical Physics; or
- 2B.1.1.2 The American Board of Health Physics; or
- 2B.1.1.3 The Canadian College of Medical Physics; or
- 2B.1.1.4 The American Board of Radiology in a radiological physics category; or
- 2B.1.1.5 American Board of Nuclear Medicine Science; or
- 2B.1.1.6 A recognized equivalent specialty board; and

2B.1.2 Written approval from the Department to design shielding or conduct specified medical physics activities as a qualified expert for:

- 2B.1.2.1 Radiography other than radiotherapy, designated QE(R), having met the applicable criteria in AAPM Report No. 42, "The Role of the Clinical Medical Physicist in Diagnostic Radiology" (January 1994), in particular page 12; or
- 2B.1.2.2 Radiation therapy, designated QE(T), with training and experience in the clinical applications of radiation physics to radiation therapy, having met the applicable criteria in AAPM Report No. 38, "The Role of a Physicist in Radiation Oncology" (1993), in particular page 7.

2B.2 Or, as an alternative to fully satisfying 2B.1, is approved by the Department as a provisional registered medical physicist to assist a registered medical physicist with assigned activities of specified duration, having provided to the Department:

- 2B.2.1 An application that includes the name and signature of each registered medical physicist for whom the applicant will be working under supervision; and
- 2B.2.2 Evidence that all training and experience requirements are met to become certified as prescribed by 2B.1.1, but full certification has not yet been received.

**PART 2, APPENDIX 2C: QUALIFIED EXPERT FOR SHIELDING DESIGN FOR OTHER THAN A
HEALING ARTS FACILITY – QE(S) – ADEQUATE RADIATION SAFETY TRAINING AND
EXPERIENCE**

As provided by 2.4.3.1(2), each qualified expert for shielding design (other than a registered medical physicist) shall be an individual who:

2C.1 Has provided evidence of:

 2C.1.1 Current certification by a physics specialty board recognized by the Department; and

 2C.1.2 Written approval from the Department as a qualified expert for shielding design, designated QE(S);

2C.2 Or, has provided written documentation that the individual:

 2C.2.1 Holds a master or doctorate degree from an accredited college or university in physics, biophysics, radiological physics, health physics, or medical physics; and

 2C.2.2 Has satisfactorily completed 2 years of training and work experience acceptable to the Department that include:

 2C.2.2.1 One year of documented, full-time training in the appropriate field; and

 2C.2.2.2 One additional year of documented, full-time practical experience, under the supervision of a qualified expert, including having designed shielding; and

 2C.2.3 Has also satisfied 2C.1.2;

2C.3 Or, has adequate prior experience as an experienced qualified expert who has:

 2C.3.1 Satisfied 2C.1.2 and 2C.2.1; and

 2C.3.2 Demonstrated to the Department sufficient experience required of a qualified expert for shielding design.

PART 2, APPENDIX 2D: X-RAY SYSTEM OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE, INCLUDING LIMITED-SCOPE X-RAY MACHINE OPERATOR (LSO)

The registrant shall require each x-ray system operator to be an individual at least 18 years of age who:

2D.1 Is certified or registered by:

2D.1.1 The American Registry of Radiologic Technologists; or

2D.1.2 A specialty board that has been recognized by the Department, including or in combination with documentation accepted by the Department of the training required by 2D.2A through 2D.2F;

2D.2 Or, is accepted by the Department as a State of Colorado-registered limited-scope x-ray machine operator to conduct specified radiographic examinations of the chest, extremities, skull, hip/pelvis and spine/sacrum, having satisfactorily completed:

[Elements of the following are from the 2009 *Content Specifications for the Examination for the Limited Scope of Practice in Radiology* and used with ARRT permission.]

2D.2.1 At least 80 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2D.2A through 2D.2F:

RADIATION SAFETY (passing score on written test of 75% or higher on the radiation safety module)

2D.2A Basic X-Ray Physics—20 hours

- (1) Structure of matter and the atom
- (2) General description of production of x-rays
- (3) X-ray emission, quantity and quality
- (4) Function of filtration and effects it has on x-ray beam collimation
- (5) Types of function of beam limiting devices
- (6) Design, features and functions of x-ray tubes
- (7) Circuitry of the x-ray machine

2D.2B Radiobiology—3 hours

- (1) Effects of ionizing radiation on the human body
- (2) Molecular and cellular radiobiology
- (3) Factors that cause somatic and genetic damage

2D.2C Radiation Protection—6 hours

- (1) ALARA

- (2) Shielding materials
- (3) Radiation quantity and units of measurement
- (4) Basic interactions of x-rays with matter
- (5) Primary and secondary scatter
- (6) Importance of time, distance, shielding
- (7) Maximum permissible doses: occupational and public
- (8) Patient protection

RADIOGRAPHIC PROCEDURES (passing score on written test of 75% or higher on radiographic procedures module

2D.2D. Principles of Exposure—15 hours

- (1) Factors that control and influence radiographic quality
- (2) Properties of x-rays
- (3) Size distortion
- (4) Shape distortion
- (5) kVp, mAs, time
- (6) AEC and manual
- (7) Grids
- (8) Collimation
- (9) Intensifying screens
- (10) X-ray films and holders
- (11) Artifacts
- (12) Inverse square law

2D.2E Procedures and Processing—4 hours

- (1) Film storage and handling
- (2) Manual, automatic processing film processing and troubleshooting
- (3) Computed Radiography (CR)
- (4) Digital Radiography (DR)
- (5) PACs

(6) Quality assurance / quality control

2D.2F Anatomy and Positioning—32 hours

- (1) Chest—4 hours
- (2) Extremity—12 hours
- (3) Spine—8 hours
- (4) Skull—8 hours; and

2D.2.2 At least 480 hours of clinical training during which time the individual may perform x-ray examinations only under personal (in attendance during the procedure) supervision of a qualified trainer, including:

- 2D.2.2.1 At least 320 hours experiential training at a clinic; and
- 2D.2.2.2 No more than 160 hours of laboratory training (exclusive of the didactic hours required by 2D.2A through 2D.2F); and

2D.2.3 Performance of the following imaging procedures (at least 80 examinations in total, with record of each examination kept on file):

- 2D.2.3.1 Ribs—4 examinations;
- 2D.2.3.2 Hand—4 examinations;
- 2D.2.3.3 Wrist—4 examinations;
- 2D.2.3.4 Forearm—4 examinations;
- 2D.2.3.5 Elbow—4 examinations;
- 2D.2.3.6 Humerus—4 examinations;
- 2D.2.3.7 Shoulder—4 examinations;
- 2D.2.3.8 Clavicle—4 examinations;
- 2D.2.3.9 Femur—4 examinations;
- 2D.2.3.10 Tibia – Fibula—4 examinations;
- 2D.2.3.11 Ankle—4 examinations;
- 2D.2.3.12 Foot—4 examinations;
- 2D.2.3.13 Sinuses—4 examinations;
- 2D.2.3.14 Skull—4 examinations;
- 2D.2.3.15 Facial Bones—4 examinations;
- 2D.2.3.16 C-Spine—4 examinations;

- 2D.2.3.17 Thoracic Spine—4 examinations;
 - 2D.2.3.18 Lumbar Spine—4 examinations;
 - 2D.2.3.19 Chest—4 examinations;
 - 2D.2.3.20 Hip / Pelvis—4 examinations; and
- 2D.2.4 Approval by the Department as having passed the ARRT Limited Scope Operator State Examination required by 2.4.5.1.
- 2D.2.4.1 The application to be registered in the State of Colorado as a Limited Scope Operator shall be submitted on the appropriate Department form(s) and shall contain all information required by the Department as indicated on the form(s) and all accompanying instructions.
 - (1) The applicant shall complete Form R-70, "Application for Registration – Limited Scope Operator" and shall attach form R-71.
 - (2) The applicant shall verify didactic training and clinical experience on Form R-71, "Clinical Supervisory and Competency Statement – Limited Scope Operator."
 - 2D.2.4.2 The application shall be accompanied by the required fee(s).
 - 2D.2.4.3 Application to take the ARRT LSO examination shall be made within one year upon completion of the requirements of 2D.2.1 and within ninety (90) calendar days upon completion of the requirements of 2D.2.2 and/or 2.D.2.3.
 - 2D.2.4.4 Upon being contacted by ARRT to schedule the LSO examination, the applicant shall complete the Core Module and at least the Radiographic Procedure Modules for Chest, Extremities, Skull/Sinuses and Spine within ninety (90) calendar days.
 - 2D.2.4.5 The Department will notify the applicant of the ARRT LSO examination result upon receipt by the Department.
- 2D.3 Has maintained a minimum of twenty-four (24) hours of continuing education every two years in the areas of radiology, radiation safety, radiography and similar fields. This education shall:
- 2D.3.1 Conform to guidelines equivalent to the August 1, 2008 ARRT *Continuing Education Requirements for Renewal of Registration*; and
 - 2D.3.2 Be documented by certificate(s) or other attestation(s) of satisfactory completion, submitted with an updated form R-90, "Application For Renewal – Limited Scope Operator".

PART 2, APPENDIX 2E: COMPUTED TOMOGRAPHY (CT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each computed tomography operator to be an individual at least 18 years of age who:

2E.1 Is certified:

- 2E.1.1 As ARRT(R) and also certified in computed tomography by ARRT; or
- 2E.1.2 As ARRT(N) or ARRT(T); or
- 2E.1.3 As CNMT by the Nuclear Medicine Technologist Certification Board; or
- 2E.1.4 By a specialty board that has been recognized by the Department, including or in combination with documentation accepted by the Department for the training required by 2E.2A through 2E.2L; or

2E.2 Is ARRT(R) and also has satisfactorily completed:

[Elements of the following are from the July 2008 *Content Specifications for the Examination in Computed Tomography* and used with ARRT permission.]

2E.2.1 At least 60 hours of didactic training providing the minimum hours of instruction in the specific subjects listed in 2E.2A through 2E.2L:

2E.2A Intravascular (IV) Procedures—2 hours

- (1) Venipuncture
 - (a) Site selection
 - (b) Aseptic and sterile techniques
- (2) Injection techniques
 - (a) Manual
 - (b) Automatic
 - (i) Single phase
 - (ii) Multi-phase
 - (iii) Flow rate

2E.2B Contrast Agent—6 hours

- (1) Types
 - (a) Ionic
 - (b) Non-ionic

- (c) Water soluble
 - (d) Air
 - (e) Water
- (2) Administration route and dose calculations
- (a) IV (angiocatheter or butterfly)
 - (b) Oral
 - (c) Rectal
 - (d) Intrathecal
 - (e) Catheters
- (3) Special considerations
- (a) Allergy preparation
 - (b) Pathologic processes
 - (c) Contraindications
 - (d) Indicators
- (4) Adverse reactions
- (a) Recognition and assessment of symptoms
 - (b) Treatment (e.g., compresses, medications)
 - (c) Documentations

2E.2C Radiation Safety and Dosimetry—6 hours

- (1) Technical factors affecting patient dose
- (2) Radiation protection
- (3) Dose Measurement
- (4) Pediatric dose reduction

2E.2D Type of Study (24 hours; 1 hour for each topic—2E.2E, 2E.2F, 2E.2G and 2E.2H—for each type of study)

- (1) Head
- (2) Neck
- (3) Chest

- (4) Abdomen
- (5) Pelvis
- (6) Musculo-skeletal

2E.2E. Sectional Anatomy (for each type of study)

- (1) Sagittal plane
- (2) Transverse plane (axial)
- (3) Coronal plane
- (4) Off-axis (oblique)
- (5) Landmarks
- (6) Pathology recognition

2E.2F Contrast Media (for each type of study)

- (1) Types of agents
- (2) Indications
- (3) Contraindications
- (4) Dose calculation
- (5) Administration route
- (6) Scan/prep delay

2E.2G Scanning Procedures (for each type of study)

- (1) Positioning
- (2) Scout
- (3) Acquisition methods (e.g., spiral, non spiral, dynamic, multi-row detector)
- (4) Parameter selection (e.g., slice thickness, mA, time, algorithm, pitch)
- (5) Protocol modification for pathology or trauma
- (6) Cardiac gating

2E.2H Special Procedures (for each type of study)

- (1) 3-D studies
- (2) Biopsies
- (3) Radiation therapy planning

- (4) Drainage and aspiration
- (5) Post-myelography
- (6) CT arthrography and angiography
- (7) Cardiac gating

2E.2I Systems Operation and Components—4 hours

- (1) Tube
- (2) Generator and transformers
- (3) Detector configuration
- (4) Data Acquisition Systems (DAS)
- (5) Collimation
- (6) Computer and array processor
- (7) Equipment maintenance

2E.2J Image Processing & Display—10 hours

- (1) Image reconstruction
 - (a) Filtered back projection reconstruction
 - (b) Reconstruction filters (algorithms)
 - (c) Raw data vs. image data
 - (d) Prospective / retrospective reconstruction (single and multi-row)
 - (e) Effective slice thickness
 - (f) Reconstruction interval
- (2) Image display
 - (a) Pixel, voxel
 - (b) Matrix
 - (c) Image magnification
 - (d) Field of view (scan, reconstruction and display)
 - (e) Attenuation coefficient
 - (f) Window level, window width
 - (g) Plane specification (X, Y, Z coordinates)

- (h) Cine
 - (i) ROI (single and multiple image)
- (3) Post-processing
- (a) Multiplanar reformation
 - (b) 3-dimensional rendering (MIP, SSD, VR)
 - (c) Quantitative measurements (volume, distance, diameter)
- (4) Data management
- (a) Hard/soft copy
 - (b) Storage / archive
 - (c) PACS
 - (d) Security and confidentiality
 - (e) Networking

2E.2K Image Quality—4 hours

- (1) Spatial resolution
- (2) Contrast resolution
- (3) Temporal resolution
- (4) Noise and uniformity
- (5) Quality assurance procedures
- (6) CT number
- (7) Linearity

2E.2L Artifact Recognition and Reduction—4 hours

- (1) Beam hardening
- (2) Partial volume averaging
- (3) Motion
- (4) Metallic
- (5) Edge gradient
- (6) Patient positioning
- (7) Equipment-induced

- (a) Rings
- (b) Streaks
- (c) Tube arcing
- (d) Cone beam; and

2E.2.2 At least 480 hours of clinical training during which time computed tomography examinations are performed only under direct supervision of an ARRT(N), ARRT(R), ARRT(T) or CNMT computed tomography operator or other qualified trainer:

2E.2.2.1 "Direct supervision" means the supervisor must be present in the facility and immediately available to furnish assistance and direction throughout the performance of a procedure. The supervisor is not required to be present in the room when the procedure is performed.

2E.2.2.2 A signed statement by the individual(s) who provided supervision and evaluation shall be kept on file to document dates and locations of clinical training; and

2E.2.3 Documented performance under direct supervision of the following imaging procedures (at least 60 examinations in total, with record of each examination kept on file):

- 2E.2.3.1 Head—10 examinations;
- 2E.2.3.2 Neck—10 examinations;
- 2E.2.3.3 Chest—10 examinations;
- 2E.2.3.4 Abdomen—10 examinations;
- 2E.2.3.5 Pelvis—10 examinations; and
- 2E.2.3.6 Musculo-skeletal—10 examinations; and

2E.2.4 If the option is appropriate, Form R-95, "Application for Registration – Computed Tomography Machine Operator," to include all information required by the Department as indicated on the form and all accompanying instructions, plus payment of any fee.

2E.3 Or, meeting all requirements of 2E.2.1 and 2E.2.2, is allowed to be a computed tomography operator at a facility that performs only the particular procedure(s) for which record(s) document prior completion of the full number of examinations required in 2E.2.3;

2E.4 Or, having completed didactic training in accord with Section 2E.2.1, is allowed under general supervision during the clinical training required by 2E.2.2 to be a computed tomography operator only for the particular procedure(s) for which record(s) document prior completion of the full number of examinations required in 2E.2.3.

PART 2, APPENDIX 2F: BONE DENSITOMETRY (BD) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each bone densitometry equipment operator (BDEO) to be an individual at least 18 years of age who:

2F.1 Is certified or registered by:

2F.1.1 ARRT(R), ARRT(M), ARRT(N), ARRT(T), or CNMT; or

2F.1.2 The International Society for Clinical Densitometry (ISCD), combined with or including the didactic radiation safety training in 2F.2A, 2F.2B and 2F.2C; or

2F.1.3 A specialty board that has been recognized by the Department, in combination with documentation accepted by the Department for the training required by 2F.2A through 2F.2I; or

2F.2 Or, is accepted by the Department as having satisfactorily completed:

[Elements of the following are from the January 2003 *Content Specifications for the Bone Densitometry Equipment Operators Examination* and used with ARRT permission.]

2F.2.1 At least 30 hours of didactic training recognized by the Department that provided the minimum hours of instruction (as part of, or in addition to, specialty certificate and equipment operation training) in the specific subjects listed in 2F.2A through 2F.2I:

RADIATION SAFETY:

2F.2A Basic X-Ray Physics—2 hours

- (1) Structure of matter and the atom
- (2) General description of production of x-rays
- (3) X-ray emission, quantity and quality
- (4) Function of filtration and effects it has on x-ray beam collimation
- (5) Types of function of beam limiting devices
- (6) Design, features and functions of x-ray tubes
- (7) Circuitry of the x-ray machine

2F.2B Radiobiology—2 hours

- (1) Effects of ionizing radiation to the human body
- (2) Molecular and cellular radiobiology
- (3) Factors that cause somatic and genetic damage

2F.2C Radiation Protection—5 hours

- (1) ALARA
- (2) Shielding materials
- (3) Radiation quantity and units of measurement
- (4) Basic interactions of x-ray with matter
- (5) Primary and secondary scatter
- (6) Importance of time, distance, shielding
- (7) Maximum permissible dose: occupational and public
- (8) Patient protection
 - (a) Patient instruction
 - (b) Comparison levels of radiation
 - (i) Natural background radiation
 - (ii) Central DXA
 - (iii) Peripheral DXA

BONE DENSITOMETRY PROCEDURES

2F.2D Basic Concepts—8 hours

- (1) Osteoporosis
 - (a) World Health Organization definition and diagnostic criteria
 - (b) Primary vs. secondary
 - (c) Type I (postmenopausal) vs. Type II (senile)
 - (d) Risk factors
 - (i) Controllable (smoking, calcium intake, estrogen, medications)
 - (ii) Uncontrollable (heredity, race, gender, age, medical conditions)
- (2) Bone physiology
 - (a) Functions of bone
 - (i) Structural support and protection
 - (ii) Storage of essential minerals
 - (b) Types of bone

- (i) Cortical
- (ii) Trabecular
- (c) Bone remodeling cycle
 - (i) Resorption / formation
 - (ii) Osteoblasts/osteoclasts
- (d) Bone health
 - (i) Nutrition
 - (ii) Exercise
- (3) BMD testing methods (anatomical sites scanned, key advantages and disadvantages)
 - (a) Dual-energy X-ray Absorptiometry (DXA)
 - (b) Single X-ray Absorptiometry (SXA)
 - (c) Quantitative Ultrasound (QUS)
 - (d) Radiographic Absorptiometry (RA)
- (4) Measuring BMD
 - (a) Basic statistical concepts
 - (i) Mean
 - (ii) Standard deviation
 - (iii) Coefficient of variation
 - (b) Reporting patient results
 - (i) BMD formula
 - (ii) Z-score
 - (iii) T-score

2F.2E Equipment Operation & Quality Control—6 hours

- (1) Computer console
 - (a) Major components
 - (b) File management
- (2) Fundamentals of x-ray energy production

- (a) Properties of x-ray beam: quality (kVp), quantity (mA), duration/time (s)
 - (b) Filters and collimators
 - (c) X-ray energy production: single; dual
- (3) Types of DXA systems
- (a) Pencil beam systems
 - (b) Fan beam systems
 - (c) Cone beam systems
- (4) Quality control
- (a) Equipment safety (electrical, pinch points, emergency stop)
 - (b) Use of phantoms and/or calibration
 - (c) Troubleshooting
 - (i) Shift or drift
 - (ii) Pass / fail
 - (d) Record maintenance
- (5) Determining quality in BMD
- (a) Precision (definition)
 - (b) Accuracy (definition)
 - (c) Factors affecting accuracy and precision
 - (i) Scanner
 - (ii) Operator
 - (iii) Patient

2F.2F DXA Scanning of Finger and Heel (OS CALCIS)—1 hour

- (1) Anatomy
- (a) Regions of interest
 - (b) Bony landmarks
 - (c) Radiographic appearance
- (2) Scan acquisition

- (a) Patient instructions
 - (b) Patient positioning
 - (c) Evaluating pre-set scan parameters
- (3) Scan analysis: BMD, T score, Z score
 - (4) Common problems
 - (a) Nonremovable artifacts
 - (b) Fractures or pathology

2F.2G DXA Scanning of Forearm—2 hours

- (1) Anatomy
 - (a) Regions of interest
 - (b) Bony landmarks
 - (c) Radiographic appearance
 - (d) Adjacent structures
- (2) Scan acquisition
 - (a) Patient instructions
 - (b) Patient positioning
 - (c) Evaluating pre-set scan parameters
- (3) Scan analysis
 - (a) Accurate ROI placement
 - (b) BMC, area, and BMD
 - (c) T-score, Z-score
- (4) Common problems
 - (a) Poor bone edge detection
 - (b) Nonremovable artifacts
 - (c) Variant anatomy
 - (d) Fractures or pathology
- (5) Follow-up scans
 - (a) Unit of comparison: BMD, T-score

- (b) Reproduce baseline study

2F.2H DXA Scanning of Lumbar Spine—2 hours

- (1) Anatomy
 - (a) Regions of interest
 - (b) Bony landmarks
 - (c) Radiographic appearance
 - (d) Adjacent structures
- (2) Scan acquisition
 - (a) Patient instructions
 - (b) Patient positioning
 - (c) Evaluating pre-set scan parameters
- (3) Scan analysis
 - (a) Accurate ROI placement
 - (b) BMC, area, and BMD
 - (c) T-score, Z-score
- (4) Common problems
 - (a) Poor bone edge detection
 - (b) Nonremovable artifacts
 - (c) Variant anatomy
 - (d) Fractures or pathology
- (5) Follow-up scans
 - (a) Unit of comparison: BMD, T score
 - (b) Reproduce baseline study

2F.2I DXA Scanning of Proximal Femur—2 hours

- (1) Anatomy
 - (a) Regions of interest
 - (b) Bony landmarks
 - (c) Radiographic appearance

- (d) Adjacent structures
- (2) Scan acquisition
 - (a) Patient instructions
 - (b) Patient positioning
 - (c) Evaluating pre-set scan parameters
- (3) Scan analysis
 - (a) Accurate ROI placement
 - (b) BMC, area, and BMD
 - (c) T-score, Z-score
- (4) Common problems
 - (a) Poor bone edge detection
 - (b) Nonremovable artifacts
 - (c) Variant anatomy
 - (d) Fractures or pathology
- (5) Follow-up scans
 - (a) Unit of comparison: BMD, T-score
 - (b) Reproduce baseline study; and

2F.2.2 At least 480 hours of clinical training during which time DXA examinations are performed only under direct supervision of a Colorado qualified bone densitometry equipment operator or other qualified trainer:

2F.2.2.1 “Direct supervision” means the supervisor must be present in the facility and immediately available to furnish assistance and direction throughout the performance of a procedure. The supervisor is not required to be present in the room when the procedure is performed.

2F.2.2.2 A signed statement by the individual(s) who provided supervision and evaluation shall be kept on file to document dates and locations of clinical training; and

2F.2.3 Performance of the following imaging procedures (at least 30 examinations in total, with record of each examination kept on file):

- 2F.2.3.1 DXA scanning of the forearm—10 examinations;
- 2F.2.3.2 DXA scanning of the lumbar spine—10 examinations;
- 2F.2.3.3 DXA scanning of the proximal femur—10 examinations; and

2F.2.4 Approval by the Department as having passed the Bone Density Equipment Operator State Examination required by 2.4.5.3.

2F.2.4.1 The application to be registered in the State of Colorado as a Bone Density Equipment Operator shall be submitted on the appropriate Department form(s) and shall contain all information required by the Department as indicated on the form(s) and all accompanying instructions.

(1) The applicant shall complete Form R-80, "Application for Registration – Bone Densitometry Equipment Operator"; or

(2) The applicant shall verify clinical experience on Form R-81, "Clinical Supervisory and Competency Statement – Bone Density Equipment Operator"; and

2F.2.4.2 The application shall be accompanied by the required fee(s).

2F.2.4.3 Application to take the BDEO examination shall be made within one year upon completion of the requirements of 2F.2.1 and within ninety (90) calendar days upon completion of the requirements of 2F.2.2 and/or 2.F.2.3.

2F.2.4.4 Upon being contacted to schedule the BDEO examination, the applicant shall complete the examination within ninety (90) calendar days.

2F.2.4.5 The Department will notify the applicant of a BDEO examination result upon receipt by the Department.

2F.3 Has maintained a minimum of eighteen (18) hours continuing education every three years, documented by certificate(s) or other attestation(s) of satisfactory completion, submitted with an updated Form R-82, "Application for Renewal – Bone Density Equipment Operator".

PART 2, APPENDIX 2G: RADIOLOGIST ASSISTANT (RA) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each radiologist assistant to be an individual who is 18 years of age and has provided written documentation as evidence of:

2G.1 Current certification as both ARRT(R) and a

2G.1.1 Registered Radiologist Assistant (RRA); or

2G.1.2 Radiology Practitioner Assistant (RPA) prior to January 1, 2008;

2G.2 Or, having:

2G.2.1 Met the specific qualifications in education recognized by the ARRT, ASRT, ACR, or equivalent nationally recognized entity; and

2G.2.2 Been trained and worked under the direction of a radiologist.

PART 2, APPENDIX 2H: ADEQUATE EDUCATION AND TRAINING TO PERFORM RADIATION MACHINE ASSEMBLY, INSTALLATION AND/OR REPAIR

The registrant shall require each individual who independently performs radiation machine assembly, installation or repair to obtain and retain evidence demonstrating that the individual is registered with the Department in accord with Appendix 2B or 2C or that the following requirements are met:

- 2H.1 Completion of a structured educational program that includes training in radiation-producing device safety, assembly, installation and repair, such as:
 - 2H.1.1 A baccalaureate degree in electrical engineering with specialized training in radiation producing devices; or
 - 2H.1.2 A one-year associate degree in biomedical equipment repair; or
 - 2H.1.3 Equivalent factory, military or other technical school training; and
- 2H.2 For each type of equipment to be serviced:
 - 2H.2.1 Education and/or experience providing familiarity with the equipment, including protective measures to reduce potentially hazardous conditions; and
 - 2H.2.2 Completion of six months of supervised equipment assembly and repair.

PART 2, APPENDIX 2I: QUALIFIED INSPECTOR (QI) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

As provided by 2.4.4, each qualified inspector shall be an individual who:

2I.1 Has provided written documentation as evidence of:

2I.1.1 Current certification by:

2I.1.1.1 The American Board of Radiology in diagnostic radiologic physics or radiological physics;

2I.1.1.2 The American Board of Radiology in therapeutic or nuclear medicine radiological physics; roentgen ray and gamma ray physics; x-ray and radium physics; or equivalent specialty;

2I.1.1.3 The American Board of Medical Physics in Diagnostic Imaging Physics or Therapeutic Radiological Physics;

2I.1.1.4 The American Board of Health Physics (comprehensive certification);

2I.1.1.5 The Canadian College of Medical Physics;

2I.1.1.6 American Board of Nuclear Medicine Science; or

2I.1.1.7 A recognized equivalent specialty board.

2I.2 Or, for a qualified inspector of mammography facilities, has provided evidence of:

2I.2.1 Current certification as provided in 2I.1.1.1, 2I.1.1.2, or an equivalent specialty of the American Board of Radiology or another certifying body recognized by the American College of Radiology;

2I.2.2 Or the following combination of training and experience:

2I.2.2.1 A master of science, master of arts, or higher degree in physics, applied physics, biophysics, radiological physics, health physics, medical physics, or equivalent, from an accredited college or university; and

2I.2.2.2 At least two years of training in medical physics in the area of clinical diagnostic radiologic physics; and

2I.2.2.3 At least three (3) years of experience in conducting mammography equipment performance evaluations;

(1) Twenty (20) contact hours of documented specialized training in conducting surveys of mammography facilities;

(2) Experience of conducting surveys of at least one mammography facility and a total of at least ten (10) mammography units;

(a) No more than one survey of a specific unit within a period of sixty (60) calendar days can be counted towards the total mammography unit survey requirement;

- (b) This experience must be accomplished under the direct supervision of a currently registered qualified inspector in mammography;

2I.2.3 And sufficient continuing education and experience, including:

- 2I.2.3.1 A minimum of fifteen (15) documented hours of continuing education in mammography which are no more than thirty-six months old;
- 2I.2.3.2 Surveys of at least two (2) mammography facilities and a total of at least six (6) mammography units within the immediately previous twenty-four (24) months;
- 2I.2.3.3 If performing a certification evaluation including a new modality of mammography imaging, a minimum of eight (8) hours of training in the new modality prior to performing such a certification evaluation independently;
- 2I.2.3.4 If the applicant fails to meet the continuing education requirement, sufficient additional continuing education hours, prior to performing any certification evaluation; and
- 2I.2.3.5 If the applicant fails to meet the continuing experience requirement, a sufficient number of certification evaluations under the supervision of a currently registered qualified inspector in mammography or a MQSA-approved medical physicist to bring the applicant's total certification evaluations up to the required two (2) facilities and six (6) units in the previous twenty-four (24) months.

2I.3 Or, for a qualified inspector other than for mammography facilities, has provided written documentation as evidence that the individual:

- 2I.3.1 Holds a degree in physics, applied physics, biophysics, biophysical engineering, medical physics, radiologic physics, health physics, or equivalent, from an accredited college or university; and
- 2I.3.2 Has satisfactorily completed appropriate, acceptable, documented, full-time work experience:
 - 2I.3.2.1 One year with a master or doctorate degree; and
 - 2I.3.2.2 Two years with an arts or sciences baccalaureate degree;
 - 2I.3.2.3 Three years with an Associate Degree; and
- 2I.3.3 Has experience with each category of radiation machine for which approval is requested, including but not limited to:
 - 2I.3.3.1 Measuring ionizing radiation;
 - 2I.3.3.2 Evaluating radiation machines and components;
 - 2I.3.3.3 Film processing;
 - 2I.3.3.4 The applicable requirements of the radiation regulations; and
 - 2I.3.3.5 Specialized training with the x-ray imaging and image processing system software and hardware, if and when applicable and available; and

2I.3.4 Has obtained training and experience required by Appendix 2I:

2I.3.4.1 Within the 7 years preceding the date of application; or

2I.3.4.2 Through documented subsequent continuing education and experience.

2I.4 Or, has adequate prior experience as an experienced qualified inspector who has satisfied 2I.3.3 and 2I.3.4 and demonstrated to the Department sufficient experience in the tasks required of a qualified inspector for which the individual is requesting authorization to be a qualified inspector;

2I.5 Or, is approved by the Department as a provisional qualified inspector, fully meeting the requirements of 2I.3.1 but as an alternative to fully satisfying 2I.3.2, 2I.3.3 and 2I.3.4, having:

2I.5.1 Submitted to the Department an application that includes the name and signature of each approved qualified inspector for whom the applicant will be working under general supervision in order to meet the requirements of 2I.3.2, 2I.3.3 and 2I.3.4; and

2I.5.2 Provided written documentation of having assisted with certification evaluation of at least five (5) radiation machines under the direct supervision of an approved qualified inspector.

PART 2, APPENDIX 2J: QUALIFIED TRAINER (QT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each qualified trainer to be an individual who:

- 2J.1 Has training and experience commensurate with criteria and standards for the radiation machine application(s) that adequately prepare the individual to carry out the specified training assignment(s).
 - 2J.1.1 An interpreting physician, radiologic technologist or medical physicist who is approved under MQSA program requirements is considered a qualified trainer for the respective competency.
 - 2J.1.2 A physician, radiologic technologist, or operator who is approved pursuant to 2.6.1 is considered a qualified trainer for the respective competency.
 - 2J.1.3 Other examples of an individual who might be considered by the Department to be a qualified trainer for the purpose of providing training to meet the requirements of this part include, but are not limited to, a trainer in a post-secondary-school training institution or a manufacturer's representative.

**PART 2, APPENDIX 2K: AUTHORIZED USER (24.3.3) FOR RADIATION THERAPY (24.7 OR 24.8)
ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

The applicant, registrant, or licensee for any therapeutic radiation machine subject to 24.7 or 24.8 shall require an authorized user of therapeutic radiation machines to be a physician who has a current active State of Colorado license and:

2K.1 Has provided evidence of current certification in:

- 2K.1.1 Radiology or therapeutic radiology by the American Board of Radiology; or
- 2K.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or
- 2K.1.3 Therapeutic radiology by the Royal College of Physicians and Surgeons of Canada; or
- 2K.1.4 Radiology, with specialization in radiotherapy, by the British Royal College of Radiology, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
- 2K.1.5 Radiation therapy by a recognized specialty board that requires each candidate for certification to:
 - 2K.1.5.1 Satisfactorily complete a certification process that includes training equivalent to that required in 2K.2.1 and supervised practical experience equivalent to that required by 2K.2.2; and
 - 2K.1.5.2 Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, treatment planning, quality assurance, and human use of therapeutic radiation machines; or

2K.2 Has satisfied the following criteria:

- 2K.2.1 Satisfactory completion of 700 hours in basic techniques applicable to the use of a therapeutic radiation machine unit, including:
 - 2K.2.1.1 At least 200 hours of classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
 - 2K.2.1.2 At least 500 hours of work experience, involving:
 - (1) Reviewing full calibration measurements and periodic quality assurance checks;
 - (2) Evaluating prepared treatment plans, calculation of treatment times, and patient treatment settings;

- (3) Using administrative controls to prevent reportable medical events;
- (4) Implementing emergency procedures to be followed in the event of the abnormal operation of a therapeutic radiation machine unit or console; and
- (5) Checking and using of radiation survey meters; and

2K.2.2 Completion of 3 years of supervised clinical experience in radiation therapy, including:

- 2K.2.2.1 An approved formal training program, approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Committee on Post Graduate Training of the American Osteopathic Association; and
- 2K.2.2.2 Supervised clinical experience, under the supervision of an authorized user who meets the requirements of this Appendix 2K, or equivalent requirements, to include:
 - (1) Examining individuals and reviewing their case histories to determine their suitability for therapeutic radiation machine treatment, and any limitations and/or contraindications;
 - (2) Selecting proper dose and how it is to be administered;
 - (3) Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reactions to radiation; and
 - (4) Post-administration follow-up and review of case histories.

2K.3 Training and experience required by Appendix 2K shall have been obtained:

- 2K.3.1 Within the 7 years preceding the date of license application; or
- 2K.3.2 Through documented subsequent continuing education and experience.

PART 2, APPENDIX 2L: RADIATION THERAPIST (24.3.5) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The applicant, registrant, or licensee shall require the operator of a therapeutic radiation machine for human use to be an individual who:

2L.1 Has provided evidence of:

2L.1.1 Successful completion of a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of:

2L.1.1.1 The Joint Review Committee on Education in Radiologic Technology (consult the 1988 Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist or the 2001 Standard for an Accredited Educational Program in Radiological Sciences); or

2L.1.1.2 An accreditation organization recognized by the Council for Higher Education Accreditation as an accrediting agency, other organizations recognized by the United States Department of Education (USDE) or the Council For Higher Education Accreditation (CHEA) to accredit educational programs in radiation therapy; and

2L.1.2 Accreditation as a radiation therapist by, and having continued to maintain registration by meeting the requirements of, The American Registry of Radiologic Technologists (ARRT), or

2L.1.3 Accreditation by a specialty board recognized by the Department as equivalent to ARRT.

2L.2 Has maintained a minimum of twenty-four (24) hours of continuing education every two years in the areas of radiology, radiation safety, radiography and similar fields. This education shall:

2L.2.1 Conform to guidelines equivalent to the August 2008 ARRT *Continuing Education Requirements for Renewal of Registration*; and

2L.2.2 Be documented by certificate(s) or other attestation(s) of satisfactory completion.

PART 2, APPENDIX 2M: QUALIFIED MAMMOGRAPHER ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each mammographer to be an individual who:

- 2M.1 Has provided evidence that the individual is certified in mammography as ARRT(M), meeting the requirements of 21 CFR 900, in particular 900.12(a)(2), April 1, 2010;
- 2M.2 Or, is an ARRT(R) accepted by the Department as an experienced mammographer who has provided evidence demonstrating to the Department mammography training and experience equivalent to the *Content Specifications for the Examination for the ARRT Mammography Certification* (July 2009), including at a minimum:
 - 2M.2.1 Forty (40) hours or more documented training including breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants; and
 - 2M.2.2 Eight (8) hours or more documented training in each mammography modality to be used by the technologist in performing mammography examinations; and
 - 2M.2.3 Performance, under the direct supervision of a mammographer, of a minimum of 25 examinations;
- 2M.3 Or, is a radiologic technologist (mammographer in training or provisional mammographer), who:
 - 2M.3.1 Is enrolled in or has completed a structured training program that includes a minimum of 40 contact hours of documented training specific to mammography;
 - 2M.3.2 Is completing or has completed, at all times during examination procedures under the direct supervision of a mammographer present on the premises and available for prompt consultation, the tasks in 2M.2.1, 2M.2.2 and 2M.2.3; and
 - 2M.3.3 Has applied for a provisional certificate on Form R-64, "Criteria for a Structured Training Program in Mammography," including all information required by the form and by all accompanying instructions, accompanied by the fee specified in Appendix 12A;
 - 2M.3.4 Has obtained from the Department a provisional certificate valid for one year from the date of issuance or a one-time renewal certificate valid for one additional year only.
- 2M.4 Continuing training and experience required by Appendix 2M shall have been obtained:
 - 2M.4.1 Within the 7 years preceding the date of application, except when an attestation of adequate training and experience prior to October 1, 1994 has been provided; or
 - 2M.4.2 Through documented subsequent continuing education and experience:
 - 2M.4.2.1 The mammographer shall document fifteen (15) hours of continuing education completed within the immediate prior 36 months.
 - (1) A mammographer who fails to meet this continuing education requirement shall obtain a sufficient number of continuing education units (CEU) in mammography to bring their total up to at least fifteen (15) CEU.

- (2) A mammographer who fails to meet this continuing education requirement shall work only under direct or personal supervision.

2M.4.2.2 The mammographer shall have performed a minimum of 200 mammography examinations within the immediate prior 24 months.

- (1) A mammographer who fails to meet this continuing experience requirement shall perform a minimum of 25 mammography examinations under the direct supervision of a mammographer before resuming the performance of unsupervised mammography examinations.

PART 2, APPENDIX 2N: INDUSTRIAL RADIATION MACHINE OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The registrant shall require each operator of an analytical, industrial or other non-healing-arts radiation generating machine to be an individual who:

- 2N.1 For industrial radiography, has complied with all applicable training and experience requirements of Part 5 and these regulations.
- 2N.2 For all non-healing-arts applications (including but not limited to analytical, forensic, morgue, and homeland security uses) not subject to Part 5, has provided written documentation as evidence of:
 - 2N.2.1 At least eight (8) hours of general training and experience in radiation safety acceptable to the Department, except as follows:
 - 2N.2.1.1 Four (4) hours for any hand-held non-healing-arts radiation generating machine; or
 - 2N.2.1.2 One (1) hour for any cabinet or self-contained airport or port-of-entry x-ray machine or system; or
 - 2N.2.1.3 Sufficient training and experience acceptable to the Department.
 - 2N.2.2 Successful completion of radiation safety training specific for each radiation machine used, and demonstration of an understanding thereof, including instruction in the:
 - 2N.2.2.1 Proper operating procedures for the equipment, having read the operating manual;
 - 2N.2.2.2 Identification of radiation hazards associated with the use of the equipment;
 - 2N.2.2.3 Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions required in such cases;
 - 2N.2.2.4 Recognition of symptoms of an acute localized exposure; and
 - 2N.2.2.5 Proper procedures for reporting an actual or suspected exposure; and
 - 2N.2.3 Has subsequent documented annual training.



Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

Part 4 – Standards for Protection Against Radiation

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

(Last Amended May 18, 2005, effective July 31, 2005)

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 4:

STANDARDS FOR PROTECTION AGAINST RADIATION

4.1 Purpose and Scope

4.1.1 Authority.

Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, CRS.

4.1.2 Basis and Purpose.

A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

4.1.3 Scope.

4.1.3.1 This Part 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

4.1.3.2 The requirements of Part 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part 4. However, nothing in Part 4 shall be construed as limiting actions that may be necessary to protect health and safety.

4.1.4 Applicability.

Except as specifically provided in other parts of these regulations, Part 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 7.26, or to exposure from voluntary participation in medical research programs.

4.2 Definitions.

Reserved.

4.3 Implementation.

Any existing license or registration condition that is more restrictive than Part 4 remains in force until there is an amendment or renewal of the license or registration.

4.4 Reserved.

RADIATION PROTECTION PROGRAMS

4.5 Radiation Protection Programs.

- 4.5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4. See 4.41 for recordkeeping requirements relating to these programs.
- 4.5.2 The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
- 4.5.3 The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.
- 4.5.4 To implement the ALARA requirements of 4.5.2 and notwithstanding the requirements in 4.14 of this part, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, shall be established by licensees, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 millisievert (10 mrem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report such event as provided in 4.53.2 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

4.6 Occupational Dose Limits for Adults.

- 4.6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 4.11, to the following dose limits:

4.6.1.1 An annual limit, which is the more limiting of:

- (1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or
- (2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

4.6.1.2 The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

- (1) A lens dose equivalent of 0.15 Sv (15 rem), and
- (2) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

- 4.6.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 4.11.5.1 and 4.11.5.2.
- 4.6.3 Assigned dose equivalent.
- 4.6.3.1 The assigned deep dose equivalent must be for the part of the body receiving the highest exposure.
- 4.6.3.2 The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.
- 4.6.3.3 The deep-dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.
- 4.6.3.4 In the case of occupational exposures to x-rays with accelerating voltages of less than 145 kVp and where the worker utilizes lead garment protection, the registrant may calculate the assigned dose equivalent using the following methods:
- (1) Lead apron and no thyroid collar:
assigned deep dose equivalent = $0.06 \times (\text{collar dose} - \text{waist dose}) + \text{waist dose}$
- (2) Lead apron and thyroid collar:
assigned deep dose equivalent = $0.02 \times (\text{collar dose} - \text{waist dose}) + \text{waist dose}$
- 4.6.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 4B1 of Appendix 4B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 4.46.
- 4.6.5 Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix 4B.
- 4.6.6 The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 4.10.3.1 and 4.10.5.
- 4.7 Compliance with Requirements for Summation of External and Internal Doses.**
- 4.7.1 If the licensee or registrant is required to monitor pursuant to both 4.18.1 and 4.18.2, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 4.18.1 or only pursuant to 4.18.2, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 4.7.2, 4.7.3 and 4.7.4. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

4.7.2 Intake by Inhalation.

If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

4.7.2.1 The sum of the fractions of the inhalation ALI for each radionuclide, or

4.7.2.2 The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

4.7.2.3 The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} , that is, $W_T \times H_{T,50}$, per unit intake for any organ or tissue.

4.7.3 Intake by Oral Ingestion.

If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

4.7.4 Intake through Wounds or Absorption through Skin.

The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 4.7.4.

4.8 Determination of External Dose from Airborne Radioactive Material.

4.8.1 Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix 4B, footnotes 1 and 2.

4.8.2 Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

4.9 Determination of Internal Exposure.

4.9.1 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to 4.18, take suitable and timely measurements of:

4.9.1.1 Concentrations of radioactive materials in air in work areas; or

4.9.1.2 Quantities of radionuclides in the body; or

- 4.9.1.3 Quantities of radionuclides excreted from the body; or
 - 4.9.1.4 Combinations of 4.9.1.1, 4.9.1.2 and 4.9.1.3.
- 4.9.2 Unless respiratory protective equipment is used, as provided in 4.24, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- 4.9.3 When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:
- 4.9.3.1 Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and
 - 4.9.3.2 Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
 - 4.9.3.3 Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix 4B.
- 4.9.4 If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in 4.9.1.2 or 4.9.1.3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 4.52 or 4.53. This delay permits the licensee or registrant to make additional measurements basic to the assessments.
- 4.9.5 If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
- 4.9.5.1 The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix 4B for each radionuclide in the mixture; or
 - 4.9.5.2 The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- 4.9.6 If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- 4.9.7 When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:
- 4.9.7.1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in 4.6 and in complying with the monitoring requirements in 4.18.2; and
 - 4.9.7.2 The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and
 - 4.9.7.3 The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

4.9.8 When determining the committed effective dose equivalent, the following information may be considered:

- 4.9.8.1 In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
- 4.9.8.2 For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table 4B1 of Appendix 4B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 4.6.1.1.2 is met.

4.10 Determination of Prior Occupational Dose.

4.10.1 For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 4.18, the licensee or registrant shall:

- 4.10.1.1 Determine the occupational radiation dose received during the current year; and
- 4.10.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose.

4.10.2 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

- 4.10.2.1 The internal and external doses from all previous planned special exposures; and
- 4.10.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
- 4.10.2.3 All lifetime cumulative occupational radiation dose.

4.10.3 In complying with the requirements of 4.10.1, a licensee or registrant may:

- 4.10.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
- 4.10.3.2 Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form R-16, Cumulative Occupational Exposure History, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

4.10.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4.10.4 Record of Exposure History.

4.10.4.1 The licensee or registrant shall record the exposure history, as required by 4.10.1, on Department Form R-16, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form R-16 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form R-16 or equivalent indicating the periods of time for which data are not available.

4.10.4.2 Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the Regulations in Part 4 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded before January 1, 1994 on Department Form R-16 or equivalent, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

4.10.5 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

4.10.5.1 In establishing administrative controls pursuant to 4.6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

4.10.5.2 That the individual is not available for planned special exposures.

4.10.6 The licensee or registrant shall retain the records on Department Form R-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form R-16 or equivalent for 3 years after the record is made.

4.11 Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 4.6 provided that each of the following conditions in 4.11.1 through 4.11.7 is satisfied:

4.11.1 The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

- 4.11.2 The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- 4.11.3 Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
 - 4.11.3.1 Informed of the purpose of the planned operation; and
 - 4.11.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 - 4.11.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- 4.11.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 4.10.2 during the lifetime of the individual for each individual involved.
- 4.11.5 Subject to 4.6.2, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 - 4.11.5.1 The numerical values of any of the dose limits in 4.6.1 in any year; and
 - 4.11.5.2 Five times the annual dose limits in 4.6.1 during the individual's lifetime.
- 4.11.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 4.45 and submits a written report in accordance with 4.54.
- 4.11.7 The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 4.6.1 but shall be included in evaluations required by 4.11.4 and 4.11.5.

4.12 Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 4.6.

4.13 Dose Equivalent to an Embryo/Fetus.

- 4.13.1 The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 4.46 for recordkeeping requirements.
- 4.13.2 The licensee or registrant shall make efforts to avoid substantial variation¹ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 4.13.1.

¹ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

4.13.3 The dose equivalent to an embryo/fetus is the sum of:

- 4.13.3.1 The deep dose equivalent to the declared pregnant woman; and
- 4.13.3.2 The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

4.13.4 If the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 4.13.1 if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

4.14 Dose Limits for Individual Members of the Public.

4.14.1 Each licensee or registrant shall conduct operations so that:

- 4.14.1.1 The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 millisievert (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 7.26, from voluntary participation in medical research programs, and from the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 4.35, and
- 4.14.1.2 The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 7.26, does not exceed 0.02 millisievert (0.002 rem) in any one hour.

4.14.2 A licensee may permit visitors to an individual who cannot be released under 7.26 to receive a radiation dose greater than 1 mSv (0.1 rem) if:

- 4.14.3.1 The radiation dose received does not exceed 5 mSv (0.5 rem); and
- 4.14.3.1 The authorized user, as defined in Part 7, has determined before the visit that it is appropriate.

4.14.3 A licensee, registrant, or an applicant for a license or registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:

- 4.14.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in 4.14.1; and
- 4.14.3.2 The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and
- 4.14.3.3 The procedures to be followed to maintain the dose ALARA.

4.14.4 In addition to the requirements of Part 4, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 (July 1, 2004) shall comply with those standards.

4.14.5 The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

4.15 Compliance with Dose Limits for Individual Members of the Public.

4.15.1 The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in 4.14.

4.15.2 A licensee or registrant shall show compliance with the annual dose limit in 4.14 by:

4.15.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

4.15.2.2 Demonstrating that:

- (1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 4B2 of Appendix 4B; and
- (2) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

4.15.3 Upon approval from the Department, the licensee or registrant may adjust the effluent concentration values in Appendix 4B, Table 4B2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

4.15.4 Rooms or areas in which diagnostic x-ray systems are the only source of radiation shall demonstrate compliance with 4.15.2.1 after construction of a new x-ray facility, after modification or renovation of an existing x-ray facility, or installation or a new x-ray machine in an existing x-ray facility when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or where there is a projected increase in the x-ray workload from that which was used for a prior x-ray shielding design.

4.15.5 Facilities using only dental intraoral or panoramic machines in single occupancy rooms are exempt from the requirements of 4.15.2.1.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

4.16 Testing for Leakage or Contamination of Sealed Sources.

4.16.1 The licensee or registrant in possession of any sealed source shall assure that:

4.16.1.1 Each sealed source, except as specified in 4.16.2, is tested for leakage or contamination and the test results are received before the sealed source is put into use

unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant. Sources that indicate contamination in excess of 185 Bq (0.005 microcuries) shall not be put into use.

- 4.16.1.2 Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Department, after evaluation of information specified by 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.
- 4.16.1.3 Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Department, after evaluation of information specified by 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.
- 4.16.1.4 For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.
- 4.16.1.5 Tests, and evaluations of tests, for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.
- 4.16.1.6 The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μ Ci) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its decay products has been determined with respect to collection method, volume and time.
- 4.16.1.7 Tests for contamination from radium decay products shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of a radium decay product which has a half-life greater than 4 days.
- 4.16.2 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:
- 4.16.2.1 Sealed sources containing only radioactive material with a half-life of less than 30 days;
- 4.16.2.2 Sealed sources containing only radioactive material as a gas;
- 4.16.2.3 Sealed sources containing 3.7 MBq (100 μ Ci) or less of beta or photon-emitting material or 370 kBq (10 μ Ci) or less of alpha-emitting material;
- 4.16.2.4 Sealed sources containing only hydrogen-3;

- 4.16.2.5 Seeds of iridium-192 encased in nylon ribbon; and
 - 4.16.2.6 Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.
- 4.16.3 Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.
- 4.16.4 Test results shall be kept in units of becquerel (or microcurie) and maintained for inspection by the Department.
- 4.16.5 The following shall be considered evidence that a sealed source is leaking:
- 4.16.5.1 The presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample.
 - 4.16.5.2 Leakage of 37 Bq (0.001 µCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
 - 4.16.5.3 The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium.
- 4.16.6 The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.
- 4.16.7 Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 4.58.

SURVEYS AND MONITORING

4.17 General.

- 4.17.1 Each licensee or registrant shall make, or cause to be made, surveys that:
- 4.17.1.1 Are necessary for the licensee or registrant to comply with Part 4; and
 - 4.17.1.2 Are necessary under the circumstances to evaluate:
 - (1) The magnitude and extent of radiation levels; and
 - (2) Concentrations or quantities of radioactive material; and
 - (3) The potential radiological hazards.
- 4.17.2 The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured unless otherwise noted in these regulations.

4.17.3 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 4.6, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

4.17.3.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

4.17.3.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

4.17.4 The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

4.18 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part 4. As a minimum:

4.18.1 Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

4.18.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 4.6.1;

4.18.1.2 Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 1mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess 5 mSv (0.5 rem);

4.18.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1mSv (0.1 rem)²; and

² All of the occupational doses in 4.6 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

4.18.1.4 Individuals entering a high radiation area or a very high radiation area.

4.18.2 Each licensee or registrant shall monitor, to determine compliance with 4.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

4.18.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 4B1, Columns 1 and 2, of Appendix 4B;

4.18.2.2 Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and

4.18.2.3 Declared pregnant women likely to receive during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

4.18.3 Upon approval of the Department, an acceptable alternative to the use of continuous individual monitoring devices in order to demonstrate compliance with 4.18.1 and 4.18.2 may be used.

4.18.3.1 Acceptable alternative demonstrations that doses will not exceed 10 percent of the annual limits in 4.6.1, 4.12 and 4.13 include submittal to the Department of:

- (1) An acceptable application documenting six months of the use of continuous individual monitoring devices; or
- (2) An acceptable assessment from a qualified expert, as defined in 1.4, that takes into account design configuration, workload, radiation-producing machine output, and survey data.

4.18.3.2 To maintain approval of an acceptable alternative to the use of continuous individual monitoring devices:

- (1) Reapplication under 4.18.3.1(1) or reassessment under 4.18.3.1(2) is required for any change in configuration, equipment or workload; and
- (2) The licensee or registrant shall include assessment of individual monitoring in the review of the radiation protection program required annually by 4.5.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

4.19 Control of Access to High Radiation Areas.

4.19.1 The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

4.19.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

4.19.1.2 A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

4.19.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

4.19.2 In place of the controls required by 4.19.1 for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4.19.3 The licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

4.19.4 The licensee or registrant shall establish the controls required by 4.19.1 and 4.19.3 in a way that does not prevent individuals from leaving a high radiation area.

- 4.19.5 The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:
- 4.19.5.1 The packages do not remain in the area longer than 3 days; and
- 4.19.5.2 The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- 4.19.6 The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part 4 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.
- 4.19.7 The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 4.19 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.

4.20 Control of Access to Very High Radiation Areas.

- 4.20.1 In addition to the requirements in 4.19, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.
- 4.20.2 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 4.20.1 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.

4.21 Control of Access to Very High Radiation Areas - Irradiators.

- 4.21.1 Section 4.21 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section 4.21 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.
- 4.21.2 Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

- 4.21.2.1 Each entrance or access point shall be equipped with entry control devices which:
- (1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and
 - (2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (3) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.
- 4.21.2.2 Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 4.21.2.1:
- (1) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (2) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
- 4.21.2.3 The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:
- (1) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
 - (2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.
- 4.21.2.4 When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- 4.21.2.5 Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 4.21.2.3 and 4.21.2.4.

4.21.2.6 Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

4.21.2.7 Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

4.21.2.8 Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

4.21.2.9 The entry control devices required in 4.21.2.1 shall be tested for proper functioning. See 4.49 for recordkeeping requirements.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

4.21.2.10 The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

4.21.2.11 Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

4.21.3 Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 4.21.2 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 4.21.2, such as those for the automatic control of radiation levels, may apply to the Department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 4.21.2. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

4.21.4 The entry control devices required by 4.21.2 and 4.21.3 shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

4.22 Use of Process or Other Engineering Controls.

The licensee shall use, to the extent practical, process or other engineering controls, such as containment, decontamination or ventilation, to control the concentrations of radioactive material in air.

4.23 Use of Other Controls.

4.23.1 When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- 4.23.1.1 Control of access; or
- 4.23.1.2 Limitation of exposure times; or
- 4.23.1.3 Use of respiratory protection equipment; or
- 4.23.1.4 Other controls.

4.23.2 If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

4.24 Use of Individual Respiratory Protection Equipment.

4.24.1 If the licensee uses respiratory protection equipment to limit intakes pursuant to 4.23:

4.24.1.1 Except as provided in 4.24.1.2, the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.1.2 If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

4.24.1.3 The licensee shall implement and maintain a respiratory protection program that includes:

- (1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

- (2) Surveys and bioassays, as appropriate, to evaluate actual intakes; and
- (3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use; and
- (4) Written procedures regarding selection, fitting, issuance, maintenance, repair, quality assurance, storage and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; limitations on periods of respirator use and relief from respirator use; breathing air quality; monitoring, including air sampling and bioassays; inventory, control and recordkeeping; and
- (5) Determination by a physician, prior to initial fitting of respirators, before the first field use of non-face-sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.
- (6) Fit testing, with fit factor 10 times the assigned protection factor (APF) for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure demand devices, before the first field use of tight-fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

4.24.1.4 The licensee shall:

- (1) Issue a written policy statement on respirator usage covering:
 - (a) The use of process or other engineering controls, instead of respirators; and
 - (b) The routine, nonroutine, and emergency use of respirators; and
 - (c) The length of periods of respirator use and relief from respirator use; and
- (2) Advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

4.24.1.5 The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

4.24.1.6 Standby rescue persons are required whenever one piece atmosphere supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

4.24.1.7 Atmosphere-supplying respirators must be supplied with respirable air of Grade D quality or better as defined by the Compressed Gas Association in Publication G-7.1, "Commodity Specification For Air," edition 5, published August 27, 2004, and included in the regulations of the Occupational Safety And Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E), July 1, 2004).

Grade D quality air criteria include:

- (1) Oxygen content (V/V) between 19.5 per cent and 23.5 per cent;
- (2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
- (3) Carbon monoxide (CO) content of 10 parts per million or less;
- (4) Carbon dioxide content of 1,000 parts per million or less; and
- (5) Lack of noticeable odor.

4.24.1.8 The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face, facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight fitting respirator facepiece.

4.24.1.9 In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

4.24.2 When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 4.23, provided that the following conditions, in addition to those in 4.24.1, are satisfied:

4.24.2.1 The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix 4A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix 4B, Table 4B1, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

4.24.2.2 The licensee shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix 4A. The Department may authorize a licensee to use higher protection factors on receipt of an application that:

- (1) Describes the situation for which a need exists for higher protection factors, and
- (2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

4.24.3 In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.4 The licensee shall notify the Department in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 4.24.1 or 4.24.2.

4.24.5 The Department may impose restrictions in addition to the provisions of 4.23.2, 4.24.1, and Appendix 4A, in order to:

4.24.5.1 Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

4.24.5.2 Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

4.25 Security of Stored Sources of Radiation.

4.25.1 The licensee shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.

4.25.2 Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

4.26 Control of Sources of Radiation not in Storage.

- 4.26.1 The licensee shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient.
- 4.26.2 The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

PRECAUTIONARY PROCEDURES

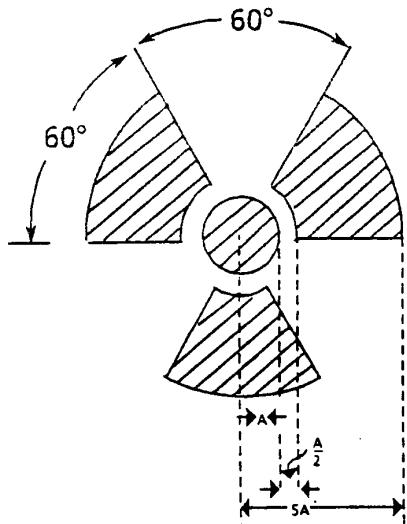
4.27 Caution Signs.

- 4.27.1 Standard Radiation Symbol. Unless otherwise authorized by the Department, the symbol prescribed by 4.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

4.27.1.1 Cross-hatched area is to be magenta, or purple, or black, and

4.27.1.2 The background is to be yellow.



4.27.2 Exception to Color Requirements for Standard Radiation Symbol.

Notwithstanding the requirements of 4.27.1, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

4.27.3 Additional Information on Signs and Labels.

In addition to the contents of signs and labels prescribed in Part 4, the licensee shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

4.28 Posting Requirements.

4.28.1 Posting of Radiation Areas.

The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words "CAUTION, RADIATION AREA."

4.28.2 Posting of High Radiation Areas.

The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

4.28.3 Posting of Very High Radiation Areas.

The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

4.28.4 Posting of Airborne Radioactivity Areas.

The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

4.28.5 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored.

The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix 4C with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

4.29 Exceptions to Posting Requirements.

4.29.1 A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

4.29.1.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part 4; and

4.29.1.2 The area or room is subject to the licensee's or registrant's control.

4.29.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 4.28 provided that the total effective dose equivalent to individual members of the public from the patient does not exceed 1 millisievert (0.1 rem) in a year.

- 4.29.3 A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.
- 4.29.4 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 4.28 if:
 - 4.29.4.1 Access to the room is controlled pursuant to 7.52; and
 - 4.29.4.2 Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.
- 4.29.5 A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

4.30 Labeling Containers and Radiation Machines.

- 4.30.1 The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol prescribed in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.
- 4.30.2 Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- 4.30.3 Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner, which cautions individuals that radiation is produced when it is energized.

4.31 Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

- 4.31.1 Containers holding licensed or registered material in quantities less than the quantities listed in Appendix 4C; or
- 4.31.2 Containers holding licensed or registered material in concentrations less than those specified in Table 4B3 of Appendix 4B; or
- 4.31.3 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part 4; or
- 4.31.4 Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation³ or

³ Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424, October 1, 2003.

4.31.5 Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

4.31.6 Installed manufacturing or process equipment, such as piping and tanks.

4.32 Procedures for Receiving and Opening Packages.

4.32.1 Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 17.2 and Appendix 17A of Part 17 of these regulations, shall make arrangements to receive:

4.32.1.1 The package when the carrier offers it for delivery; or

4.32.1.2 The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

4.32.2 Each licensee or registrant shall:

4.32.2.1 Monitor the external surfaces of a labeled⁴ package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 1.4 of these regulations; and

⁴ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440, October 1, 2003.

4.32.2.2 Monitor the external surfaces of a labeled⁵ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 17.2 and Appendix 17A to Part 17 of these regulations; and

⁵ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440, October 1, 2003.

4.32.2.3 Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

4.32.3 The licensee or registrant shall perform the monitoring required by 4.32.2 as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

4.32.4 The licensee or registrant shall immediately notify the final delivery carrier and the Department by telephone, when:

4.32.4.1 Removable radioactive surface contamination exceeds the limits of 17.15.8 of these regulations; or

4.32.4.2 External radiation levels exceed the limits of 17.15.9 and 17.15.10 of these regulations.

4.32.5 Each licensee or registrant shall:

- 4.32.5.1 Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
- 4.32.5.2 Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

4.32.6 Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 4.32.2, but are not exempt from the monitoring requirement in 4.32.2 for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

4.33 General Requirements.

4.33.1 A licensee or registrant shall dispose of licensed or registered material only:

- 4.33.1.1 By transfer to an authorized recipient as provided in 4.38 or in Parts 3, 14, or 18 of these regulations, or to the U.S. Department of Energy; or
- 4.33.1.2 By decay in storage; or
- 4.33.1.3 By release in effluents within the limits in 4.14; or
- 4.33.1.4 As authorized pursuant to 4.34, 4.35, 4.36 or 4.37.

4.33.2 A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

- 4.33.2.1 Treatment prior to disposal; or
- 4.33.2.2 Treatment or disposal by incineration; or
- 4.33.2.3 Decay in storage; or
- 4.33.2.4 Disposal at a land disposal facility pursuant to Part 14 of these regulations or as authorized under Parts 3 or 18 of these regulations; or
- 4.33.2.5 Storage until transferred to a storage or disposal facility authorized to receive the waste.

4.34 Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the Department for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

4.34.1 A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

- 4.34.2 An analysis and evaluation of pertinent information on the nature of the environment; and
- 4.34.3 The nature and location of other potentially affected facilities; and
- 4.34.4 Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part 4.

4.35 Disposal by Release into Sanitary Sewerage.

- 4.35.1 A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:
 - 4.35.1.1 The material is "readily soluble," or is "readily dispersible biological material," in water; and
 - 4.35.1.2 The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table 4B3 of Appendix 4B; and
 - 4.35.1.3 If more than one radionuclide is released, the following conditions must also be satisfied:
 - (1) The licensee or registrant shall determine the fraction of the limit in Table 4B3 of Appendix 4B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table 4B3 of Appendix 4B; and
 - (2) The sum of the fractions for each radionuclide required by 4.35.1.3.1 does not exceed unity; and
 - 4.35.1.4 The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.
- 4.35.2 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 4.35.1.

4.36 Treatment or Disposal by Incineration.

A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in 4.37 or as specifically approved by the Department pursuant to 4.34.

4.37 Disposal of Specific Wastes.

- 4.37.1 A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:
 - 4.37.1.1 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

- 4.37.1.2 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.
- 4.37.2 A licensee or registrant shall not dispose of tissue pursuant to 4.37.1.2 in a manner that would permit its use either as food for humans or as animal feed.
- 4.37.3 The licensee or registrant shall maintain records in accordance with 4.48.

4.38 Transfer for Disposal and Manifests.

- 4.38.1 The requirements of 4.38 and Appendix 4D are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.
- 4.38.2 Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix 4D.
- 4.38.3 Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix 4D.
- 4.38.4 Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix 4D.

4.39 Compliance with Environmental and Health Protection Regulations.

Nothing in 4.33, 4.34, 4.35, 4.37 or 4.38 relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to 4.33, 4.34, 4.35, 4.37 or 4.38.

RECORDS

4.40 General Provisions.

- 4.40.1 Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part 4.
- 4.40.2 The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part 4 (e.g., total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, committed effective dose equivalent).
- 4.40.3 The licensee or registrant shall be consistent in their use of SI or special units. The licensee or registrant shall not change the units used on records required by Part 4 except at the beginning of the calendar year or with Department approval.

4.41 Records of Radiation Protection Programs.

- 4.41.1 Each licensee or registrant shall maintain records of the radiation protection program, including:
 - 4.41.1.1 The provisions of the program; and
 - 4.41.1.2 Audits and other reviews of program content and implementation.
- 4.41.2 The licensee or registrant shall retain the records required by 4.41.1.1 until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 4.41.1.2 for 3 years after the record is made.

4.42 Records of Surveys.

- 4.42.1 Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 4.17 and 4.32.2. The licensee or registrant shall retain these records for 3 years after the record is made.
- 4.42.2 The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:
 - 4.42.2.1 Records of the results of surveys to determine the dose from external sources of radiation and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and
 - 4.42.2.2 Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
 - 4.42.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to 4.24.1.3(1) and 4.24.1.3(2); and
 - 4.42.2.4 Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

- 4.42.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.43 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by 4.16 shall be kept in units of becquerel (or microcurie) and maintained for inspection by the Department for 5 years after the records are made.

4.44 Records of Prior Occupational Dose.

- 4.44.1 The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 4.10 on Department Form R-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form R-16 or equivalent for 3 years after the record is made.

4.44.2 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.45 Records of Planned Special Exposures.

4.45.1 For each use of the provisions of 4.11 for planned special exposures, the licensee or registrant shall maintain records that describe:

4.45.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

4.45.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

4.45.1.3 What actions were necessary; and

4.45.1.4 Why the actions were necessary; and

4.45.1.5 What precautions were taken to assure that doses were maintained ALARA; and

4.45.1.6 What individual and collective doses were expected to result; and

4.45.1.7 The doses actually received in the planned special exposure.

4.45.2 The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

4.45.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.46 Records of Individual Monitoring Results.

4.46.1 Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 4.18, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:

4.46.1.1 The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

4.46.1.2 The estimated intake of radionuclides (see 4.7);

4.46.1.3 The committed effective dose equivalent assigned to the intake of radionuclides;

4.46.1.4 The specific information used to assess and calculate the committed effective dose equivalent pursuant to 4.9.1 and 4.9.3, and when required by 4.18;

4.46.1.5 The total effective dose equivalent when required by 4.7; and

4.46.1.6 The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

4.46.2 Recordkeeping Frequency.

The licensee or registrant shall make entries of the records specified in 4.46.1 at intervals not to exceed 1 year.

4.46.3 Recordkeeping Format.

The licensee or registrant shall maintain the records specified in 4.46.1 on Department Form R-17, Occupational Exposure Record for a Monitoring Period, in accordance with the instructions for Department Form R-17, or in clear and legible records containing all the information required by Department Form R-17.

4.46.4 The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

4.46.5 The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

4.46.6 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.47 Records of Dose to Individual Members of the Public.

4.47.1 Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 4.14.

4.47.2 The licensee or registrant shall retain the records required by 4.47.1 until the Department terminates each pertinent license or registration requiring the record.

4.48 Records of Waste Disposal.

4.48.1 Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to 4.34, 4.35, 4.36, 4.37, Part 14 of these regulations, and disposal by burial in soil, including burials authorized before December 30, 1985.

4.48.2 The licensee or registrant shall retain the records required by 4.48.1 in accordance with 3.15.4 until the Department terminates each pertinent license or registration requiring the record.

4.49 Records of Testing Entry Control Devices for Very High Radiation Areas.

4.49.1 Each licensee or registrant shall maintain records of tests made pursuant to 4.21.2.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

4.49.2 The licensee or registrant shall retain the records required by 4.49.1 for 3 years after the record is made.

4.50 Form of Records.

Each record required by Part 4 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in Department-approved electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

4.51 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

4.51.1 Telephone Reports.

Each licensee or registrant shall report to the Department by telephone as follows:

4.51.1.1 Immediately after its occurrence becomes known to the licensee or registrant, stolen lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix 4C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

4.51.1.2 Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix 4C that is still missing.

4.51.1.3 Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

4.51.2 Written Reports.

Each licensee or registrant required to make a report pursuant to 4.51.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

4.51.2.1 A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

4.51.2.2 A description of the circumstances under which the loss or theft occurred; and

4.51.2.3 A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4.51.2.4 Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

4.51.2.5 Actions that have been taken, or will be taken, to recover the source of radiation; and

4.51.2.6 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

4.51.3 Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

4.51.4 The licensee or registrant shall prepare any report filed with the Department pursuant to 4.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

4.52 Notification of Incidents.

4.52.1 Immediate Notification.

Notwithstanding other requirements for notification, each licensee or registrant shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event:

4.52.1.1 Involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

(a) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures.

4.52.1.2 That prevents immediate protective actions necessary to avoid exposures to radiation and/or radioactive materials that could exceed regulatory limits, or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

4.52.2 Twenty-Four Hour Notification.

Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department:

4.52.2.1 Each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

- (1) An individual to receive, in a period of 24 hours:
 - (a) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
 - (b) A lens dose equivalent exceeding 0.15 Sv (15 rem); or
 - (c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
 - (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- 4.52.2.2 An unplanned contamination event that:
- (1) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
 - (2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and
 - (3) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
- 4.52.2.3 An event in which equipment is disabled or fails to function as designed when:
- (1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and
 - (2) The equipment is required to be available and operable when it is disabled or fails to function during the event; and
 - (3) No redundant equipment is available and operable to perform the required safety function.
- 4.52.2.4 An event that requires unplanned medical treatment at a medical facility of an individual whose body or clothing is contaminated with spreadable radioactive material.
- 4.52.2.5 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
- (1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and
 - (2) The damage affects the integrity of the licensed material or its container.

4.53 Preparation and Submission of Reports.

4.53.1 Reports made by licensees or registrants in response to the requirements of 4.52, must be made as follows:

4.53.1.1 Licensees or registrants shall make the reports required by 4.52.1 and 4.52.2 to the Department by telephone. To the extent that the information is available at the time of notification, the information provided in these reports must include:

- (1) The caller's name and call back telephone number;
- (2) A description of the event including date and time;
- (3) The exact location of the event;
- (4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (5) Any personnel radiation exposure data available.

4.53.1.2 Each licensee or registrant who makes a report required by 4.52.1 or 4.52.2 shall submit a written follow-up report to the Department pursuant to 4.53.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

4.53.1.3 The provisions of 4.52 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 4.54.

4.53.2 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

In addition to the notification required by 4.52, each licensee or registrant shall submit a written report to the Department within 30 days after learning of any of the following occurrences:

4.53.2.1 Incidents for which notification is required by 4.52; or

4.53.2.2 Doses in excess of any of the following:

- (1) The occupational dose limits for adults in 4.6; or
- (2) The occupational dose limits for a minor in 4.12; or
- (3) The limits for an embryo/fetus of a declared pregnant woman in 4.13; or
- (4) The limits for an individual member of the public in 4.14; or
- (5) Any applicable limit in the license or registration; or
- (6) The ALARA constraints for air emissions established under 4.5.4.

- 4.53.2.3 Levels of radiation or concentrations of radioactive material in:
- (1) A restricted area in excess of applicable limits in the license or registration; or
 - (2) An unrestricted area in excess of 10 times the applicable limit set forth in Part 4 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 4.14; or
- 4.53.2.4 For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, July 1, 2004, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

4.53.3 Contents of Written Reports.

- 4.53.3.1 Each report required by 4.53.1.2 or 4.53.2 shall include the following, as appropriate:
- (1) A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
 - (2) The exact location of the event;
 - (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
 - (4) Date and time of the event;
 - (5) The results of any evaluations or assessments, including:
 - (a) Estimates of each individual's dose;
 - (b) The levels of radiation and concentrations of radioactive material involved;
 - (c) The cause of the elevated exposures, dose rates, or concentrations; and
 - (d) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.
- 4.53.3.2 Each report filed pursuant to 4.53 shall include for each occupationally overexposed individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 4.13, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure".

4.54 Reports of Planned Special Exposures.

The licensee or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with 4.11, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 4.45.

4.55 Reserved.

4.56 Reports of Individual Monitoring.

4.56.1 This section applies to each person licensed or registered by the Department to:

4.56.1.1 Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts 3 and 5 of these regulations; or

4.56.1.2 Receive radioactive waste from other persons for disposal pursuant to Part 14 of these regulations; or

4.56.1.3 Possess or use at any time, for processing or manufacturing for distribution pursuant to Part 3 or 7 of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity⁶	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

⁶ The Department may require as a license condition, or by rule, regulation, or order pursuant to 1.9, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

- 4.56.2 Each licensee or registrant in a category listed in 4.56.1 shall submit an annual report to the Department of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 4.18 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Department Form R-17 or equivalent or Department-approved electronic media containing all the information required by Department Form R-17.
- 4.56.3 The licensee or registrant shall file the report required by 4.56.2, covering the preceding year, on or before April 30 of each year.

4.57 Notifications and Reports to Individuals.

- 4.57.1 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 10.4 of these regulations.
- 4.57.2 When a licensee or registrant is required pursuant to 4.53 to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of 10.4.1 of these regulations.

4.58 Reports of Leaking or Contaminated Sealed Sources.

The licensee or registrant shall file a report within 5 days with the Department if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

4.59 Vacating Premises.

Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's or registrant's activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

4.60 Permissible Levels of Radioactive Material in Uncontrolled Areas.

- 4.60.1 Plutonium. Contamination of the soil in excess of 2.0 disintegrations per minute (0.03 Bq) of plutonium per gram of dry soil or square centimeter of surface area (0.01 microcurie [370 Bq] per square meter) presents a sufficient hazard to the public health to require the utilization of special techniques of construction upon property so contaminated. Evaluation of proposed control techniques shall be available from the Department upon request.

4.61 Radiological Criteria For License Termination.

- 4.61.1 The criteria in this section apply to the decommissioning of facilities licensed under Parts 3, 5, 7, 14, 16, and 19 of these regulations. For low-level waste disposal facilities licensed under Part 14, the criteria apply only to the ancillary surface facilities that support radioactive waste disposal activities.

4.61.1.1 The criteria in this section do not apply to uranium and thorium recovery facilities already subject to Appendix 18A of Part 18; uranium solution extraction facilities; sites which have been decommissioned and the license terminated prior to July 1, 1999; or sites which submitted a decommissioning plan prior to July 1, 2000 and received Department approval of that decommissioning plan prior to July 1, 2001.

4.61.1.2 When calculating the TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1000 years after decommissioning. In accordance with 1.5.1, the Department may authorize the licensee to exclude dose contributions from the inhalation of radon and its decay products when calculating TEDE.

4.61.1.3 Determination of dose and residual radioactivity levels which are as low as reasonably achievable (ALARA) must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

4.61.2 Radiological Criteria For Unrestricted Use.

A site will be considered acceptable for license termination under conditions of unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 0.25 mSv per year (25 mrem/y), including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA.

4.61.3 Radiological Criteria For Restricted Use.

A site will be considered acceptable for license termination under restricted conditions if:

4.61.3.1 The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 4.61.2 would result in net public or environmental harm or were not being made because the residual levels of contamination associated with restricted conditions are ALARA;

4.61.3.2 The licensee has made provisions for durable, legally enforceable institutional controls which provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv per year (25 mrem/y); and

4.61.3.3 Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either: 1 mSv per year (100 mrem/y); or 5 mSv per year (500 mrem/y), provided the licensee demonstrates that further reductions in residual radioactivity necessary to comply with the 1-mSv-per-year (100 mrem/y) value of this paragraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm.

4.61.4 Alternate Criteria For License Termination.

4.61.4.1 The Department may terminate a license using alternate criteria greater than the dose criterion of 4.61.2 or 4.61.3.2, if:

- (1) The licensee has performed an analysis for possible sources of exposure to radiation which provides assurance that public health and safety would continue to be protected, and that it is unlikely the TEDE to an average member of the critical group from all radiation that is distinguishable from background radiation, other than medical, would be more than 1 mSv per year (100 mrem/y);
- (2) The licensee has employed, to the extent practical, restrictions on site use which minimize exposures at the site in accordance with the provisions of 4.61.3; and
- (3) The licensee has reduced doses to levels which are ALARA.

PART 4, APPENDIX 4A:

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS^a

	Operating Mode	Assigned Protection Factors
I. Air purifying respirators [particulate ^b only] ^c :		
Filtering facepiece disposable	Negative pressure	(^d)
Facepiece, half ^e	Negative pressure	10
Facepiece, full	Negative pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators [particulate, gases and vapors ^f]:		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous flow	50
Facepiece, half	Pressure demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous flow	1000
Facepiece, full	Pressure demand	1000
Helmet/hood	Continuous flow	1000
Facepiece, loose-fitting	Continuous flow	25

Suit	Continuous flow	^(g)
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	^h 100
Facepiece, full	Pressure demand	ⁱ 10,000
Facepiece, full	Demand, recirculating	^h 100
Facepiece, full	Positive pressure recirculating	ⁱ 10,000
III. Combination respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

^a These assigned protection factors apply only in a respiratory protection program that meets the requirements of this part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with department of labor regulations.

Radioactive contaminants for which the concentration values in Table 4B1, Column 3 of Appendix 4B are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

^b Air-purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air-purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air-purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

^c The licensee may apply to the commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

^d Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 4.24.1 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

^e Under-chin type only. No distinction is made in this appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this part are met.

^f The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

^g No National Institute of Occupational Safety and Health (NIOSH) approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (that is, 4.24.1).

^h The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

ⁱ This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

PART 4, APPENDIX 4B:

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, Table 4B1 indicates the chemical form which is to be used for selecting the appropriate ALIs and DACs for inhalation. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm , micron, and for three classes (D, W, Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table 4B2 provides concentration limits for airborne and liquid effluents released to the general environment. Table 4B3 provides concentration limits for discharges to sanitary sewerage.

Note:

The values in Table 4B1, Table 4B2, and Table 4B3 are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^2 or 600, and 6E+0 represents 6×10^0 or 6.

Table 1 "Occupational Values"

Note that the columns in Table 4B1 of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "reference man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T , to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in 4.3. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract — stomach, small intestine, upper large intestine, and lower large intestine — are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;

St. wall = stomach wall;

Blad wall = bladder wall; and

Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ (intake (in μCi) of each radionuclide/ ALI_{ns}) \leq 1.0. If there is an external deep dose equivalent contribution of H_d , then this sum must be less than $1 - (H_d/50)$, instead of \leq 1.0.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$DAC = ALI \text{ (in } \mu\text{Ci}) / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = (ALI / 2.4 \times 10^9) \mu\text{Ci/ml}$, where 2×10^4 ml is the volume of air breathed per minute at work by reference man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any ingrowth of decay product radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and decay product radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 4.7. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table 2 “Effluent Concentrations”

The columns in Table 4B2 of this appendix captioned “Effluents,” “Air” and “Water” are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 4.15. The concentration values given in Columns 1 and 2 of Table 4B2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table 4B2. For this reason, the DAC and airborne effluent limits are not always proportional as they were in Appendix A of Part D of the Eighth Edition of Volume I of the *Suggested State Regulations for Control of Radiation*, April 2004.

The air concentration values listed in Table 4B2, Column 1, were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 , relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table 4B1, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7 . The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of reference man.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table 3 “Releases to Sewerage”

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 4.35. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by reference man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of 0.5 rem.

Table 4B1, Table 4B2, and Table 4B3 are found at

<http://www.cdphe.state.co.us/regulations/radiationcontrol/10070104app.pdf>

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
Actinium	Ac	89
Aluminum	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Osmium	Os	76
Palladium	Pd	46

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30

LIST OF ELEMENTS

Atomic

Name	Symbol	Number
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Zirconium	Zr	40
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PART 4, APPENDIX 4C:**QUANTITIES^j OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING**

Radionuclide	Quantity (μ Ci)*	Radionuclide	Quantity (μ Ci)*
* To convert μ Ci to kBq, multiply the μ Ci value by 37.			
Actinium-224	1	Barium-126	1,000
Actinium-225	0.01	Barium-128	100
Actinium-226	0.1	Barium-131	100
Actinium-227	0.001	Barium-131m	1,000
Actinium-228	1	Barium-133	100
Aluminum-26	10	Barium-133m	100
Americium-237	1,000	Barium-135m	100
Americium-238	100	Barium-139	1,000
Americium-239	1,000	Barium-140	100
Americium-240	100	Barium-141	1,000
Americium-241	0.001	Barium-142	1,000
Americium-242	10	Berkelium-245	100
Americium-242m	0.001	Berkelium-246	100
Americium-243	0.001	Berkelium-247	0.001
Americium-244	10	Berkelium-249	0.1
Americium-244m	100	Berkelium-250	10
Americium-245	1,000	Beryllium-10	1
Americium-246	1,000	Beryllium-7	1,000

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Americium-246	1,000	Bismuth-200	1,000
Antimony-115	1,000	Bismuth-201	1,000
Antimony-116	1,000	Bismuth-202	1,000
Antimony-116m	1,000	Bismuth-203	100
Antimony-117	1,000	Bismuth-205	100
Antimony-118m	1,000	Bismuth-206	100
Antimony-119	1,000	Bismuth-207	10
Antimony-120(16m)	1,000	Bismuth-210	1
Antimony-120(5.76d)	100	Bismuth-210m	0.1
Antimony-122	100	Bismuth-212	10
Antimony-124	10	Bismuth-213	10
Antimony-124m	1,000	Bismuth-214	100
Antimony-125	100	Bromine-74	1,000
Antimony-126	100	Bromine-74m	1,000
Antimony-126m	1,000	Bromine-75	1,000
Antimony-127	100	Bromine-76	100
Antimony-128(10.4m)	1,000	Bromine-77	1,000
Antimony-128(9.01 h)	100	Bromine-80	1,000
Antimony-129	100	Bromine-80m	1,000
Antimony-130	1,000	Bromine-82	100

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Antimony-131	1,000	Bromine-83	1,000
Argon-39	1,000	Bromine-84	1,000
Argon-41	1,000	Cadmium-104	1,000
Arsenic-69	1,000	Cadmium-107	1,000
Arsenic-70	1,000	Cadmium-109	1
Arsenic-71	100	Cadmium-113	100
Arsenic-72	100	Cadmium-113m	0.1
Arsenic-73	100	Cadmium-115	100
Arsenic-74	100	Cadmium-115m	10
Arsenic-76	100	Cadmium-117	1,000
Arsenic-77	100	Cadmium-117m	1,000
Arsenic-78	1,000	Calcium-41	100
Astatine-207	100	Calcium-45	100
Astatine-211	10	Calcium-47	100
Californium-244	100	Curium-245	0.001
Californium-246	1	Curium-246	0.001
Californium-244	100	Curium-245	0.001
Californium-246	1	Curium-246	0.001
Californium-248	0.01	Curium-247	0.001
Californium-249	0.001	Curium-248	0.001

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Californium-250	0.001	Curium-249	1,000
Californium-251	0.001	Dysprosium-155	1,000
Californium-252	0.001	Dysprosium-157	1,000
Californium-253	0.1	Dysprosium-159	100
Californium-254	0.001	Dysprosium-165	1,000
Carbon-11	1,000	Dysprosium-166	100
Carbon-14	1,000	Einsteinium-250	100
Cerium-134	100	Einsteinium-251	100
Cerium-135	100	Einsteinium-253	0.1
Cerium-137	1,000	Einsteinium-254	0.01
Cerium-137m	100	Einsteinium-254m	1
Cerium-139	100	Erbium-161	1,000
Cerium-141	100	Erbium-165	1,000
Cerium-143	100	Erbium-169	100
Cerium-144	1	Erbium-171	100
Cesium-125	1,000	Erbium-172	100
Cesium-127	1,000	Europium-145	100
Cesium-129	1,000	Europium-146	100
Cesium-130	1,000	Europium-147	100
Cesium-131	1,000	Europium-148	10

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Cesium-132	100	Europium-149	100
Cesium-134	10	Europium-150 (12.62h)	100
Cesium-134m	1,000	Europium-150 (34.2y)	1
Cesium-135	100	Europium-152	1
Cesium-135m	1,000	Europium-152m	100
Cesium-136	10	Europium-154	1
Cesium-137	10	Europium-155	10
Cesium-138	1,000	Europium-156	100
Chlorine-36	10	Europium-157	100
Chlorine-38	1,000	Europium-158	1,000
Chlorine-39	1,000	Fermium-252	1
Chromium-48	1,000	Fermium-253	1
Chromium-49	1,000	Fermium-254	10
Chromium-51	1,000	Fermium-255	1
Cobalt-55	100	Fermium-257	0.01
Cobalt-56	10	Fluorine-18	1,000
Cobalt-57	100	Francium-222	100
Cobalt-58	100	Francium-223	100
Cobalt-58m	1,000	Gandolinium-145	1,000
Cobalt-60	1	Gandolinium-146	10

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Cobalt-60m	1,000	Gandolinium-147	100
Cobalt-61	1,000	Gandolinium-148	0.001
Cobalt-62m	1,000	Gandolinium-149	100
Copper-60	1,000	Gandolinium-151	10
Copper-61	1,000	Gandolinium-152	100
Copper-64	1,000	Gandolinium-153	10
Copper-67	1,000	Gandolinium-159	100
Curium-238	100	Gallium-65	1,000
Curium-240	0.1	Gallium-66	100
Curium-241	1	Gallium-67	1,000
Curium-242	0.01	Gallium-68	1,000
Curium-243	0.001	Gallium-70	1,000
Curium-244	0.001	Gallium-72	100
Gallium-73	1,000	Indium-119m	1,000
Germanium-66	1,000	Iodine-120	100
Germanium-67	1,000	Iodine-120m	1,000
Germanium-68	10	Iodine-121	1,000
Germanium-69	1,000	Iodine-123	100
Germanium-71	1,000	Iodine-124	10
Germanium-75	1,000	Iodine-125	1

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Germanium-77	1,000	Iodine-126	1
Germanium-78	1,000	Iodine-128	1,000
Gold-193	1,000	Iodine-129	1
Gold-194	100	Iodine-130	10
Gold-195	10	Iodine-131	1
Gold-198	100	Iodine-132	100
Gold-198m	100	Iodine-132m	100
Gold-199	100	Iodine-133	10
Gold-200	1,000	Iodine-134	1,000
Gold-200m	100	Iodine-135	100
Gold-201	1,000	Iridium-182	1,000
Hafnium-170	100	Iridium-184	1,000
Hafnium-172	1	Iridium-185	1,000
Hafnium-173	1,000	Iridium-186	100
Hafnium-175	100	Iridium-187	1,000
Hafnium-177m	1,000	Iridium-188	100
Hafnium-178m	0.1	Iridium-189	100
Hafnium-179m	10	Iridium-190	100
Hafnium-180m	1,000	Iridium-190m	1,000
Hafnium-181	10	Iridium-192 (73.8d)	1

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Hafnium-182	0.1	Iridium-192m (1.4m)	10
Hafnium-182m	1,000	Iridium-194	100
Hafnium-183	1,000	Iridium-194m	10
Hafnium-184	100	Iridium-195	1,000
Holmium-155	1,000	Iridium-195m	1,000
Holmium-157	1,000	Iron-52	100
Holmium-159	1,000	Iron-55	100
Holmium-161	1,000	Iron-59	10
Holmium-162	1,000	Iron-60	1
Holmium-162m	1,000	Krypton-74	1,000
Holmium-164	1,000	Krypton-76	1,000
Holmium-164m	1,000	Krypton-77	1,000
Holmium-166	100	Krypton-79	1,000
Holmium-166m	1	Krypton-81	1,000
Holmium-167	1,000	Krypton-83m	1,000
Hydrogen-3	1,000	Krypton-85	1,000
Indium-109	1,000	Krypton-85m	1,000
Indium-110 (69.1m)	1,000	Krypton-87	1,000
Indium-110m (4.9h)	1,000	Krypton-88	1,000
Indium-111	100	Lanthanum-131	1,000

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Indium-112	1,000	Lanthanum-132	100
Indium-113m	1,000	Lanthanum-135	1,000
Indium-114m	10	Lanthanum-137	10
Indium-115	100	Lanthanum-138	100
Indium-115m	1,000	Lanthanum-14	1,000
Indium-116m	1,000	Lanthanum-140	100
Indium-117	1,000	Lanthanum-141	100
Indium-117m	1,000	Lanthanum-143	1,000
Lead-195m	1,000	Neodymium-147	100
Lead-198	1,000	Neodymium-149	1,000
Lead-199	1,000	Neodymium-151	1,000
Lead-200	100	Neptunium-232	100
Lead-201	1,000	Neptunium-233	1,000
Lead-202	10	Neptunium-235	100
Lead-202m	1,000	Neptunium-236 (1.15E+5y)	0.001
Lead-203	1,000	Neptunium-236 (22.5h)	1
Lead-205	100	Neptunium-237	0.001
Lead-209	1,000	Neptunium-238	10
Lead-210	0.01	Neptunium-239	100
Lead-211	100	Neptunium-240	1,000

Radionuclide	Quantity (μCi)*	Radionuclide	Quantity (μCi)*
Lead-212	1	Neptunium-234	100
Lead-214	100	Nickel-56	100
Lutetium-169	100	Nickel-57	100
Lutetium-170	100	Nickel-59	100
Lutetium-171	100	Nickel-63	100
Lutetium-172	100	Nickel-65	1,000
Lutetium-173	10	Nickel-66	10
Lutetium-174	10	Niobium-88	1,000
Lutetium-174m	10	Niobium-89 (122 min)	1,000
Lutetium-176	100	Niobium-89m (66 min)	1,000
Lutetium-176m	1,000	Niobium-90	100
Lutetium-177	100	Niobium-93m	10
Lutetium-177m	10	Niobium-94	1
Lutetium-178	1,000	Niobium-95	100
Lutetium-178m	1,000	Niobium-95m	100
Lutetium-179	1,000	Niobium-96	100
Magnesium-28	100	Niobium-97	1,000
Manganese-51	1,000	Niobium-98	1,000
Manganese-52	100	Osmium-180	1,000
Manganese-52m	1,000	Osmium-181	1,000

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Manganese-53	1,000	Osmium-182	100
Manganese-54	100	Osmium-185	100
Manganese-56	1,000	Osmium-189m	1,000
Mendelevium-257	10	Osmium-191	100
Mendelevium-258	0.01	Osmium-191m	1,000
Mercury-193	1,000	Osmium-193	100
Mercury-193m	100	Osmium-194	1
Mercury-194	1	Palladium-100	100
Mercury-195	1,000	Palladium-101	1,000
Mercury-195m	100	Palladium-103	100
Mercury-197	1,000	Palladium-107	10
Mercury-197m	100	Palladium-109	100
Mercury-199m	1,000	Phosphorus-32	10
Mercury-203	100	Phosphorus-33	100
Molybdenum-101	1,000	Platinum-186	1,000
Molybdenum-90	100	Platinum-188	100
Molybdenum-93	10	Platinum-189	1,000
Molybdenum-93m	100	Platinum-191	100
Molybdenum-99	100	Platinum-193	1,000
Neodymium-136	1,000	Platinum-193m	100

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Neodymium-138	100	Platinum-195m	100
Neodymium-139	1,000	Platinum-197	100
Neodymium-139m	1,000	Platinum-197m	1,000
Neodymium-141	1,000		
Platinum-199	1,000	Radium-225	0.1
Platinum-200	100	Radium-226	0.1
Plutonium-234	10	Radium-227	1,000
Plutonium-235	1,000	Radium-228	0.1
Plutonium-236	0.001	Radon-220	1
Plutonium-237	100	Radon-222	1
Plutonium-238	0.001	Rhenium-177	1,000
Plutonium-239	0.001	Rhenium-178	1,000
Plutonium-240	0.001	Rhenium-181	1,000
Plutonium-241	0.01	Rhenium-182 (12.7h)	1,000
Plutonium-242	0.001	Rhenium-182 (64.0h)	100
Plutonium-243	1,000	Rhenium-184	100
Plutonium-244	0.001	Rhenium-184m	10
Plutonium-245	100	Rhenium-186	100
Polonium-203	1,000	Rhenium-186m	10
Polonium-205	1,000	Rhenium-187	1,000

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Polonium-207	1,000	Rhenium-188	100
Polonium-210	0.1	Rhenium-188m	1,000
Potassium-40	100	Rhenium-189	100
Potassium-42	1,000	Rhodium-100	100
Potassium-43	1,000	Rhodium-101	10
Potassium-44	1,000	Rhodium-101m	1,000
Potassium-45	1,000	Rhodium-102	10
Praseodymium-136	1,000	Rhodium-102m	10
Praseodymium-137	1,000	Rhodium-103m	1,000
Praseodymium-138m	1,000	Rhodium-105	100
Praseodymium-139	1,000	Rhodium-106m	1,000
Praseodymium-142	100	Rhodium-107	1,000
Praseodymium-142m	1,000	Rhodium-99	100
Praseodymium-143	100	Rhodium-99m	1,000
Praseodymium-144	1,000	Rubidium-79	1,000
Praseodymium-145	100	Rubidium-81	1,000
Praseodymium-147	1,000	Rubidium-81m	1,000
Promethium-141	1,000	Rubidium-82m	1,000
Promethium-143	100	Rubidium-83	100
Promethium-144	10	Rubidium-84	100

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Promethium-145	10	Rubidium-86	100
Promethium-146	1	Rudidium-87	100
Promethium-147	10	Rubidium-88	1,000
Promethium-148	10	Rubidium-89	1,000
Promethium-148m	10	Ruthenium-103	100
Promethium-149	100	Ruthenium-105	1,000
Promethium-150	1,000	Ruthenium-106	1
Promethium-151	100	Ruthenium-94	1,000
Protactinium-227	10	Ruthenium-97	1,000
Protactinium-228	1	Samarium-141	1,000
Protactinium-230	0.1	Samarium-141m	1,000
Protactinium-231	0.001	Samarium-142	1,000
Protactinium-232	1	Samarium-145	100
Protactinium-233	100	Samarium-146	1
Protactinium-234	100	Samarium-147	100
Radium-223	0.1	Samarium-151	10
Radium-224	0.1	Samarium-153	100
Samarium-155	1,000	Tantalum-182m	1,000
Samarium-156	1,000	Tantalum-183	100
Scandium-43	1,000	Tantalum-184	100

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Scandium-44	100	Tantalum-185	1,000
Scandium-44m	100	Tantalum-186	1,000
Scandium-46	10	Technetium-101	1,000
Scandium-47	100	Technetium-104	1,000
Scandium-48	10	Technetium-93	1,000
Scandium-49	1,000	Technetium-93m	1,000
Selenium-70	1,000	Technetium-94	1,000
Selenium-73	100	Technetium-94m	1,000
Selenium-73m	1,000	Technetium-96	100
Selenium-75	100	Technetium-96m	1,000
Selenium-79	100	Technetium-97	1,000
Selenium-81	1,000	Technetium-97m	100
Selenium-81m	1,000	Technetium-98	10
Selenium-83	1,000	Technetium-99	100
Silicon-2	1	Technetium-99m	1,000
Silicon-31	1,000	Tellurium-116	1,000
Silver-102	1,000	Tellurium-121	100
Silver-103	1,000	Tellurium-121m	10
Silver-104	1,000	Tellurium-123	100
Silver-104m	1,000	Tellurium-123m	10

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Silver-105	100	Tellurium-125m	10
Silver-106	1,000	Tellurium-127	1,000
Silver-106m	100	Tellurium-127m	10
Silver-108m	1	Tellurium-129	1,000
Silver-111	100	Tellurium-129m	10
Silver-112	100	Tellurium-131	100
Silver-115	1,000	Tellurium-131m	10
Silver-110m	10	Tellurium-132	10
Sodium-22	10	Tellurium-133	1,000
Sodium-24	100	Tellurium-133m	100
Strontium-80	100	Tellurium-134	1,000
Strontium-81	1,000	Terbium-147	1,000
Strontium-83	100	Terbium-149	100
Strontium-85	100	Terbium-150	1,000
Strontium-85m	1,000	Terbium-151	100
Strontium-87m	1,000	Terbium-153	1,000
Strontium-89	10	Terbium-154	100
Strontium-90	0.1	Terbium-155	1,000
Strontium-91	100	Terbium-156	100
Strontium-92	100	Terbium-156m (5.0h)	1,000

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Sulfur-35	100	Terbium-156m (24.4h)	1,000
Tantalum-172	1,000	Terbium-157	10
Tantalum-173	1,000	Terbium-158	1
Tantalum-174	1,000	Terbium-160	10
Tantalum-175	1,000	Terbium-161	100
Tantalum-176	100	Thallium-194	1,000
Tantalum-177	1,000	Thallium-194m	1,000
Tantalum-178	1,000	Thallium-195	1,000
Tantalum-179	100	Thallium-197	1,000
Tantalum-180	100	Thallium-198	1,000
Tantalum-180m	1,000	Thallium-198m	1,000
Tantalum-182	10	Thallium-199	1,000
Thallium-200	1,000	Uranium-231	100
Thallium-201	1,000	Uranium-232	0.001
Thallium-202	100	Uranium-233	0.001
Thallium-204	100	Uranium-234	0.001
Thorium-226	10	Uranium-235	0.001
Thorium-227	0.01	Uranium-236	0.001
Thorium-228	0.001	Uranium-237	100
Thorium-229	0.001	Uranium-238	100

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Thorium-230	0.001	Uranium-239	1,000
Thorium-231	100	Uranium-240	100
Thorium-232	100	Uranium-natural	100
Thorium-234	10	Vanadium-47	1,000
Thorium-natural	100	Vanadium-48	100
Thulium-162	1,000	Vanadium-49	1,000
Thulium-166	100	Xenon-120	1,000
Thulium-167	100	Xenon-121	1,000
Thulium-170	10	Xenon-122	1,000
Thulium-171	10	Xenon-123	1,000
Thulium-172	100	Xenon-125	1,000
Thulium-173	100	Xenon-127	1,000
Thulium-175	1,000	Xenon-129m	1,000
Tin-110	100	Xenon-131m	1,000
Tin-111	1,000	Xenon-133	1,000
Tin-113	100	Xenon-133m	1,000
Tin-117m	100	Xenon-135	1,000
Tin-119m	100	Xenon-135m	1,000
Tin-121	1,000	Xenon-138	1,000
Tin-121m	100	Ytterbium-162	1,000

Radionuclide	Quantity (μCi)[*]	Radionuclide	Quantity (μCi)[*]
Tin-123	10	Ytterbium-166	100
Tin-123m	1,000	Ytterbium-167	1,000
Tin-125	10	Ytterbium-169	100
Tin-126	10	Ytterbium-175	100
Tin-127	1,000	Ytterbium-177	1,000
Tin-128	1,000	Ytterbium-178	1,000
Titanium-44	1	Yttrium-86	100
Titanium-45	1,000	Yttrium-86m	1,000
Tungsten-176	1,000	Yttrium-87	100
Tungsten-177	1,000	Yttrium-88	10
Tungsten-178	1,000	Yttrium-90	10
Tungsten-179	1,000	Yttrium-90m	1,000
Tungsten-18	100	Yttrium-91	10
Tungsten-181	1,000	Yttrium-91m	1,000
Tungsten-187	100	Yttrium-92	100
Tungsten-188	10	Yttrium-93	100
Uranium-230	0.01	Yttrium-94	1,000
		Yttrium-95	1,000
Zinc-62	100		
Zinc-63	1,000		

Radionuclide	Quantity (μCi) [*]	Radionuclide	Quantity (μCi) [*]
Zinc-65	10		
Zinc-69	1,000		
Zinc-69m	100		
Zinc-71m	1,000		
Zinc-72	100		
Zirconium-86	100		
Zirconium-88	10		
Zirconium-89	100		
Zirconium-93	1		
Zirconium-95	10		
Zirconium-97	100		
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

Note: For purposes of 4.28.5, 4.31.1, and 4.51.1, where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" - that is, unity.

^j The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table 4B1, Columns 1 and 2, of Appendix 4B, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except Rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

PART 4, APPENDIX 4D:

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

A. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable forms 540, uniform low-level radioactive waste manifest (shipping paper), and 541, Uniform Low-Level Radioactive Waste Manifest (container and waste description), and, if necessary, on an applicable Form 542, Uniform Low-Level Radioactive Waste Manifest (manifest index and regional compact tabulation). Forms 540 and 540a must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between the shipper and consignee, Forms 541 and 541a and 542 and 542a may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate and complete records on the respective forms.

B. Licensees are not required by this department to comply with manifesting requirements of this part when they ship:

1. Low-level radioactive waste for processing and expect its return (that is, for storage under their license) prior to disposal at a licensed land disposal facility;
2. Low-level radioactive waste that is being returned to the licensee who is the "waste generator" or "generator" as defined in this appendix; or
3. Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste".

C. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

D. As used in this appendix, the following definitions apply:

"Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, and polycarboxylic acids.

"Chemical description" means a description of the principal chemical characteristics of the low-level radioactive waste.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Decontamination facility" means a facility operating under a U.S. Nuclear Regulatory Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for the purposes of this Part, is not considered to be a consignee for low-level radioactive waste shipments.

“Disposal container” means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see “high integrity container”). Note that for some shipments, the disposal container may be the transport package.

“EPA identification number” means the number received by a transporter following application to the administrator of the U.S. Environmental Protection Agency as required by 40 CFR Part 263, July 1, 2004.

Forms 540, 540a, 541, 541a, 542, and 542a are official forms referenced in this appendix. Licensees need not use originals of these forms so long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Form 541 (and 541a) and Form 542 (and 542a) may be completed, transmitted and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

“Generator” means a licensee operating under a Nuclear Regulatory Commission or Agreement State license who (1) is a waste generator as defined in this appendix or (2) is a licensee to whom waste can be attributed (for example, waste generated as a result of decontamination or recycle activities).

“High integrity container” (HIC) means a container commonly designed to meet the applicable Nuclear Regulatory Commission structural stability requirements and to meet U.S. Department of Transportation requirements for a Type A package.

“Land disposal facility” means the same as in Part 14 of these regulations.

“Physical description” means the items called for on Form 541 to describe a low-level radioactive waste.

“Residual waste” means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

“Shipper” means the licensed entity (that is, the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

“Shipping paper” means Form 540 and, if required, Form 540a which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172, October 1, 2003.

“Uniform low-level radioactive waste manifest” or “uniform manifest” means the combination of Nuclear Regulatory Commission Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

“Waste collector” means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

“Waste description” means the physical, chemical and radiological description of a low-level radioactive waste as called for in Form 541.

“Waste generator” means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a “waste generator” if the transfer low-level radioactive waste from the facility is defined as “residual waste”.

“Waste processor” means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to process, repackaging, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

“Waste type” means a waste within a disposal container having a unique physical description (that is, a specific waste descriptor code or description, or a waste sorbed on or solidified in a specifically defined media).

II. **Information requirements**

A. General information. The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;
2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
3. The name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number for the carrier transporting the waste.

B. Shipment information. The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;
2. The total number of packages/disposal containers;
3. The total disposal volume and disposal weight of the shipment;
4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and
 6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.
- C. Disposal container and waste information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:
1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
 2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;
 3. The volume displaced by the disposal container;
 4. The gross weight of the disposal container, including the waste;
 5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
 6. A physical and chemical description of the waste;
 7. The total weight percentage of chelating agent for any waste containing more than 0.1 % chelating agents by weight, plus the identity of the principal chelating agent;
 8. The approximate volume of waste within the container;
 9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;
 10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;
 11. The total radioactivity within each container; and
 12. For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix 4E. Waste not meeting the structural stability requirements of Appendix 4E shall be identified.

D. Uncontaminated waste information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;
2. A physical and chemical description of the waste;
3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 % by weight, plus the identity of the principal chelating agent;
4. For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix 4E; Waste not meeting the structural stability requirements of Appendix 4E shall be identified;
5. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material;
6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-generator disposal container information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. The origin of the low-level radioactive waste resulting from a processor's activities may be attributable to one or more "generators," including "waste generators," as defined in this Part. This section also applies to mixtures of wastes shipped in an uncontaminated form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.
2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container.

For each generator, provide the following:

1. The volume of waste within the container
2. A physical and chemical description of the waste, including the solidification agent, if any;
3. The total weight percentage of chelating agent for any disposal container containing more than 0.1% chelating agents by weight, plus the identity of the principal chelating agent;

4. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix 4E;
5. Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

III. Certification

An authorized representative of the waste generator, collector or processor shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

IV. Control and tracking

A. Any license who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in IV.A.1. through IV.A.9. of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of IV.A.4. through IV.A.9. of this section.

A licensee shall:

1. Prepare all wastes so that the waste is classified according to Section I of Appendix 4E and meets the waste characteristics requirements in Section II of Appendix 4E;
2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I of Appendix 4E;
3. Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix 4E; the program shall include management evaluation of audits;
4. Prepare the uniform manifest as required by this appendix;
5. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:
 - a. Receipt of the manifest precedes the low-level radioactive waste shipment or
 - b. The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;
6. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in Section IV.A.5.;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;
 8. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and
 9. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.
- B. Any waste collector licensee who handles only prepackaged waste shall:
1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;
 2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;
 3. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level radioactive waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
 4. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in Section IV.B.3.;
 5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;
 6. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and
 7. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.
 8. Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.
- C. Any licensed waste processor who treats or repackages wastes shall:
1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;
 2. Prepare a new manifest that meet the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information required in Section II.E of this appendix;

3. Prepare all wastes so that the waste is classified according to Appendix 4E and meets the waste characteristics requirements in Section I of Appendix 4E;
 4. Label each package of waste to identify whether is Class A waste, Class B waste, or Class C waste in accordance with Appendix 4E;
 5. Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix 4E; the program shall include management evaluation of audits;
 6. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:
 - a. Receipt of the manifest precedes the low-level radioactive waste shipment or
 - b. The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;
 7. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in IV.C.6;
 8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;
 9. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and
 10. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.
 11. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.
- D. The land disposal facility operator shall:
1. Acknowledge receipt of the waste within 1 week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the uniform manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;
 2. Maintain copies of all completed manifests and electronically store the information required by Part 14 of these Regulations until license termination;
 3. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

V. **Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section shall:**

- A. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
- B. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation shall file a written report with the Department within 2 weeks of completion of the investigation.
- C. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

APPENDIX E:

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

A. Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

B. Classes of waste.

1. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II.A. If Class A waste also meets the stability requirements set forth in Section II.B. It is not necessary to segregate the waste for disposal.

2. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

C. Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table 4B1, classification shall be determined as follows:

1. If the concentration does not exceed 0.1 times the value in Table 4B1, the waste is Class A.

2. If the concentration exceeds 0.1 times the value in Table 4B1, but does not exceed the value in Table 4B1, the waste is Class C.

3. If the concentration exceeds the value in Table 4B1, the waste is not generally acceptable for land disposal.

4. For wastes containing mixtures of radionuclides listed in Table 4B1, the total concentration shall be determined by the sum of fractions rule described in Section I.G. of this appendix.

TABLE 1

Radionuclide	Concentration
curie/cubic meter ^k (Ci/m ³)	nanocurie/gram ^l (nCi/g)
C-14 in activated metal	80
C-14	8
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
I-129	0.08
Tc-99	3
Alpha-emitting transuranic radionuclides with half-life greater than five years	100
Cm-242	20,000
Ra-226	100
Pu-241	3,500

^k To convert the Ci/m³ values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37.

^l To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

D. Classification determined by short-lived radionuclides.

If the waste does not contain any of the radionuclides listed in Table 4B1, classification shall be determined based on the concentrations shown in Table 4B2. However, as specified in Section I.F. of this appendix, if radioactive waste does not contain any nuclides listed in either Table 4B1 or Table 4B2, it is Class A.

1. If the concentration does not exceed the value in Column 1, the waste is Class A.
2. If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3. If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.
4. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
5. For wastes containing mixtures of the radionuclides listed in Table 4B2, the total concentration shall be determined by the sum of fractions rule described in Section I.G.

TABLE 2

Radionuclide	Concentration, curie/cubic meter*		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
Co-60	700	*	*
Cs-137	1	44	4600
H-3	40	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000

*Department Note: To convert the Ci/m³ value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 4B2 determine the waste to be Class C independent of these radionuclides.

E. Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table 4B1 and some of which are listed in Table 4B2, classification shall be determined as follows:

1. If the concentration of a radionuclide listed in Table 4B1 is less than 0.1 times the value listed in Table 4B1, the class shall be that determined by the concentration of radionuclides listed in Table 4B2.

2. If the concentration of a radionuclide listed in Table 4B1 exceeds 0.1 times the value listed in Table 4B1, but does not exceed the value in Table 4B1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 4B2 does not exceed the value shown in Column 3 of Table 4B2.

F. Classification of wastes with radionuclides other than those listed in Table 4B1 and Table 4B2. If the waste does not contain any radionuclides listed in either Table 4B1 or Table 4B2, it is Class A.

G. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m³ (50 Ci/m³) and Cs-137 in a concentration of 814 GBq/m³ (22 Ci/m³). Since the concentrations both exceed the values in Column 1, Table 4B2, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33, for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

H. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (microcurie) per gram.

II. Radioactive Waste Characteristics

A. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1. Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part 4, the site license conditions shall govern.

2. Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3. Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4. Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 % of the volume.

5. Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6. Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.A.8.

7. Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.
 8. Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20 °C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.
 9. Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.
- B. The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.
1. Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
 2. Notwithstanding the provisions in Section II.A.3. and II.A.4., liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 % of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.
 3. Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling.

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

PART 4, APPENDIX 4F:**QUANTITIES FOR USE WITH DECOMMISSIONING**

<u>Material</u>	<u>Microcurie*</u>
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115	100
Cadmium-115m	10
Calcium-45	10
Calcium-47	10
Carbon-14	100

<u>Material</u>	<u>Microcurie*</u>
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134	1
Cesium-134m	100
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58	10
Cobalt-58m	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (13 yr)	1

<u>Material</u>	<u>Microcurie*</u>
Europium-152 (9.2 h)	100
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115	10
Indium-115m	100
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1

<u>Material</u>	<u>Microcurie*</u>
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197	100
Mercury-197m	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100

<u>Material</u>	<u>Microcurie*</u>
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191	100
Osmium-191m	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193	100
Platinum-193m	100
Platinum-197	100
Platinum-197m	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10

<u>Material</u>	<u>Microcurie*</u>
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Ruthenium-97	100
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10

<u>Material</u>	<u>Microcurie*</u>
Silicon-31	100
Silver-105	10
Silver-111	100
Silver-110m	1
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur -35	100
Tantalum-182	10
Technetium-96	10
Technetium-97	100
Technetium-97m	100
Technetium-99	10
Technetium-99m	100
Tellurium-125m	10
Tellurium-127	100
Tellurium-127m	10

<u>Material</u>	<u>Microcurie*</u>
Tellurium-129	100
Tellurium-129m	10
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)***	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01

<u>Material</u>	<u>Microcurie*</u>
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69	1,000
Zinc-69m	100
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

* To convert μCi to kBq, multiply the μCi value by 37.

** Based on alpha disintegration rate of Th-232. Th-

Material

Microcurie*

230 and their decay products.

*** Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" — that is, unity.



**Colorado Department
of Public Health
and Environment**

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 6: X-RAY IMAGING IN THE HEALING ARTS

Last amended 06/16/10, effective 07/30/2010

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

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STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 6:

X-RAY IMAGING IN THE HEALING ARTS

6.1 Purpose and Scope.

6.1.1 Authority.

6.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

6.1.2 Basis and Purpose.

6.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

6.1.3 Scope.

6.1.3.1 Part 6 establishes requirements, for which a registrant is responsible, for use of x-ray imaging systems by or under the supervision of an individual authorized by and licensed in accordance with State of Colorado statutes to engage in the healing arts.

6.1.4 Applicability

6.1.4.1 The provisions of this part are in addition to, and not in substitution for, other applicable provisions in Part 1, 2, 4, 7, 10 and other parts of these regulations.

6.1.4.2 Part 9 and Part 24 specifically apply to some particular healing arts x-ray imaging registrants.

6.1.4.3 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted.

6.1.5 Published Material Incorporated by Reference.

6.1.5.1 Published material incorporated in Part 6 by reference is available in accord with 1.4.

6.2 Definitions.

As used in Part 6, these terms have the definitions set forth as follows:

“AAPM Online Report 03” means “Assessment of Display Performance for Medical Imaging Systems”, AAPM Online Report No. 03 by Task Group 18 of the American Association of

Physicists in Medicine (April 2003).

“AAPM Report 4” means “Basic Quality Control In Diagnostic Radiology”, AAPM Report No. 4 by the Diagnostic Radiology Committee, Task Force on Quality Assurance Protocol of the American Association of Physicists in Medicine (November 1977).

“AAPM Report 74” means “Quality Control in Diagnostic Radiology”, AAPM Report No. 74 by Task Group 12 of the Diagnostic X-ray Imaging Committee of the American Association of Physicists in Medicine (July 2002).

“AAPM Report 93” means “Acceptance Testing and Quality Control of Photostimulable Storage Phosphor Imaging Systems”, AAPM Report No. 93 by Task Group 10 of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (October 2006).

“AAPM Report 96” means “The Measurement, Reporting, and Management of Radiation Dose in CT”, AAPM Report No. 96 by Task Group 23 (CT Dosimetry) of the Radiography and Fluoroscopy Subcommittee of the Diagnostic Imaging Council CT Committee of the American Association of Physicists in Medicine (January 2008).

“Added filtration” means addition of a filter to the inherent filtration.

“Aluminum equivalent” means the thickness of aluminum (type 1100 alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) affording the same attenuation, under specified conditions, as the material in question.

“Attenuation block” means a block or stack that has a thickness of 3.8 cm, is made of aluminum (type 1100 aluminum alloy with a nominal chemical composition of aluminum 99.00 percent minimum and copper 0.12 percent maximum) or other material(s) having equivalent attenuation, and is large enough to intercept the entire x-ray beam.

“Automatic exposure control” (AEC) means a device that automatically controls settings in order to obtain at the pre-selected location a required quantity of radiation. See also “phototimer”.

“Automatic exposure rate control” (AERC) means a device that automatically controls one or more exposure settings in order to obtain at the pre-selected location(s) a required quantity of radiation per unit time.

“Automatic film processor” means a device that produces an image from a film-screen system in mechanical steps with limited human intervention.

“Barrier”. See “protective barrier”.

“Beam axis” means, for purposes of Part 6, a line from the source through the center of the x-ray field.

“Beam-limiting device” means a device that provides a means to restrict the dimensions of the x-ray field.

“Bone densitometry system” means a device that uses electronically-produced ionizing radiation for the sole or primary purpose of determining the density of bone structures in human patients.

“C-arm x-ray system” means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system or coordinated in order to maintain a desired spatial relationship. This system is designed to allow a change in the

projection of the beam through the patient without a change in the position of the patient.

“Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“Certified component” means an x-ray imaging system component that is subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

“Certified system” means any x-ray system that has any certified component.

“Changeable filters” means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process under operator control.

“Coefficient of variation” (C) means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population

\bar{x} = Mean value of observations in sample

x_i = i^{th} observation in sample

n = Number of observations sampled

“Computed radiography” (CR). See “photostimulable storage phosphor system.”

“Computed tomography” (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

“Contrast-to-noise ratio” (CNR) relates the contrast of an object in an acquired image to the inherent noise in the image.

“Control panel” means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for the operator to manually select exposure settings.

“CT” (see “computed tomography”).

“CT conditions of operation” means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the exposure settings.

“CT gantry” means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

“Dead-man switch” means a switch so constructed that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

“Diagnostic imaging system” (also “diagnostic x-ray imaging system” or “diagnostic x-ray system”) means an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image, with the assembled system designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

“Diagnostic source assembly” means the tube housing assembly with a beam-limiting device attached.

“Digital radiography” means use of an x-ray imaging processing system to produce a radiographic image displayed on a video monitor after mathematical transformation.

“Direct scattered radiation” means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam. See “scattered radiation”.

“Dose profile” means the dose as a function of position along a line.

“Elemental area” means the smallest area within a digitally acquired image for which the x-ray attenuation properties of a body are depicted. See also “picture element”.

“Equipment”. See “x-ray equipment”.

“Established operating level” means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility’s quality assurance program.

“Facility”, for mammography (to supplement the Part 1 meaning of “facility”), means a hospital, outpatient Department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

“Field emission equipment” means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“Filter” means material placed in the useful beam to preferentially absorb selected radiations.

“Floor plan” means, for purposes of Part 6, a plan view of the overall layout to scale of a room or group of rooms, including the location and configuration of any radiation producing machines in each room.

“Fluoroscopic air kerma display device” means a device, subsystem, or component that provides the display of air kerma rate and cumulative air kerma. It includes radiation detectors (if any), electronic and computer components, associated software, and data displays.

“Fluoroscopic imaging assembly” means a subsystem in which x-ray photons produce a set of visible images. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“Fluoroscopic irradiation time” means the cumulative duration during an examination or procedure of operator-enabled x-ray tube activation in any fluoroscopic mode of operation.

“Fluoroscopy” means a technique for generating x-ray images and presenting them

simultaneously and continuously as visible images.

"Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer" (HVL) means the thickness of specified material needed to reduce a radiation beam to one-half of its original intensity. This definition excludes all scattered radiation other than any present initially in the beam.

"Hand-held x-ray equipment". See "x-ray equipment", under "portable x-ray equipment".

"Hard copy processor" means a device that produces a printed image from digital image data.

"Healing arts screening" means, for purposes of these regulations, the exposure of any human being using an x-ray imaging machine for the detection or evaluation of health indications when such a test is not specifically and individually ordered by a licensed physician, chiropractor, dentist or podiatrist legally authorized to prescribe such a test for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds ($kVp \cdot mA \cdot second$).

"HVL". See "half-value layer".

"Image intensifier" means a device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding visible light image and electronically amplifies the brightness of that visible image.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, x-ray image intensifier tube, photostimulable phosphor, or solid-state or gaseous detector, that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

"Image receptor support device" means, for mammographic systems, that part of the system designed to support the image receptor perpendicular to the beam axis during a mammographic examination and also designed to provide a primary protective barrier.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak". See "peak tube potential".

"kV" means kilovolt.

"kVp". See "peak tube potential".

"kWs" means kilowatt-second.

"Last image hold radiograph" (LIH) means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Laterality", in mammography, means the designation of either the left or right breast.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage control settings" means the exposure settings associated with the diagnostic source assembly that are used in measuring leakage radiation, defined as follows:

- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulomb, that is, 10 mAs, or the minimum obtainable from the unit, whichever is larger;
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for that maximum-rated peak tube potential.

"Leakage radiation" means the portion of ionizing radiation originating from the x-ray imaging system that is not part of the useful beam. See "useful beam".

"Light field" means that area of the intersection of the light beam from the beam-limiting device, and one of the set of planes parallel to, and including, the plane of the image receptor, whose perimeter is the locus of points, at which the illumination is one-fourth of the maximum in the intersection.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. Percent line-voltage regulation = $100(V_n - V_l)/V_l$, where V_n = no-load line potential and V_l = load line potential.

"Luminance" means the amount of light that passes through or is emitted from a particular area and falls within a given solid angle.

"Mammogram" means a radiographic image produced through mammography.

"Mammography" means radiography of the breast. See also 6.10.1.1.

"Mammography phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Mammography medical outcomes audit" means a systematic comparison of positive mammogram assessment data to corresponding pathology results.

"Mammography modality" means a technology for radiography of the breast.

“Manual film process” means a way to produce an image that requires human intervention to move the film from developer to fixer to wash.

“Maximum line current” means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

“Mini-c-arm x-ray system” means a system that meets the following criteria:

- (1) Source-image receptor distance less than or equal to 45 cm (18 inches);
- (2) Field of view less than or equal to 15 cm (6 inches);
- (3) Maximum kVp less than or equal to 80 kVp; and
- (4) Maximum mA less than or equal to 0.25 mA.

“Mobile x-ray equipment”. See “x-ray equipment”.

“Mode of operation” means a distinct method of fluoroscopy, mammography, or radiography provided by the manufacturer and selected with a set of several exposure control settings uniquely associated with the mode.

- (1) The set of distinct settings for the mode may be selected by the operation of a single control.
- (2) Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, mammography and photospot recording.
- (3) In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

“NCRP Report 147” means National Council on Radiation Protection and Measurements Report No. 147, “Structural Shielding Design For Medical Imaging Facilities” (November 2004).

“Noise” means the fluctuation of a signal within a measured region of interest, for example, as a result of statistical fluctuation of the signal and electronic noise in the detector.

“Optical Density” (OD) equals $\log(1/\text{transmittance})$, where the transmittance of the film is the fraction of incident light transmitted by the film.

“Patient” means a human being or an animal to whom radioactive materials or machine-produced radiation is delivered for healing arts examination, diagnosis, or treatment. In addition, for mammography, patient means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“PBL”. See “positive beam limitation”.

“Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.

“Photostimulable storage phosphor imaging” (PSP) means an x-ray image processing system that employs reusable imaging plates and associated hardware and software to acquire and display digital projection radiographs.

“Phototimer” means a method for controlling radiation exposure to image receptors by the amount of radiation that reaches radiation monitoring device(s) as part of an electronic circuit that controls the duration of time the tube is activated. See “automatic exposure control”.

“Picture element” (pixel) means an elemental area of a digitally acquired image.

“PID”. See “position indicating device”.

“Pixel”. See “picture element”.

“Portable x-ray equipment”. See “x-ray equipment”.

“Position indicating device” (PID) means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance, without regard to whether the device incorporates or serves as a beam-limiting device.

“Positive beam limitation” (PBL) means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

“Primary protective barrier” means the material, excluding filters, placed to attenuate the useful beam for radiation protection purposes.

“Protective apron” means a garment made of radiation-absorbing materials used to reduce radiation exposure to the torso of the wearer.

“Protective barrier” means a barrier of radiation absorbing material(s) used to reduce radiation exposure. See “primary protective barrier” and “secondary protective barrier”.

“Protective glove” means a glove made of radiation-absorbing materials used to reduce radiation exposure to the wearer.

“Pulsed mode” means operation of a fluoroscopic x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

“Radiation therapy simulation system” means a radiographic/fluoroscopic x-ray system or a computed tomography system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“Radiograph” means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

“Radiographic imaging system” means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

“Radiography” means a technique for generating and recording an x-ray pattern for the purpose of providing the user with the image(s) after termination of the exposure.

“Rating” means the operating limits specified by the manufacturer.

"Recording" means producing a retrievable form of an image resulting from x-ray photons.

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. See "direct scattered radiation".

"Secondary protective barrier" means a barrier sufficient to attenuate scattered and leakage radiation for radiation protection purposes.

"Shutter" means a device attached to the tube housing assembly that can intercept the entire cross sectional area of the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

"SID". See "source-image receptor distance".

"Signal-to-noise ratio" (SNR) means the magnitude of the signal of interest compared to the magnitude of the noise of the background of that signal.

"Solid state x-ray imaging device" means an assembly that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device.

"Source", for an x-ray machine, means the focal spot of the x-ray tube.

"Source-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.

"Source-skin distance" (SSD) means the distance between the source and the skin of the patient.

"Spot check" means a procedure that is performed to assure that a previous calibration continues to be valid.

"Spot image" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot-image device" means a device intended to transport and/or position a radiographic image receptor (for example, a film-screen cassette or a CR cassette) between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

"SSD". See "source-skin distance".

"Standard breast" means a 4.2-cm-thick compressed breast consisting of fifty (50) percent glandular and fifty (50) percent adipose tissue.

“Stationary x-ray equipment”. See “x-ray equipment”.

“Stray radiation” means the sum of leakage and scattered radiation.

“Technique factor” means an exposure control setting that specifies the peak tube potential in kV and

- (1) Either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs; or
- (2) For capacitor energy storage equipment, quantity of charge in mAs; or
- (3) For field emission equipment rated for pulsed operation, number of x-ray pulses; or
- (4) For CT systems, either:
 - (a) Tube current in mA and scan time in seconds; or
 - (b) The product of tube current and rotation time in mAs, as modified to account for helical pitch.

“Termination of irradiation” means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“Tomogram” means the depiction of the x-ray attenuation properties of a section through the body.

“Tomographic plane” means that geometric plane that is identified as corresponding to the output tomogram.

“Tomographic section” means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

“Tomosynthesis” means to mathematically reconstruct a planar image using views acquired from multiple x-ray beam projection angles.

“Tube” means an x-ray tube, unless otherwise specified.

“Tube housing assembly” means the tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

“Tube rating chart” means the set of curves that specify the rated limits of operation of the tube in terms of the exposure settings. These curves are typically displayed on a graph.

“Useful beam” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

“Variable-aperture beam-limiting device” means a beam-limiting device that has capacity for stepless adjustment of the x-ray field size at a given SID.

“Visible area” means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

“Volumetric dental imaging system” means an x-ray machine that produces, for oral and maxillofacial structures, a three-dimensional tomographic data set or a time sequence of three-dimensional tomographic data sets. A dental x-ray machine only capable of producing a two-dimensional image is not considered to be a volumetric dental imaging system.

“Wedge filter” means a filter that effects continuous change in transmission over all or a part of the useful beam.

“X-ray exposure control” means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

“X-ray equipment” means an x-ray system, subsystem, or component thereof.

- (1) “Mobile or portable x-ray equipment” means x-ray equipment that is designed to be transported from place to place.
 - (a) Mobile x-ray equipment is often mounted in a vehicle or on a permanent base with wheels and/or casters for moving while completely assembled.
 - (b) Portable x-ray equipment includes x-ray equipment that is designed to be hand-carried and hand-held during use.
- (2) “Stationary x-ray equipment” means x-ray equipment that is installed in a fixed location.

“X-ray field” means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the air kerma rate is one-fourth of the maximum in the intersection.

“X-ray high-voltage generator” means a device that transforms electrical energy from the potential supplied by the x-ray exposure control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other elements.

“X-ray image processing system” means an assemblage of components for creating a visible or viewable image.

“X-ray imaging subsystem” means any combination of two or more components of an x-ray imaging system.

“X-ray imaging system” or “x-ray system” means an assemblage of components for the controlled production of x-rays.

- (1) At a minimum, an x-ray imaging system includes an x-ray high-voltage generator, an x-ray exposure control, a tube housing assembly, a beam-limiting device, and necessary supporting structures.
- (2) Additional components such as the image receptor(s) that function with the system are considered integral parts of the system.

“X-ray table” means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or above table fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image

receptor, or spot-film device beneath the tabletop.

"X-ray tube" means any electron tube that is designed to be used primarily for the production of x-rays.

"X-ray system". See "x-ray imaging system".

GENERAL REGULATORY PROVISIONS

6.3 General Requirements.

6.3.1 Administrative Controls.

- 6.3.1.1 Each radiation machine used in the healing arts in the State of Colorado shall be registered with the Department as required by 2.4 and inspected as prescribed in 2.5.
- 6.3.1.2 Each radiation machine used on humans shall meet the Federal Performance Standards, Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33 (July 1, 2009).
 - (1) X-ray imaging systems and their associated components certified pursuant to 21 CFR 1020.30 through 1020.33 (July 1, 2009) shall be maintained in compliance with applicable requirements of 21 CFR 1020.30 through 1020.33 (July 1, 2009).
 - (2) Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 shall not be modified such that the component or system fails to comply with any applicable requirement of 21 CFR Part 1020 or Part 6.
 - (3) The owner shall keep a record of the date, service provider and details of each component or system modification.
 - (4) Limited exemption from this requirement may be granted by the Department for a radiation machine manufactured prior to August 4, 1974, provided the registrant demonstrates that such exemption will not result in undue risk.
- 6.3.1.3 The registrant shall direct operation of the x-ray imaging system(s) under the registrant's administrative control.
- 6.3.1.4 The registrant or the registrant's agent shall assure that all applicable requirements of Parts 1, 2, 4, 6 and 10 are met in the operation of the x-ray imaging system(s).
- 6.3.1.5 The registrant or the registrant's agent shall use approved providers of services, consistent with 2.6.1, including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.
- 6.3.1.6 An x-ray imaging system that continues to be in noncompliance with a requirement of these regulations shall not be used for any purpose unless such use or operation is explicitly authorized by the Department, for example, by correction in accordance with 2.6.3 and/or Form 59-1.
- 6.3.1.7 An x-ray imaging system that is determined as provided in Appendix 6D to be unsafe for human use shall not be operated for diagnostic or therapeutic purposes.
- 6.3.1.8 Use of a radiation machine in the healing arts shall be by or under the general

supervision of a physician, chiropractor, dentist, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.

6.3.1.9 Adequate Radiation Safety Training and Experience for a Radiation Machine Operator.

- (1) Each individual who will be operating an x-ray imaging system shall:
 - (a) Be adequately instructed in the safe operating procedures;
 - (b) Be competent in the safe use of the equipment; and
 - (c) Meet each applicable registration requirement of 2.6.1.

6.3.1.10 If radioactive materials are also present at the facility, the facility registrant shall coordinate, as appropriate, requirements under Part 6 with any related requirement of the license.

6.3.2 General Specifications for Facility and Equipment Design, Configuration and Preparation.

6.3.2.1 Evaluation of Shielding Design Prior to Commencement of Operation.

- (1) The floor plan and equipment configuration of a radiation machine facility shall be designed to meet all applicable requirements of these regulations and in particular to preclude an individual from receiving a dose in excess of the limits in 4.6, 4.12, 4.13, 4.14 and 4.15.
- (2) The floor plan and equipment configuration of each radiation machine facility shall be submitted to a qualified expert for determination of shielding requirements in accordance with Appendices 6A, 6B and 6C.
- (3) The qualified expert shielding design required by 6.3.2.1(2) shall be completed prior to:
 - (a) Construction of a new facility;
 - (b) Any renovation or modification of an existing facility that has a potential to reduce the effectiveness of existing shielding from x-ray radiation; or
 - (c) Installation of a new radiation machine in an existing facility.
- (4) A qualified expert who completes the shielding design required by 6.3.2.1(2) shall provide the shielding design to the facility registrant, including the annotated dimensional drawing specified by 6.3.2.3.
- (5) The facility registrant shall construct the shielding and configure the equipment in accordance with the recommendation(s) provided by the qualified expert pursuant to 6.3.2.1(4).

6.3.2.2 Evaluation of Shielding Design After Commencement of Operations.

- (1) A qualified expert shall review and modify shielding design, consistent with 6.3.2.1 and Appendices 6A, 6B and 6C, whenever:
 - (a) A certification evaluation or a survey during operation shows that a dose in excess of a limit in Part 4 is possible;

- (b) An existing facility is to be modified such that the existing shielding might be inadequate;
 - (c) The primary beam orientation is changed;
 - (d) The primary shielding is altered due to the modification or renovation of a facility;
 - (e) Mobile or non-handheld portable x-ray equipment is used regularly in the same location;
 - (f) Radiation machine workload (for example, mA-minute-per-week workload) has increased or is projected to increase above that which was the basis for the original shielding design; or
 - (g) The registrant is unable to produce for inspection a written shielding design completed in accordance with 6.3.2.1 and/or 6.3.2.2.
- (2) If qualified expert analysis of operating conditions required by 6.3.2.2(1) indicates that an individual might receive a dose in excess of the limits in 4.6, 4.12, 4.13, 4.14 or 4.15, then the facility registrant shall modify the shielding and/or equipment configuration in accordance with the recommendation(s) of the qualified expert.

6.3.2.3 The registrant shall retain, for each room in which a stationary x-ray imaging system is located, a current dimensional drawing that includes indication of the:

- (1) Use of each area adjacent to the room and an estimation of the extent of occupancy in each such area; and
- (2) Results by a qualified expert from calculation(s) for the type and thickness of material(s) in each protective barrier (for example, lead equivalency):
 - (a) After installation and, if possible, prior to commencement of operation, consistent with 6.3.2.1; and
 - (b) Whenever shielding is modified, consistent with 6.3.2.2; and/or
- (3) If the registrant is unable to produce for inspection the calculation(s) required by 6.3.2.3(2), results from survey(s) conducted by a qualified expert to determine radiation levels present under specified test conditions at the operator's position and at cognizable points outside the room.

6.3.2.4 A facility area is exempt from the requirements of 6.3.2.1 (and consequently exempt from 6.3.2.2 and 6.3.2.3) if:

- (1) Only dental intraoral, dental panoramic, mini-c-arm or bone densitometry equipment is used in the area;
- (2) Mobile or portable x-ray equipment is used infrequently not routinely in the same location; or
- (3) Exemption for a particular area or location has been applied for in writing and granted by the Department.

6.3.2.5 The registrant shall maintain for inspection, for each x-ray imaging system, the model and serial number of each tube housing assembly and control panel:

- (1) One unique identification number that designates the entire radiation machine shall be permanently assigned by the facility registrant to each radiation machine and provided in all correspondence with the Department.
 - (a) If feasible, the identification number shall be the "control serial number" in Item 4 on FDA Form 2579, or equivalent.
- (2) If available, the serial number(s) from the manufacturer shall be clearly visible as a label or stencil on the control panel and on the tube housing assembly.
 - (a) Each serial number shall be the same as the corresponding number found on FDA Form 2579, unless prior written approval is obtained from the Department.
- (3) If either the control panel or the tube housing assembly serial number from the manufacturer is used as the one unique identification number that designates the entire radiation machine, and then subsequently the designated control panel or the tube housing assembly is replaced, the registrant shall assign a new unique identification number for the entire radiation machine and immediately provide that new number to the Department.

6.3.2.6 The registrant shall maintain for inspection, for each x-ray imaging system for which a shielding design is required:

- (1) The installation as-built drawing(s); and
- (2) The signed statement required by 2.7.1.1 (without exception after June 30, 2010) and retained in accord with 2.4.1.1(4), that all floor plan and equipment configuration specifications in any applicable written shielding designs required by 6.3.2 were explicitly followed.

6.3.3 General Radiation Safety and Control of Radiation Exposure.

6.3.3.1 Written safety procedures shall be developed and provided for safe operation of each x-ray imaging system.

- (1) The written safety procedures shall be readily available to each individual radiation machine operator prior to operating x-ray imaging equipment.
- (2) The operator shall be able to demonstrate familiarity with the procedures applicable to safe use of the system being operated.
- (3) The procedures shall include:
 - (a) Any restriction on technique particular to the system, consistent with 6.3.3.2;
 - (b) Limitation on beam size, to the smallest area that is clinically necessary, including appropriate collimation:
 - (i) For each tube with variable collimation, the collimation procedure shall specify whether positive beam limitation (PBL) or manual

collimation shall be used; and

- (ii) For tubes collimated manually, all images shall provide a positive indication of collimation, except as provided by 6.10.2.3 or when diagnosis might be compromised;

- (c) Patient holding instructions consistent with 6.3.3.8.

6.3.3.2 To reduce radiation exposure to the minimum that is necessary, the registrant shall maintain a documented protocol for technique selection for each type of examination performed by each x-ray imaging system.

- (1) A chart based on the protocol(s) shall be located near each system's control panel.
 - (a) The chart shall state the exposure settings to be used corresponding to the patient's body part and anatomical size, or body part thickness, or age (for pediatrics), including but not limited to:
 - (i) Type of image receptor to be used;
 - (ii) Type and focal distance of the grid to be used, if any and if variable;
 - (iii) Source to image receptor distance to be used, except for intraoral radiography in accordance with 6.7.2.2(1);
 - (iv) kVp;
 - (v) Mode of operation; and
 - (vi) mAs, if manual mode is used; and
 - (b) Type and location of placement of patient shielding (for example, gonad or thyroid shielding) to be used.
- (2) The requirement of 6.3.3.2(1)(a) is considered met if anatomically programmable controls are used.
- (3) For computed and digital radiography, the chart required by 6.3.3.2(1) shall:
 - (a) Portray how to determine applicable exposure settings in accord with documented protocol;
 - (b) Specify a control range for the exposure indicator in accordance with the manufacturer's recommendation; and
 - (c) Specify pediatric protocol for each unit that images pediatric patients.
- (4) The settings to be used during an exposure shall be indicated before the exposure begins.
 - (a) If automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.

- (b) The requirement of 6.3.3.2(4) may be met by permanent markings on equipment having fixed exposure settings.
 - (5) The chart shall be revised as necessary whenever a certified component is replaced or added.
- 6.3.3.3 Exposure under Part 6 of any human being to the useful beam shall be solely for healing arts purposes and only after such exposure has been authorized by a physician, chiropractor, dentist, or podiatrist who has a current active State of Colorado license and has met all applicable requirements of Part 2.
- (1) Deliberate exposure of an human being for training, demonstration or other non-healing-arts purposes is strictly prohibited; and
 - (2) Authorization for healing arts screening may be granted by the Department provided the registrant demonstrates that such healing arts screening will not result in undue risk.
 - (a) Each healing arts screening program shall obtain prior written approval by the Department.
 - (b) Each applicant for Department approval of a healing arts screening program shall submit to the Department a completed Form R-300, "Application for Registration – Healing Arts Screening," including as provided in 2.4.1.2 all of the information required by Appendix 6F and/or by Form R-300 and any accompanying instructions, together with the required fee(s).
 - (c) The Department shall be notified immediately if any information submitted to the Department becomes invalid or outdated.
 - (3) FDA/MQSA-certified facilities that are registered with the Department for the use of dedicated mammographic equipment for mammography screening are approved for mammography screening only and are considered to have met 6.3.3.3(2).
- 6.3.3.4 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic or fluoroscopic exposure.
- 6.3.3.5 Each facility shall have protective aprons and gloves available in sufficient numbers to provide protection to all individuals who are involved with x-ray operations and who are otherwise not shielded.
- 6.3.3.6 To reduce direct radiation exposure, individual shielding shall be provided for all modalities (except for a case in which shielding would interfere with the gonad, thyroid, dental or other diagnostic procedure).
- (1) For a human patient who has not passed beyond the reproductive age, during radiographic procedures in which the gonads are in the useful beam, gonad shielding of not less than 0.5 millimeter lead equivalent shall be used.
 - (2) For a human patient during all radiographic procedures in which the thyroid is in the useful beam, thyroid shielding of not less than 0.25 millimeter lead equivalent shall be used.

- (3) In a case where the patient must hold the image receptor (except during an intraoral dental examination), any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
- (4) Each individual other than the patient being examined shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent.

6.3.3.7 To reduce scatter radiation exposure, individual shielding shall be provided as follows:

- (1) The operator, other staff and ancillary personnel, and each other individual required for the medical procedure or who cannot be removed from the room, shall be protected from direct scatter radiation:
 - (a) By a protective apron or whole body protective barrier of not less than 0.25 millimeter lead equivalent; and/or
 - (b) Shall be so positioned that the nearest portion of the body is at least a distance of 2 meters (more than 6 feet) from the:
 - (i) Tube head; and
 - (ii) Nearest edge of the image receptor; and
 - (iii) Patient;
 - (c) Except that protective positioning shall be as determined by the operator of a mini-c-arm x-ray system or a portable hand-held x-ray device (as provided in Appendix 6E).

6.3.3.8 When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

- (1) Mechanical holding devices shall be used when the technique permits; and
- (2) The written safety procedures required by 6.3.3.1 shall:
 - (a) Indicate the requirements for selecting a holder and the procedure the holder shall follow; and
 - (b) Expressly limit routine use of personnel who are subject to the occupational dose limits in 4.6 for holding a patient solely to immobilize the patient during radiographic examinations; and
- (3) The human holder shall be instructed in personal radiation safety and protected as required by 6.3.3;
- (4) No individual shall be used routinely to hold image receptors or patients.

6.3.3.9 Image processing procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

- (1) The speed of film, or film-screen combination, imaging plate or receptor and

image processing, shall be the fastest speed or speed equivalent consistent with the diagnostic objective of the examinations.

- (2) X-ray systems subject to 6.6 shall not be utilized in procedures where the source to patient distance is less than 30 cm, except for veterinary systems.
- (3) If anti-scatter grids are used between the patient and the image receptor to decrease scattered radiation to the film and improve contrast, the grid shall be:
 - (a) Positioned properly, with the tube side facing the correct direction, and centered to the central ray; and
 - (b) Of the proper focal distance for the SID being used.

6.3.3.10 Each individual who is associated with the operation of an x-ray imaging system shall meet the requirements of 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18.

- (1) When personnel dosimetric monitoring devices are required, they shall be worn in accordance with 4.6.3.
- (2) Each operator of portable hand-held x-ray equipment shall wear whole body and extremity personnel dosimetric monitoring devices.
- (3) Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is strictly prohibited.

6.3.4 Measurements, Maintenance, and Records.

- 6.3.4.1 The registrant shall maintain for inspection by the Department records for the previous three (3) years of survey measurements, calibrations, maintenance, modifications, certification evaluations pursuant to 2.5, Department Forms 59-1 and 59-2, and corrective actions for each x-ray imaging system with the names of persons who performed such services.
- 6.3.4.2 The registrant shall retain a dimensional drawing and accompanying calculation(s) and/or survey(s) as provided in 6.3.2.3 for each room in which a stationary x-ray system is located, except as exempted under 6.3.2.4.
- 6.3.4.3 Consistent with 2.4.1 and 6.3.2, the registrant shall retain on file at the facility for the life of the facility each shielding design along with installer as-built drawings.
- 6.3.4.4 Each facility shall have available a printed or electronic record containing each patient's name, the type of examination(s), and the date(s) the examination(s) were performed.

6.3.5 Quality Assurance (QA) Program.

- 6.3.5.1 To avoid unnecessary or duplicative radiation exposures, each human use facility shall have an active image processing quality control and quality assurance (QA) program that follows manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine.
- 6.3.5.2 Each registrant that uses a hard copy imaging system with transmission viewing, whether with or without liquid chemistry, shall document that quality control and quality assurance have been performed according to specifications of the manufacturer or a registered

medical physicist and/or a nationally recognized organization, including:

- (1) Periodic printing of a sensitometric strip or pattern;
- (2) Documentation of low, medium and high density calibration and that any calibration which failed to meet a manufacturer's specification was corrected before the image printer was used to print another image; and
- (3) Annual review of all quality control tests.

6.3.5.3 Each registrant that uses an automatic film processor shall adopt an acceptable sensitometric quality control program.

- (1) Film processors used to develop radiographs shall be adjusted and maintained to meet the technical development specifications for the radiography film in use.
- (2) For all x-ray imaging systems, a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast and fog, shall be performed according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization.

6.3.5.4 Each registrant that uses a manual film process shall:

- (1) Follow applicable manufacturer's development time and temperature specifications, which shall be available for review;
- (2) Measure and log development temperature each day of use; and
- (3) Document in a written log the change of developer chemicals at least every month.

6.3.5.5 The registrant shall control darkroom lighting such that:

- (1) Exposure of a film to the darkroom safelight for one minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.
- (2) If used, daylight film handling boxes preclude fogging of the film.
- (3) The base plus fog of an unexposed film does not exceed 0.25 optical density units when developed by the routine procedure used by the facility.

6.3.5.6 All film storage, including pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

6.3.5.7 The registrant shall ensure that each monitor used for primary image interpretation is evaluated according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in AAPM Online Report OR-03 (April 2005), including but not limited to:

- (1) Frequent careful cleaning of each primary image interpretation workstation and data acquisition workstation monitor;

- (2) Periodic visual assessment of Society of Motion Picture and Television Engineers (SMPTE) Pattern or equivalent test pattern;
 - (3) Initial and annual verification that monitor calibration conforms with the DICOM Part 14 Grayscale Standard Display Function (see AAPM Online Report OR-03), or equivalent:
 - (a) Visualization of low contrast patches;
 - (b) Visualization of spatial resolution targets;
 - (c) Measurement of ambient light levels;
 - (d) Measurement of the luminance from a sufficient number of driving levels;
 - (e) Measurements to assure that the luminance for multiple monitors are within 5% of each other when more than one monitor is being utilized at a primary image interpretation workstation.
- 6.3.5.8 The registrant shall ensure that computed and digital radiography cassettes and cassette readers used for primary image interpretation are evaluated periodically according to specifications of the manufacturer and/or a registered medical physicist and/or a nationally recognized organization, for example, in AAPM Report 93, in a program reviewed annually by a registered medical physicist.
- 6.3.5.9 Special requirement for viewboxes and lighting in mammography.
- (1) A viewbox used for clinical quality review and interpreting mammograms shall be capable of producing a luminance of at least 3,000 candela per square meter ($\text{cd}\cdot\text{m}^{-2}$).
 - (2) The registrant shall make special lights for film illumination (that is, hot lights), capable of producing light levels greater than that provided by the view box, available to the interpreting physician.

6.4 Requirements for Safe Use of a Diagnostic X-ray Imaging System of Any Kind.

- 6.4.1 Administrative Controls.
- 6.4.1.1 In addition to the general requirements of 6.3, the requirements of 6.4 apply to all diagnostic x-ray imaging equipment and associated facilities, except as provided by 6.7.5.1 for dental uses and 6.8.5.1 for veterinary uses.
- 6.4.1.2 Each individual who operates an x-ray imaging system used on living humans shall meet the applicable radiation safety training and experience requirements of 2.6.1.
- 6.4.2 Each diagnostic x-ray imaging system shall meet the following equipment design and configuration requirements.

6.4.2.1 Warning Label.

- (1) The control panel containing the main power switch shall bear this or an equivalent warning statement, legible and accessible to view:
- “WARNING: This x-ray unit may be dangerous to patient and operator unless

safe exposure factors and operating instructions are observed."

6.4.2.2 Battery Charge Indicator.

- (1) On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6.4.2.3 Leakage Radiation from the Diagnostic Source Assembly.

- (1) The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 mGy (100 mR) in any 1 hour when the x-ray tube is operated at its leakage exposure settings.
- (2) Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6.4.2.4 Radiation from Components Other Than the Diagnostic Source Assembly.

- (1) The radiation emitted by a component other than the diagnostic source assembly shall not exceed 18 μ Gy (2 mR) in any one hour at 5 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) of the component when it is operated in an assembled x-ray system under any conditions for which it was designed.
- (2) Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6.4.2.5 Beam Quality: Half-value Layer

- (1) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 6-1.

Table 6-1

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Dental X-ray Systems With Intraoral Image Receptors	All X-ray Systems Other Than Dental X-ray Systems	
		Made On, Before, or After December 1, 1980	Made Before June 10, 2006	Made On or After June 10, 2006
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3

	60	1.5		1.3	1.5
	70	1.5	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.1	2.5
	80	2.3	2.3	2.3	2.9
	90	2.5	2.5	2.5	3.2
	100	2.7	2.7	2.7	3.6
	110	3.0	3.0	3.0	3.9
	120	3.2	3.2	3.2	4.3
	130	3.5	3.5	3.5	4.7
	140	3.8	3.8	3.8	5.0
	150	4.1	4.1	4.1	5.4

- (2) If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 6-1, linear interpolation or extrapolation is acceptable.

6.4.2.6 Beam Quality: Additional Special Requirements.

- (1) Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 mm aluminum equivalent filtration permanently installed in the useful beam.
- (2) For capacitor energy storage equipment, compliance with the requirements of 6.4.2.5 shall be determined with the system fully charged and for the highest clinically used mAs.
- (3) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials that are always present between the source and the patient.
- (4) For x-ray systems that have variable kVp and variable filtration for the useful beam, a filtration control device shall:
 - (a) Link the kVp selector with the filter(s); and
 - (b) Prevent an exposure unless the minimum amount of filtration required by 6.4.2.5 is in the useful beam for the given kVp that has been selected.

6.4.2.7 Tube Heads.

- (1) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

- (2) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure.
 - (a) This indication shall be both on the x-ray control and at or near the tube housing assembly that has been selected.
- (3) Any information displayed at the tube head shall meet manufacturer's specifications.

6.4.2.8 Locks.

- (1) All position locking, holding, and centering devices on the x-ray system and/or components shall function as designed.

6.4.2.9 The x-ray control shall provide:

- (1) Visual indication observable at or from the operator's protected position whenever x-rays are produced; and
- (2) A signal audible to the operator to indicate that the exposure has terminated.

6.5 Special Requirements for Safe Use of Fluoroscopy Systems.

6.5.1 Administrative Controls.

6.5.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.5 apply to all fluoroscopic x-ray imaging equipment and facilities.

6.5.1.2 Supervision and use of a fluoroscopic x-ray system for the purpose of localization to obtain images for diagnostic purposes shall be by an individual who has adequate radiation safety training and experience.

- (1) A physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts shall directly supervise use of a fluoroscopic x-ray system.
- (2) Training and experience shall be as provided in 2.6.1, in particular 2.6.1.5 and any applicable appendix to Part 2, and 6.3.1.9.
- (3) Interpretation of both real-time and stored fluoroscopic images shall be by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.

6.5.2 Each fluoroscopic x-ray system shall meet the following equipment design and configuration requirements.

6.5.2.1 Only image-intensified or direct-digital-receptor fluoroscopic equipment shall be used.

6.5.2.2 Limitation of the Useful Beam.

- (1) Primary Protective Barrier to Limit the Useful Beam.
 - (a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful

beam at any SID.

- (b) The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.
- (2) Limitation of the X-ray Field.
 - (a) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following apply:
 - (i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID.
 - (ii) The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
 - (iii) The error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.
- (3) To permit further limitation of the x-ray field, the following specifications shall also be met.
 - (a) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the x-ray field.
 - (b) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less.
 - (c) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 cm by 5 cm or less.
 - (d) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable:
 - (i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
 - (ii) The entire cross section of the useful beam shall be intercepted by the primary protective barrier at any SID.
 - (e) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
 - (i) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.

- (ii) For collimating systems that are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the video monitor image yielding the smallest dimension in each direction.

(4) Additional X-ray Field Specifications for Spot-film Devices:

- (a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor that has been selected on the spot film selector.
 - (i) Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the image receptor is smaller than that of the selected portion of the image receptor.
 - (ii) If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.
- (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three (3) percent of the SID when adjusted for full coverage of the selected portion of the image receptor.
 - (i) The sum, without regard to sign, of the length and width differences shall not exceed four (4) percent of the SID.
- (c) It shall be possible to adjust the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor.
 - (i) The minimum field size at the greatest SID shall be equal to, or less than, 5 cm by 5 cm, or 125 cm² for a fixed SID.
- (d) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two (2) percent of the SID.
- (e) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(5) Override.

- (a) If a means exists to override any of the automatic x-ray field size adjustments required in 6.5.2.2, that means shall:
 - (i) Be designed for use only in the event of system failure and not as a substitute for prompt repair;

- (ii) Incorporate a signal visible at the operator's position that will indicate whenever the automatic field size adjustment is overridden; and
- (iii) Be clearly and durably labeled as follows:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

6.5.2.3 Activation of the Fluoroscopic Tube.

- (1) X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of any exposure.
- (2) When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6.5.2.4 Fluoroscopic Timer for Units Made Before June 10, 2006.

- (1) Means shall be provided to preset the cumulative irradiation time of the fluoroscopic x-ray tube.
- (2) The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.
- (3) A signal audible to the operator shall indicate the completion of any preset cumulative irradiation time and shall continue to sound while x-rays are produced until the timing device is reset.
- (4) Fluoroscopic equipment may be modified in accordance with 1020.30(q) to comply with the requirements of 1020.32(h)(2), and, if modified, shall bear a label indicating the statement: "Modified to comply with 21 CFR 1020.32(h)(2)."

6.5.2.5 For x-ray controls manufactured on or after June 10, 2006, each fluoroscopic tube shall be provided with both a display and audible signal.

- (1) The display, which shall show the fluoroscopic irradiation time in minutes and tenths of minutes at the fluoroscopist's working position independently of the audible signal required by 6.5.2.5(2), shall:
 - (a) Display continuously when the x-ray tube is activated and be updated at least once every 6 seconds (0.1 minute);
 - (b) Display within 6 seconds (0.1 minute) of termination of an exposure and remain displayed until reset; and
 - (c) Be provided with means to reset the display to zero prior to the beginning of a new examination or procedure.
- (2) A signal audible to the fluoroscopist shall sound:
 - (a) For each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure; and
 - (b) Until manually reset or, if automatically reset, for at least 2 seconds.

6.5.2.6 Indication of potential and current is required.

- (1) During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

6.5.2.7 Last-Image-Hold (LIH) display.

- (1) For an LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.
- (2) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the exposure settings for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.
- (3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.
- (4) The predetermined or selectable options for producing the LIH radiograph shall include a description of any exposure settings applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

6.5.2.8 The following requirements apply to displays of the values of AKR and cumulative air kerma for each x-ray tube used during an examination or procedure:

- (1) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma.
- (2) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.
- (3) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.
- (4) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.
- (5) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users as required by 2.7.1.3.
 - (a) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in 6.5.4.1 (1), 6.5.4.1 (2), or 6.5.4.1 (4) for measuring compliance with air-kerma rate limits.

- (b) For c-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.
- (6) Consistent with 6.5.2.8(1), a method shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.
- (7) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/-35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.
- (8) AKR and air kerma display calibration shall be verified annually by a registered medical physicist.

6.5.2.9 Spot Imager Exposure Reproducibility.

- (1) Fluoroscopic systems equipped with spot image mode shall meet the following exposure reproducibility requirements when operating in the spot image mode:
 - (a) When all exposure settings are held constant, including control panel selections associated with an automatic exposure control system, the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.

6.5.2.10 Barrier Transmitted Radiation Rate Limits.

- (1) The AKR due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.334×10^{-6} of the entrance AKR (one-third of one millionth of the entrance AKR) at 10 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) of the fluoroscopic imaging assembly beyond the plane of the image.

6.5.3 Radiation Exposure Control Devices And Operation.

6.5.3.1 Air Kerma Rate (AKR) Limits for Fluoroscopic Equipment Manufactured Before May 19, 1995.

- (1) Equipment without AERC is not permitted.
- (2) Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4:
 - (a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or
 - (b) Except when an optional high-level control is provided.

- (i) Unless the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 44 mGy per minute (5 R/min) at the point where the center of the useful beam enters the patient.
 - (ii) Special means of activation of high-level controls shall be operable only when continuous manual activation is provided by the operator.
 - (iii) A continuous signal audible to the operator shall indicate that the high-level control is being employed.
- (3) Fluoroscopic equipment that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4:
- (a) Except during recording of fluoroscopic images when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts; or
 - (b) Except when the mode or modes have an optional high-level control.
 - (i) Unless the high-level control is activated, that mode or modes shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 6.5.3.1(1)(a), 6.5.3.1(2)(a), or 6.5.3.1(3)(a) as measured per 6.5.4.
 - (ii) Special means of activation of high-level controls shall be required.
 - (iii) The high-level control shall be operable only when continuous manual activation is provided by the operator.
 - (iv) A continuous signal audible to the operator shall indicate that the high-level is being employed.
- (4) Fluoroscopic units that have the high-level control activated and an entrance AKR exceeding 0.1 Gy per minute (11 R/min) shall be posted with the measured maximum AKR, on a sign that:
- (a) Is visible at the operator's position;
 - (b) States that "The system may exceed an entrance AKR exceeding 0.1 Gy per minute (more than 10 R/min)".

6.5.3.2 Entrance AKR Limits For Fluoroscopic Equipment Manufactured on and after May 19, 1995.

- (1) Fluoroscopic equipment operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC.

- (a) Manual selection of exposure settings may also be provided.
- (2) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min) measured per 6.5.4.
- (3) For equipment manufactured prior to June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode when the recorded images are intended for subsequent interpretation by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.
- (4) For equipment manufactured on or after June 10, 2006, exception to 6.5.3.2(2) is allowed during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure.
 - (a) Such recording does not include images resulting from a last-image-hold feature that are not recorded.
- (5) Exception to 6.5.3.2(2) is allowed when the high-level control is activated.
 - (a) The equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 176 mGy per minute (20 R/min) at the point where the center of the useful beam enters the patient.
 - (b) Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.
 - (c) A continuous signal audible to the operator shall indicate that the high-level control is being employed.

6.5.3.3 A mini-c-arm x-ray system shall have an exposure rate less than or equal to 88 mGy (10 R) per minute at the exit port.

6.5.3.4 Control of Scattered Radiation.

- (1) Conventional fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table.
 - (a) The attenuation required shall be not less than 0.25 millimeter lead equivalent.
- (2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities or head, shall be exposed to unattenuated scattered radiation unless that individual:
 - (a) Is at least 2m (more than 6 feet) from the center of the useful beam, or
 - (b) The radiation has passed through not less than 0.25 millimeter lead

equivalent material including, but not limited to, drapes, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 6.3.3.5.

- (3) Exception to 6.5.3.4(2) is allowed if the facility has a written policy that applies to when the use of drapes or self-supporting curtains is contra-indicated and the diagnosis might be compromised, such as where a sterile field will not permit the use of the normal protective barriers.
- (a) If the use of pre-fitted sterilized covers for the barriers is practical, exemption is not appropriate.

6.5.3.5 Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

6.5.4 Each fluoroscopic x-ray system shall fulfill the following measurement and maintenance requirements.

6.5.4.1 Compliance with the requirements of 6.5.3 shall be determined as follows:

- (1) If the source is below the table, AKR shall be measured one centimeter above the tabletop or cradle.
- (2) If the source is above the table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- (3) For a c-arm type of fluoroscope, the AKR shall be measured 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the spacer assembly or beam-limiting device is not closer than 30 cm from the input surface of the fluoroscopic imaging assembly.
- (a) For a c-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD, or corrected to the minimum SSD using the inverse square law.
- (4) Each lateral-type fluoroscope, either stationary or mobile, AKR shall be measured at a point 15 cm from the centerline of the table (isocenter) and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- (a) If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the table.
- (5) Periodic measurement of AKR shall be performed as follows:
- (a) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate.
- (b) Conditions of periodic measurement of AKR are as follows:
- (i) The measurement shall be made under the conditions that satisfy the requirements of 6.5.4.1;

- (ii) The kVp shall be the maximum kVp that can be produced by the x-ray system;
 - (iii) The x-ray system(s) that incorporates automatic exposure rate control shall have the beam collimated to the size of the detector and have sufficient material placed in the useful beam to intercept the entire beam so that output of the machine is a maximum for the x-ray system; and
 - (iv) X-ray system(s) that do not incorporate an automatic exposure rate control shall utilize the maximum milliamperage typical of the clinical use of the x-ray system.
- (6) For other fluoroscopic systems not described above, the AKR shall be measured at the point specified by the manufacturer for maximum dose rate measurements.

6.5.4.2 Source-skin distance (SSD) shall not be less than:

- (1) 38 cm on stationary fluoroscopes;
- (2) 30 cm on all mobile and portable fluoroscopes, including c-arm fluoroscopes having a maximum source-image receptor distance greater than or equal to 45 cm and o-arm fluoroscopes;
- (3) 20 cm for mobile fluoroscopes used for specific surgical application;
 - (a) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems;
- (4) 19 cm for stationary, mobile, or portable mini-c-arm fluoroscopic systems having a maximum source-image receptor distance less than 45 cm manufactured on or after June 10, 2006;
 - (a) Such systems shall be labeled for extremity use only;
 - (b) In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm;
 - (c) The written safety procedures must provide precautionary measures to be adhered to during the use of these systems; and
- (5) The distance in cm recommended by the manufacturer for equipment not specified in 6.5.4.2(1) through 6.5.4.2(4).

6.5.4.3 Measuring Barrier Transmission.

- (1) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.
- (2) If the source is below the tabletop, the measurement shall be made with the input

surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

- (3) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.
- (4) Movable grids and compression devices shall be removed from the useful beam during the measurement.
- (5) The attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of AKR and between this point and the input surface of the fluoroscopic imaging assembly.

6.5.4.4 Each registered facility shall maintain records of:

- (1) Cumulative fluoroscopic exposure time and/or other patient dose estimation data (for example, kerma-area-product); and
- (2) The type and date of each examination, patient identification, system used, and operator's name.

6.5.5 Each fluoroscopic x-ray system shall have written quality control and quality assurance procedures.

6.5.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

- (1) Specifications of the manufacturer; and
- (2) Specifications of a registered medical physicist; and/or
- (3) Standards of an appropriate nationally recognized organization.

6.5.5.2 Systems shall be evaluated periodically by a registered medical physicist in accordance with standards and protocols published by nationally recognized organizations (for example, AAPM Report 4 and AAPM Report 74), unless the registered medical physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used.

6.5.6 Radiation Therapy Simulation Systems.

6.5.6.1 Radiation therapy simulation systems shall be exempt from all the requirements of 6.5.2.2, 6.5.2.4, 6.5.2.5, 6.5.2.10, 6.5.3.1 and 6.5.3.2, provided that:

- (1) Each system is designed and used in such a manner that no individual other than the patient, required staff and ancillary personnel is in the x-ray room during any period of time when the system is producing x-rays; and
- (2) Each system that does not meet the requirements of 6.5.2.4 and 6.5.2.5 is provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.
- (3) Staff and ancillary personnel shall be protected in accordance with 6.3.3.5,

6.3.3.6, 6.3.3.7 and 6.3.3.8.

SPECIAL REQUIREMENTS FOR GENERAL PURPOSE DIAGNOSTIC X-RAY IMAGING SYSTEMS

6.6 Design and Configuration for Safe Use of a General Purpose X-ray Imaging System (Other Than Dental, Fluoroscopic, Veterinary, Computed Tomography, or Mammography).

6.6.1 Administrative Controls.

6.6.1.1 In addition to the provisions of 6.3 and 6.4, the special requirements of 6.6 apply to all x-ray imaging equipment and associated facilities other than:

- (1) Fluoroscopy (in 6.5);
- (2) Dental (in 6.7, with cross-reference in 6.7.2.1 to 6.6.2 and in 6.7.3.1 to 6.6.3);
- (3) Veterinary (in 6.8);
- (4) Computed tomography (in 6.9);
- (5) Mammography (in 6.10).

6.6.1.2 Each individual who operates an x-ray imaging system subject to 6.6 shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1.

6.6.2 For each general purpose stationary, mobile and/or portable x-ray imaging system subject to 6.6, the useful beam shall be limited to the area of clinical interest.

6.6.2.1 A means for stepless adjustment of the size of the x-ray field shall be provided.

- (1) For certified systems, stepless adjustment of the size of the x-ray field shall be provided such that the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm by 5 cm.

6.6.2.2 A method shall be provided for visually defining the perimeter of the x-ray field.

- (1) The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (2) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
- (2) A light localizer used to define the x-ray field of a certified system shall provide illumination sufficient to permit visual determination of the x-ray field under ambient light conditions of up to 500 lux (46 foot candles).

6.6.2.3 The Department may grant an exemption on non-certified x-ray systems to 6.6.2.1 and 6.6.2.2 provided the registrant makes a written application for such exemption and in that application demonstrates that:

- (1) It is impractical to comply with 6.6.2.1 and 6.6.2.2; and
- (2) The purpose of 6.6.2.1 and 6.6.2.2 will be met by other methods.

6.6.2.4 Additional Beam Limitation Requirements for Each Stationary General Purpose X-Ray

System.

- (1) A method shall be provided to:
 - (a) Indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
 - (b) Align the center of the x-ray field with respect to the center of the image receptor to within two (2) percent of the SID; and
 - (c) Indicate the SID to within two (2) percent.
- (2) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.
- (3) Indication of field size dimensions and SID's shall be specified in inches and/or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

6.6.2.5 Beam Limitation Requirements for Each X-Ray System Designed for One Image Receptor Size.

- (1) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID; or
- (2) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.2.6 Beam Limitation Requirements for Each X-Ray System Other Than Governed by 6.6.2.1 through 6.6.2.5.

- (1) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two (2) percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- (2) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two (2) percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- (3) 6.6.2.6(1) and 6.6.2.6(2) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 6.6.2.1 and 6.6.2.2, or, when alignment means are also provided, may be met with either:
 - (a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such

device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

- (b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6.6.2.7 Positive Beam Limitation (PBL) for a diagnostic x-ray system with any certified component.

- (1) When a PBL system is provided, it shall prevent x-ray production when:
- (a) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three (3) percent of the SID; or
 - (b) The sum of the length and width differences as stated in 6.6.2.7(1)(a) without regard to sign exceeds four (4) percent of the SID.
 - (c) The beam-limiting device is at a SID for which PBL is not designed for sizing.
- (2) When provided, the PBL system shall function as described in 6.6.2.7(1) whenever all the following conditions are met:
- (a) The image receptor is inserted into a permanently mounted cassette holder;
 - (b) The image receptor length and width are less than 50 cm;
 - (c) The x-ray beam axis is within \pm three (3) degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within \pm three (3) degrees of horizontal and the SID is 90 cm to 205 cm inclusive;
 - (d) The x-ray beam axis is perpendicular to the plane of the image receptor to within \pm three (3) degrees;
 - (e) Neither tomographic nor stereoscopic radiography is being performed;
 - (f) Manual collimation is not used;
 - (g) The machine is used for procedures other than therapy simulation; and
 - (h) The PBL system has not been intentionally overridden.
- (3) If a means of overriding the PBL system exists, that means shall:
- (a) Be designed for use only in the event of PBL system failure, or if the system is being serviced; and
 - (b) Require, if in a position that the operator would consider it part of the operational controls, or if it is referenced in the operator's manual, or in other materials intended for the operator, that:

- (i) A key be utilized to defeat the PBL;
 - (ii) The key remain in place during the entire time the PBL system is overridden; and
 - (iii) The key or key switch be clearly and durably labeled as follows:
“FOR X-RAY FIELD LIMITATION SYSTEM FAILURE”; and
- (c) Not be used as a substitute for prompt repair.
- (4) Compliance with 6.6.2.7 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 6.6.2.7(2) are met.
- (5) Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.
- (6) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size.
- (7) The minimum field size at an SID of 100 cm shall be equal to or less than 5 cm by 5 cm.
- (8) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 6.6.2.7, then any change of image receptor size or SID must cause the automatic return.

6.6.3 Radiation Exposure Control Devices.

6.6.3.1 Timers.

- (1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
- (2) It shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided.
- (3) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero”.

6.6.3.2 X-ray Control.

- (1) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
 - (a) Exposure of one-half (0.5) second or less, or
 - (b) During serial radiography when a means shall be provided to permit completion of any single exposure of the series in process.
- (2) Except for a bone densitometry system, each x-ray control shall be located in such a way as to meet the following requirements:

- (a) For stationary x-ray systems, and mobile or portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure.
 - (b) Mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam.
 - (i) Mobile and portable x-ray systems used in surgery are considered to be not routinely used in one location.
 - (ii) A separate exposure switch is not required for portable hand-held x-ray equipment that has the control on the device.
- (3) The settings to be used during an exposure shall be indicated before the exposure begins.
- (a) When automatic exposure controls are used, the exposure settings that are set prior to the exposure shall be indicated.
 - (b) On equipment having fixed exposure settings, permanent markings visible from the operator's position are acceptable.

6.6.3.3 Automatic Exposure Controls.

- (1) When an automatic exposure control is provided, indication shall be made on the control panel when this mode of operation is selected;
- (2) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;
- (3) The minimum exposure time for all equipment other than that specified in 6.6.3.3(2) shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
- (4) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
- (5) A visible signal shall indicate when an exposure has been terminated at the limits required by 6.6.3.3(4), and manual resetting shall be required before further automatically timed exposures can be made.

6.6.3.4 Timer Reproducibility.

- (1) For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

- (2) Measuring compliance for linearity shall be in accord with 21 CFR 1020.31.

6.6.3.5 Source-Skin Distance.

- (1) Each mobile or portable radiographic x-ray imaging system shall be provided with means to limit the source-skin distance to equal to or greater than 30 cm.

6.6.3.6 Exposure Reproducibility.

- (1) When all exposure settings are held constant, including control panel selections associated with automatic exposure control systems the coefficient of variation of air kerma for both manual and automatic exposure control systems shall not exceed 0.05.
- (2) The facility registrant may request an exemption for any machines manufactured prior to 1974, that cannot meet this requirement. The exemption request must verify that this exposure reproducibility variation will not result in unnecessary patient radiation exposure due to the need for repeat examinations.

6.6.3.7 Radiation from Capacitor Energy Storage Equipment in Standby Status.

- (1) Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.5 $\mu\text{C}/\text{kg}$ (2 mR) per hour at 5 cm from any accessible surface (that can be easily or accidentally touched by an individual without the use of a tool) of the diagnostic source assembly, with the beam-limiting device fully open.

6.6.3.8 Linearity for a diagnostic x-ray system with any certified component shall be in accord with 21 CFR 1020.31(c)(3).

6.6.3.9 Accuracy for a diagnostic x-ray system with any certified component.

- (1) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (2) If manufacturer specifications are not available, the following criteria shall be used:
 - (a) The kVp shall not deviate from indicated values by more than ten (10) percent.
 - (b) The timer accuracy shall not deviate from indicated values by more than:
 - (i) Ten (10) percent for an indicated time of greater than 20 ms; or
 - (ii) Fifty (50) percent for an indicated time of 20 ms or less, or 1 pulse, whichever is greater.

6.6.4 For each general purpose x-ray imaging system, the registrant shall ensure that manufacturer maintenance specifications are followed.

6.6.5 For each general-use diagnostic radiographic x-ray system, the registrant shall ensure that written quality control and quality assurance procedures are available and in use, including for facility operations and emergencies.

6.6.5.1 The quality control and quality assurance procedures shall be consistent with 6.3.5 and shall follow:

- (1) Specifications of the manufacturer; and
- (2) Specifications of a registered medical physicist; and/or
- (3) Standards of an appropriate nationally recognized organization.

6.6.5.2 Routine periodic quality control shall be comparable to the following:

- (1) Cassette maintenance (for example, erasure and/or screen cleaning);
- (2) Images inspected for evidence of clinically relevant artifacts (for example, dust and non-uniformities) with appropriate corrective action (for example, cleaning of screens) taken as needed and documented;
- (3) Analysis of repeated and/or rejected images;
- (4) Investigation of errors outside a control range;
- (5) Measurements using phantoms, if required (for example, in bone densitometry); and
- (6) Measurements of scattered radiation at the operator's position, if required (for example, in bone densitometry).

6.6.5.3 Annual quality assurance shall be comparable to the following:

- (1) All quality control tests shall be reviewed annually;
- (2) Imaging systems shall be tested in accordance with standards and protocols published by a nationally recognized organization; and
- (3) The frequency of quality control testing and corrective actions taken as a result are followed and documented.

6.7 Safe Use of a Dental X-Ray imaging System.

6.7.1 Administrative Controls.

6.7.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.7 apply to equipment and associated facilities used for dental x-ray imaging.

6.7.1.2 Each individual who operates a dental x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of 2.6.1, in particular 2.6.1.11.

6.7.2 Each dental x-ray imaging system shall meet the following equipment design and configuration requirements.

6.7.2.1 Cephalometric and volumetric dental x-ray systems shall meet the equipment design and configuration requirements of 6.3.2 and 6.6.2, except that:

- (1) The shielding design described in 6.3.2 is required for the room(s) of any facility

having a cephalometric and/or volumetric dental x-ray system regardless of occupancy.

- (2) A dental facility may apply in writing and be granted exemption by the Department for a particular room and x-ray equipment configuration.

6.7.2.2 Intraoral and panoramic dental x-ray systems shall meet the following requirements:

- (1) Source-Skin Distance (SSD) for Intraoral Dental X-ray Systems.
- (a) Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than 18 cm if operable above 50 kVp.
- (2) Field Limitation for Intraoral Dental X-ray Systems.
- (a) Each x-ray imaging system designed for use with an intraoral image receptor shall be provided with means to limit the beam such that:
- (i) If the minimum SSD is 18 cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 cm; and
- (ii) If the minimum SSD is less than 18 cm, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 cm.
- (3) As provided in 6.3.2.4, neither the shielding design described in 6.3.2 nor the dimensional drawing, calculation or survey described in 6.3.2.3 are required for intraoral or panoramic dental equipment.

6.7.3 Each dental x-ray imaging system shall meet the following radiation exposure operational control requirements.

6.7.3.1 Cephalometric and volumetric beam dental x-ray systems shall meet the radiation exposure control requirements of 6.6.3:

6.7.3.2 Intraoral and panoramic dental x-ray systems shall meet the following radiation exposure control requirements instead of the requirements in 6.6.3:

- (1) Timers.
- (a) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
- (b) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
- (c) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
- (d) Timer Reproducibility.
- (i) With a timer setting of 0.5 seconds or less, the average exposure

period (T_{avg}) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed:
 $T_{avg} \geq 5(T_{max} - T_{min})$.

- (2) X-ray Control for Intraoral or Panoramic Dental X-ray Systems.
- (a) A control shall be incorporated into each x-ray imaging system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (0.5) second or less.
- (b) Each control shall be located as follows:
- (i) For stationary x-ray systems, and mobile or non-handheld portable systems used routinely in one location, the x-ray control permanently mounted in a separated area behind a whole body protective barrier (of not less than 0.25 millimeter lead equivalent) where the operator is required to remain during the entire exposure, or the exposure control shall be such that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam;
- (ii) Mobile and non-hand-held portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters (more than 6 feet) from the patient, the x-ray tube and the useful beam; or
- (iii) Portable hand-held x-ray equipment shall meet Appendix 6E.
- (3) Exposure Reproducibility.
- (a) The estimated coefficient of variation of radiation exposure shall be no greater than 0.05, for any specific combination of selected exposure settings.
- (4) Linearity shall be in accord with 21 CFR 1020.31(c)(3).
- (5) Accuracy.
- (a) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (b) If manufacturer specifications are not available, accuracy of all exposure factors shall be within ten (10) percent of the selected factor(s).
- (6) Beam Quality.
- (a) All dental x-ray systems shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent.
- (b) Systems operating above 70 kVp are subject to the filtration requirements of 6.4.2.5(1).
- (7) Patient and image receptor holding devices shall be used when the techniques

permit.

- (8) The tube housing and the PID shall not be hand-held during an exposure, except as provided in Appendix 6E for portable hand-held x-ray equipment.
- (9) The x-ray system shall be operated in such a manner that the area of the useful beam at the patient's skin is minimized.
- (10) Dental fluoroscopy without image intensification or direct digital receptors shall not be used.

6.7.3.3 The x-ray control shall provide:

- (1) Visual indication observable at the operator's protected position whenever x-rays are produced; and
- (2) A signal audible to the operator shall indicate that the exposure has terminated.

6.7.3.4 A thyroid shield shall be used to reduce patient exposure to scattered radiation (except for a case in which shielding would interfere with the diagnostic procedure).

6.7.3.5 Absent structural protection against scatter radiation, during radiation machine operation at least a 2-meter distance (more than 6 feet) shall be maintained from any bystander location and between patient operating chairs.

6.7.4 For each dental x-ray imaging system, manufacturer maintenance specifications shall be followed.

6.7.5 For each dental x-ray imaging system, written quality control and quality assurance procedures shall include:

6.7.5.1 For processing of intraoral films, performance of the following:

- (1) Follow applicable manufacturer's time and temperature specifications, which shall be available for review;
- (2) Measure and log temperature each day of use; and
- (3) Document in a written log the change of developer chemicals at least every month.

6.7.5.2 For volumetric dental systems, conduct periodic calibrations and annual quality control tests according to the manufacturer's specifications, including any additional or more frequent testing necessary at the recommendation of the registered medical physicist.

6.7.5.3 Annual review of all quality control tests.

6.8 Safe Use of a Veterinary Medicine Imaging System.

6.8.1 Administrative Controls.

6.8.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of this 6.8, and as appropriate also 6.5 and 6.9, apply to equipment and associated facilities used for veterinary x-ray imaging.

6.8.1.2 Each individual who operates a veterinary x-ray imaging system shall meet the applicable adequate radiation safety training and experience requirements of Part 2.6.1, in particular 2.6.1.13.

6.8.2 Each veterinary medicine installation shall meet the following equipment design and configuration requirements.

6.8.2.1 Equipment.

- (1) The protective tube housing shall be equivalent to the requirements of 6.4.2.3.
- (2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
- (3) The total filtration permanently in the useful beam shall meet the requirement of 6.4.2.5(1).

6.8.2.2 A method shall be provided for visually defining the perimeter of the x-ray field.

- (1) The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 (two) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

6.8.2.3 Structural Shielding.

- (1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 4.6, 4.12, 4.13, and 4.14.
- (2) A veterinary installation shall meet the requirements of 6.3.2 in order to minimize radiation exposure to personnel and individual members of the public.
- (3) Veterinary facilities are exempt from the requirements of Appendix 6B so long as the requirements of 6.8.3 are met.

6.8.2.4 Linearity shall be in accord with 21 CFR 1020.31(c)(3).

6.8.2.5 Accuracy.

- (1) Deviation of exposure settings from indicated values shall not exceed the limits specified for that system by its manufacturer.
- (2) If manufacturer specifications are not available, the following criteria shall be used:
 - (a) The kVp shall not deviate from indicated values by more than ten (10) percent.
 - (b) The timer accuracy shall not deviate from indicated values by more than:
 - (i) Ten (10) percent for an indicated time of greater than 20 ms; or
 - (ii) Fifty (50) percent for an indicated time of 20 ms or less, or

1 pulse, whichever is greater.

6.8.2.6 Timers.

- (1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
- (2) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
- (3) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

6.8.2.7 Exposure Reproducibility.

- (1) The coefficient of variation of exposure shall not exceed 0.05 when all exposure settings are held constant.

6.8.2.8 A dead-man type of exposure switch or equivalent remote device shall enable the operator to stand out of the useful beam.

6.8.3 Each veterinary medicine installation shall have the following operating and radiation exposure control procedures.

6.8.3.1 Whenever possible, the operator shall be positioned during radiographic exposures so that the nearest portion of the body is at least 2 meters (more than 6 feet) from both the tube head and the nearest edge of the image receptor.

6.8.3.2 No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required and the person is adequately protected by shielding and/or distance.

- (1) All other staff and ancillary personnel required for the procedure shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

6.8.3.3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

- (1) Each individual other than the animal being examined shall be positioned such that no part of the body will be struck by the useful beam unless protected by a minimum of 0.5 millimeter lead equivalent.
- (2) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and the individual shall be so positioned that no part of the individual's body will be struck by the useful beam.
- (3) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.4 No human shall hold the image receptor during radiography unless that individual is protected with appropriate shielding devices, such as protective gloves and apron, and that any part of his/her body struck by the useful beam shall be monitored.

- (1) The exposure of any individual used for this purpose shall be maintained below the limits specified in 4.6, 4.12, and 4.13.

6.8.3.5 Use of portable hand-held x-ray equipment shall be consistent with Appendix 6E.

6.8.4 Each veterinary x-ray imaging system shall follow manufacturer maintenance specifications.

6.8.5 Each veterinary x-ray imaging system shall have written quality control and quality assurance procedures that include:

6.8.5.1 For processing of veterinary films, performance of the following:

- (1) Follow applicable manufacturer's time and temperature specifications, which shall be available for review;
- (2) Measure and log temperature each day of use; and
- (3) Document in a written log the change of developer chemicals at least every month.

6.8.5.2 Annual review of all quality control tests.

SPECIAL REQUIREMENTS FOR COMPUTED TOMOGRAPHY

6.9 Safe Use of a Computed Tomography System.

6.9.1 Administrative Controls.

6.9.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.9 apply to equipment and associated facilities used for computed tomography.

6.9.1.2 Supervision and operation of a computed tomography system used on living humans shall be by an individual who has adequate radiation safety training and experience.

- (1) Supervision shall be consistent with 6.3.1.8.
- (2) Training and experience shall be as provided in 2.6.1, in particular 2.6.1.9 and Appendix 2E, and 6.3.1.7

6.9.2 Each computed tomography facility shall meet the following equipment design and configuration requirements.

6.9.2.1 Termination of Exposure.

- (1) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection.
 - (a) Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices that monitor equipment function.
- (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 6.9.2.1(1).

- (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

6.9.2.2 Tomographic Plane Indication and Alignment.

- (1) Means shall be provided to permit visual determination of the location of a reference tomographic plane.
- (2) If a device using a light source is used to satisfy 6.9.2.2(1), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 foot candles).

6.9.2.3 Beam-On and Shutter Status Indicators and Control Switches.

- (1) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
- (2) Each emergency button or switch shall be clearly labeled as to its function.

6.9.2.4 Patient Communication.

- (1) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- (2) Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
- (3) Patient scanning shall be allowed only when a viewing system is available and in use.

6.9.3 Each computed tomography facility shall have the following operating procedures and radiation exposure controls.

6.9.3.1 Console Performance.

- (1) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.
- (2) Information shall be readily available regarding the operation of the system.
- (3) Information regarding calibration of the system shall be readily available, including:
 - (a) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;
 - (b) Instructions on the use of the CT performance phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
 - (c) When operators must select exposure settings, a current protocol shall

be available at the control panel that specifies for each routine examination the CT conditions of operation and the typical number of scans per examination, including guidance for age-appropriate scanning.

6.9.3.2 Indication of CT Conditions of Operation.

- (1) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence.
- (2) On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings.
- (3) Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

6.9.3.3 Extraneous Radiation.

- (1) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 6.4.2.3.

6.9.3.4 Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 2, 1992.

- (1) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
- (2) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
- (3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kg resting on the support device.
 - (a) The patient support device shall be incremented from a typical starting position to the maximum incremented distance, the manufacturer's specified distance, or 30 cm, whichever is less, and then returned to the starting position.
 - (b) Measurement of actual versus indicated scan increment may be taken anywhere along this travel.
 - (c) When table increment is not the primary means of slice position location, the registered medical physicist may provide for prior written Department review and approval alternative measurement procedures to determine the accuracy of slice position.
- (4) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

- 6.9.4 Each computed tomography facility shall conduct required surveys, evaluations, calibrations, and spot checks.

6.9.4.1 Surveys and Evaluations.

- (1) A radiation survey shall be made by, or under the direct supervision of, a registered medical physicist, to verify and document compliance with 4.14 and 4.15 for:
 - (a) Any change in the facility or equipment that might cause a significant increase in radiation hazard; or
 - (b) Any initial or new location for a CT imaging system that is designed to be transported from place to place.
- (2) Notwithstanding the provisions of 2.5.1.2, CT x-ray systems that have undergone an x-ray tube change within 12 months of the last annual evaluation do not require a complete calibration at the time of the x-ray tube change, provided that:
 - (a) The CT x-ray system operation after the tube change meets the criteria established by the registered medical physicist.
 - (b) Each CT system shall receive a certification evaluation (CE) at least within one year of the previous CE.

6.9.4.2 Radiation Dosimetry.

- (1) The radiation output of the CT x-ray system shall be measured by, or under the personal supervision of, a registered medical physicist:
 - (a) At intervals (not exceeding one year) specified by a registered medical physicist;
 - (b) In accordance with protocols published by nationally recognized organizations (for example, AAPM Report 96), unless the registered medical physicist determines that a particular recommendation of such report is not warranted for the clinical tasks for which the equipment will be used;
 - (c) With a calibrated dosimetry system:
 - (i) Traceable to a national standard; and
 - (ii) Calibrated within the preceding two (2) years.
- (2) CT dosimetry shall be evaluated by a registered medical physicist in accordance with protocols published by a nationally recognized organization.
- (3) Records of measurements performed shall be maintained for a period of three (3) years for inspection by the Department.

6.9.4.3 Spot Checks.

- (1) The spot-check procedures shall be in writing and shall have been developed by a registered medical physicist.
- (2) The spot-check procedures shall incorporate the use of a commensurate CT performance phantom.

- (3) All spot checks shall be performed at time intervals and under system conditions specified by a registered medical physicist.
 - (4) Images shall be retained, at least until a new calibration is performed, as follows:
 - (a) Photographic copies of the images obtained from the image recording device; or
 - (b) Images stored in digital form on a storage medium compatible with the CT x-ray system.
 - (5) Written or electronic records of the spot checks performed shall be maintained for inspection by the Department.
- 6.9.5 Each computed tomography system shall have written quality control and quality assurance procedures, including:
- 6.9.5.1 If a calibration required by 6.9.4.2 or a spot check required by 6.9.4.3 identifies that a system operating parameter is outside a specified or recommended tolerance or range:
 - (1) The CT x-ray system shall not be used on a patient except as permitted by documented instructions of the registered medical physicist; and
 - (2) Correction or modification shall be made within 30 days of the date of the test identifying the problem.
 - 6.9.5.2 The computed tomography system shall meet the specifications of the manufacturer or registered medical physicist and/or appropriate nationally recognized organization, or equivalent approved by the Department, for:
 - (1) Alignment light accuracy;
 - (2) Slice thickness;
 - (3) Image quality; and
 - (4) CT number accuracy.
 - 6.9.5.3 All quality control tests shall be reviewed by a registered medical physicist at least annually.

SPECIAL REQUIREMENTS FOR MAMMOGRAPHY

6.10 Safe Use at a Mammography Facility.

6.10.1 Administrative Controls.

- 6.10.1.1 In addition to the provisions of 6.3 and 6.4, the requirements of 6.10 apply to equipment and associated facilities used for mammography.
- 6.10.1.2 Each facility performing mammography shall:
 - (1) Meet the requirements of 21 CFR 900;
 - (2) Have a valid certificate issued by the U.S. Department of Health and Human

Services pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 CFR 900;

- (3) Ensure that 21 CFR 900 quality control and quality assurance standards for maintaining viewing conditions and interpretation of an image are met.

6.10.1.3 Each qualified inspector who conducts a mammography facility and x-ray machine certification evaluation shall meet the requirements of Appendix 2I.

6.10.1.4 Each Individual who performs a mammography examination shall meet the adequate radiation safety training and experience requirements of 2.4.5.4, 2.6.1.8 and Appendix 2M.

6.10.1.5 In the State of Colorado, the regulatory requirements of Part 6 shall also apply as appropriate to radiography of the breast performed:

- (1) During invasive interventions for localization or biopsy (for example, stereotactic biopsy procedures); or
- (2) With an investigational device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
- (3) During any other procedure for radiography of the breast that the Department determines and designates.

6.10.1.6 The registrant shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility, which program shall:

- (1) Follow manufacturers' specifications and/or the standards of an appropriate nationally recognized organization, for example, the American College of Radiology or American Association of Physicists in Medicine; and
- (2) Apply to and be adhered to for each procedure subject to 6.10.1.

PART 6, APPENDIX 6A: INFORMATION REQUIRED FOR EVALUATION OF RADIATION SHIELDING

6A.1 In order to provide an evaluation and technical advice on shielding requirements for a radiation installation, the following information shall be submitted to the qualified expert or registered medical physicist.

6A.1.1 The submittals shall show at least the following:

- (1) The normal location of the x-ray imaging system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
- (2) The structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
- (3) The dimensions of the room(s) concerned and inter-floor distances if space above or below is occupied.
- (4) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned.
- (5) If there is an exterior wall, the distance to the closest area(s) where it is likely that individuals may be present.
- (6) A description of the x-ray imaging system and components, including the make and model of the equipment.
- (7) The type of examination(s) or treatment(s) that will be performed with the equipment.

6A.1.2 Information on the anticipated workload of the x-ray imaging system(s).

PART 6 APPENDIX 6B: DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

6B.1 Space Requirements:

- 6B.1.1 The operator shall be allotted not less than 0.7 m^2 (8 ft^2) of unobstructed floor space in the booth.
- 6B.1.2 The operator's booth may be of any geometric configuration with no dimension less than 0.6 m (2 ft).
- 6B.1.3 The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- 6B.1.4 The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's location within the booth.

6B.2 Structural Requirements:

- 6B.2.1 The booth walls shall be permanently fixed barriers at least 2 m (7 ft) high.
- 6B.2.2 When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed in its shielding position.
- 6B.2.3 Shielding shall be provided to meet the requirements of Part 4.

6B.3 Viewing System Requirements:

6B.3.1 Each booth shall have at least one viewing device that will:

- (1) Be so placed that the operator can view the patient during any exposure, and
- (2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have either an interlock controlling the exposure that will prevent the exposure if the door is not closed; or a warning light must be activated at the control panel when the door is opened.

6B.3.2 When the viewing system is a window, the following requirements also apply:

- (1) The viewing area shall be at least 0.1 m^2 (1 ft^2).
- (2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 0.5 m (1.5 ft) from the edge of the booth.
- (3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

6B.3.3 When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 6B.3.1.

6B.3.4 When the viewing system is by electronic means:

- (1) The camera shall be so located as to accomplish the general requirements of 6B.3.1.
- (2) There shall be an alternate viewing system as a backup for the primary system, unless the x-ray room is not used in the case of viewing system failure.

PART 6, APPENDIX 6C: CONTENT OF A SHIELDING DESIGN

- 6C.1 Each written shielding design prepared by a qualified expert shall include identifying information, if available, such as the facility name, address, owner, contact telephone numbers and contact e-mail addresses.
- 6C.2 Each written shielding design prepared by a qualified expert shall include:
 - 6C.1.2 Evaluation from a radiation protection point-of-view of the overall layout of the room(s) floor plan, including the location and configuration any radiation producing machines in each room, based on the information required in Appendix 6A and 6B.
 - 6C.1.3 Evaluation of suitable workload, based on the volume of work and equipment usage anticipated in the information provided pursuant to 6A.1.2, in relation to the overall layout.
 - 6C.1.4 Detailed consideration, using guidelines based on National Council on Radiation Protection and Measurements Report No. 147, "Structural Shielding Design for Medical Imaging Facilities", or equivalent guidance, of:
 - 6C.1.4.1 Location and types of permanent and temporary barriers and shielding;
 - 6C.1.4.2 Location of controls and any control booth;
 - 6C.1.4.3 Location of exposure switch; and
 - 6C.1.4.4 Interior and exterior walls, doors and windows, and floors and ceilings.
 - 6C.1.5 Calculations of potential exposures based on occupancy and workload distribution.
 - 6C.1.6 For each room in which a stationary x-ray imaging system is located, a current dimensional drawing as required by 6.3.2.3 with accompanying specifications for construction and layout to meet all requirements of these regulations, in particular to preclude an individual from receiving a dose in excess of the limits in 4.6, 4.12, 4.13, 4.14 and 4.15.
 - 6C.1.7 The signature of the qualified expert who prepared the shielding design and the date signed.

PART 6, APPENDIX 6D: CRITERIA FOR CLASSIFYING A RADIATION MACHINE UNSAFE FOR ROUTINE HUMAN, ANIMAL OR OTHER USE

- 6D.1 The operating condition of an radiation machine and related equipment shall not be such that the continued operation of that machine endangers the public health and safety.
- 6D.2 An radiation machine shall be considered unsafe for human, animal or other use if:
- 6D.2.1 The radiation machine system has a malfunctioning component or components that could result in an inadvertent exposure to members of the public, the operator, or the patient. Examples include but are not limited to: a timer that fails to terminate the exposure, an exposure switch when activated once produces multiple exposures, a system that produces x-rays without activation of the exposure switch.
- 6D.2.2 The radiation machine is not equipped with a means of determining when x-rays are in production.
- 6D.2.3 The radiation machine is equipped with variable exposure settings and the selectors and/or indicators of these exposure settings do not permit the operator to determine the factors in use or if the indicated versus the exposure settings are in error by fifty (50) percent or more, except for exposure times selected less than 50 millisecond.
- 6D.2.4 The collimation of the x-ray beam of a fluoroscopic/spot film system is such that either the length or width of the x-ray field in the plane of the image receptor differs (in excess) from the corresponding image receptor dimensions by more than 25 percent of the source to image distance (SID).
- 6D.2.5 The half-value layer of aluminum (or equivalent) filtration in the useful beam is more than fifty (50) percent below the values specified in 6.4.2.5.
- 6D.2.6 In addition to the above items a fluoroscopic x-ray system will be considered unsafe if:
- (1) In normal fluoroscopic mode:
- (a) No operational image intensifier or direct digital image receptor is provided.
- (b) Except for radiation oncology simulators, the primary protective barrier does not intercept 100 percent of the x-ray beam of a fluoroscopic x-ray system.
- (c) Except for radiation oncology simulators, the fluoroscopic x-ray system is capable of producing x-rays when the primary protective barrier is not in position to intercept the beam.
- (d) The fluoroscopic x-ray system has a tabletop AKR equal to or greater than 220 mGy per minute (25 R/min) at the point where the useful beam enters the patient, except:
- (i) During the recording of fluoroscopic images, or
- (ii) When an optional high-level control is activated.
- (2) Note that this is normal fluoroscopic mode, and the FDA's regulations (21 CFR

1020.32(e)(2)(II), April 1, 2004) allow up to 176 mGy per minute (20 R/min) when recording or using high-level control.

- 6D.2.7 An electro-mechanical defect exists that endangers human life or safety when a radiograph is made or fluoroscopy is performed.

PART 6, APPENDIX 6E: HUMAN USE OF PORTABLE HAND-HELD X-RAY EQUIPMENT

6E.1 The following requirements are applicable, as determined by the Department, to any human use x-ray radiographic device, in particular for dental intraoral use, that is designed to be operated as a hand-held unit.

6E.1.1 Requirements for any location:

6E.1.1.1 Each operator of a hand-held device shall be specifically trained to operate such equipment.

6E.1.1.2 The operator shall ensure there are no bystanders within a radius of at least 2 meters (six feet) from the patient being examined with a hand-held intraoral radiographic unit.

6E.1.1.3 If a hand-held device was designed with an optional, removable secondary radiation block, it shall be installed and used during patient examination.

6E.1.1.4 The device shall be held without any motion, in order to prevent repeat imaging due to motion that reduces image quality. If the operator has difficulty in holding the device stationary, the operator shall use a stand or tripod to immobilize the device.

6E.1.1.5 The operator shall be protected from direct scatter radiation by protective material of not less than 0.25 millimeter lead equivalent and a thyroid collar unless the radiation safety officer and Department determine that no added protection is needed for the device model and/or use.

6E.1.1.6 Personnel monitoring shall be at least as required by 6.3.3.10.

6E.1.2 Additional requirements for operations in permanent facilities:

6E.1.2.1 As provided in 6.3.2.4, a hand-held device is exempt from 6.3.2.1 and consequently is exempt from 6.3.2.2 and 6.3.2.3.

6E.1.2.2 A hand-held device shall not be used for patient examinations in hallways and waiting rooms.

6E.2 Portable hand-held x-ray equipment shall be kept in a secured location when not in use.

PART 6, APPENDIX 6F: INFORMATION TO BE SUBMITTED BY A PERSON PROPOSING TO CONDUCT HEALING ARTS SCREENING

- 6F.1 A person requesting that the Department approve a healing arts screening program shall submit the following information and evaluation when completing Department Form R-300:
- 6F.1.1 Name and address of the applicant and, when applicable, the names and addresses of all locations within this State, where the service will be provided.
 - 6F.1.2 Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
 - 6F.1.3 A detailed description of the x-ray examinations proposed in the screening program.
 - 6F.1.4 Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
 - 6F.1.5 An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.
 - 6F.1.6 An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program prior to being placed into operation. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
 - 6F.1.7 A description of the image processing quality control program, if applicable.
 - 6F.1.8 A copy of the technique protocols for the x-ray examination procedures to be used as required under 6.3.3.2.
 - 6F.1.9 Documentation that each individual who will be operating the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience.
 - 6F.1.10 Documentation that each individual who will be supervising the operators of the x-ray system(s) fulfills Department requirements for adequate radiation safety training and experience. The extent of supervision and the method of work performance evaluation shall be specified.
 - 6F.1.11 The name and address of the individual who will interpret the radiograph(s) or other results from the x-ray examinations.
 - 6F.1.12 Name of who will oversee the program with a current license from Board of Medical Examiners of Physician(s) of a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts.
 - 6F.1.13 A copy of the order for the screening program to be conducted, prescribed by a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts.
 - 6F.1.14 A description of the procedures to be used by a physician, chiropractor, dentist or podiatrist who has a current active State of Colorado license to practice the healing arts to advise the individuals screened about the results of the screening procedure and any further medical needs indicated.
 - 6F.1.15 A description of the procedures for the retention or disposition of the radiographs, if

applicable, and other records pertaining to the x-ray examinations.

6F.1.16 A shielding analysis, if applicable.

6F.1.17 A copy of the policy and procedures to ensure that all applicable dose limitation requirements of Part 4, "Standards for Protection Against Radiation", are met.

6F.1.18 A copy of the ALARA policy and procedures.

6F.1.19 Copies of personnel monitoring reports for any employee involved in screening.

6F.1.20 Any additional information that has been requested by the Department.



**Colorado Department
of Public Health
and Environment**

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 10: NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS

Last amended 06/16/10, effective 07/30/2010

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

PART 10: NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS

10.1 Purpose and Scope.

10.1.1 Authority.

10.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, and 24-60-2205, CRS.

10.1.2 Basis and Purpose.

10.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

10.1.3 Scope.

10.1.3.1 This part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions.

10.1.4 Applicability

10.1.4.1 The regulations in this part apply to all persons who receive, possess, use, own, transfer or dispose sources of radiation registered with or licensed by the Department pursuant to Part 2 and/or Part 3 of these regulations.

GENERAL REGULATORY PROVISIONS AND SPECIFIC REQUIREMENTS

10.2 Posting of Notices to Workers.

10.2.1 Each licensee or registrant shall post current copies of the following documents:

10.2.1.1 The regulations in this part and in Part 4 of these regulations;

10.2.1.2 The license, certificate of registration, conditions, or documents incorporated into the license by reference and amendments thereto;

10.2.1.3 The operating procedures applicable to activities under the license or registration; and

- 10.2.1.4 Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part 1 of these regulations, and any response from the licensee or registrant.
- 10.2.2 If posting of a document specified in 10.2.1.1, 10.2.1.2, or 10.2.1.3 is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- 10.2.3 Department Form R-15 *Notice to Employees* shall be posted by each licensee or registrant as required by these regulations.
- 10.2.4 Department documents posted pursuant to 10.2.1.4 shall be posted within 5 working days after receipt of the documents from the Department; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant.
- 10.2.4.1 Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.
- 10.2.5 Documents, notices, or forms posted pursuant to 10.2 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.
- 10.3 Instructions to Workers.**
- 10.3.1 All individuals who in the course of employment are likely to receive in a year an occupational dose (see also 10.3.2) in excess of 1 millisievert (100 mrem) shall be:
- 10.3.1.1 Kept informed of the storage, transfer, or use of sources of radiation;
- 10.3.1.2 Instructed in the health protection problems associated with exposure to radiation and/or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
- 10.3.1.3 Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;
- 10.3.1.4 Instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or registrations, or unnecessary exposure to radiation and/or radioactive material;
- 10.3.1.5 Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and
- 10.3.1.6 Advised as to the radiation exposure reports which workers shall be furnished pursuant to 10.4.
- 10.3.2 In determining those individuals subject to the requirements of 10.3.1, licensees and registrants must take into consideration:

10.3.2.1 Assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility; and

10.3.2.2 The result of instruction for maintaining exposures ALARA pursuant to 4.5.2.

10.3.3 The extent of these instructions shall be commensurate with potential radiological health protection problems present in the work place.

10.4 Notification and Reports to Individuals.

10.4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 10.4.

10.4.1.1 The information reported shall include data and results obtained pursuant to these regulations, orders, or license or registration conditions, as shown in records maintained by the licensee or registrant pursuant to 4.46 of these regulations.

10.4.1.2 Each notification and report shall:

- (1) Be in writing;
- (2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;
- (3) Include the individual's exposure information; and
- (4) Contain the following statement:

"This report is furnished to you under the provisions of *Colorado Rules and Regulations Pertaining to Radiation Control*, Part 10. You should preserve this report for further reference."

10.4.2 Each licensee or registrant shall make dose information available to each worker as shown in records maintained by the licensee or registrant pursuant to 4.46 of these regulations.

10.4.2.1 The licensee or registrant shall provide an annual report to each individual monitored under 4.18 of the dose received in that monitoring year if that individual:

- (1) Received an occupational dose greater than 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or
- (2) Requests an annual dose report.

10.4.3 Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant.

10.4.3.1 The report shall include the dose record for each year the worker was required to be monitored pursuant to 4.18 of these regulations.

10.4.3.2 Such report shall be furnished within 30 days from the date of the request or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later.

- 10.4.3.3 The report shall cover the period of time the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.
- 10.4.4 When a licensee or registrant is required pursuant to 4.53 of these regulations to report to the Department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein.
- 10.4.4.1 Such reports shall be transmitted at a time not later than the transmittal to the Department.
- 10.4.5 At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year.
- 10.4.5.1 If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.
- 10.5 Presence of Representatives of Licensees or Registrants and Workers During Inspections.**
- 10.5.1 Each licensee or registrant shall afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.
- 10.5.2 During an inspection, Department inspectors may consult privately with workers as specified in 10.6.
- 10.5.2.1 The licensee or registrant may accompany Department inspectors during other phases of an inspection.
- 10.5.3 If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
- 10.5.4 Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 10.3.
- 10.5.5 Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection.
- 10.5.5.1 However, only one workers' representative at a time may accompany the inspectors.
- 10.5.6 With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

10.5.7 Notwithstanding the other provisions of 10.5, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection.

10.5.7.1 With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

10.6 Consultation with Workers During Inspections.

10.6.1 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses or registrations to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

10.6.2 During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or cause any violation of the Act, these regulations, or license or registration condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control.

10.6.2.1 Any such notice in writing shall comply with the requirements of 10.7.1.

10.6.3 The provisions of 10.6.2 shall not be interpreted as authorization to disregard instructions pursuant to 10.3.

10.7 Requests by Workers for Inspections.

10.7.1 Any worker or representative of workers believing that a violation of the Act, these regulations, or license or registration conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Department.

10.7.1.1 Any such complaint shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers.

10.7.1.2 A copy shall be provided to the licensee or registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

10.7.2 If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in 10.7.1, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred.

10.7.2.1 Inspection pursuant to 10.7 need not be limited to matters referred to in the complaint.

10.7.3 No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified, or is about to testify in any such proceeding, or because of the exercise by such worker on behalf of such worker or others of any option afforded by this part.

10.8 Inspections Not Warranted; Informal Review.

- 10.8.1 If the Department determines, with respect to a complaint under 10.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination.
- 10.8.1.1 The complainant may obtain review of such determination by submitting a written statement of position with the Department.
- 10.8.1.2 The Department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant and the name of individuals referred to therein.
- 10.8.1.3 The licensee or registrant may submit an opposing written statement of position with the Department.
- 10.8.1.4 The Department will provide the complainant with a copy of such statement by certified mail.
- 10.8.1.5 Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee or registrant may each orally present its views.
- 10.8.1.6 An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant or individuals referred to in the complaint will be made only following receipt of written authorization from the complainant.
- 10.8.1.7 After considering all written and oral views presented, the Department shall affirm, modify, or reverse the determination and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.
- 10.8.2 If the Department determines that an inspection is not warranted because the requirements of 10.7.1 have not been met, the complainant shall be notified in writing of such determination.
- 10.8.2.1 Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 10.7.1.



**Colorado Department
of Public Health
and Environment**

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

6 CCR 1007-1

STATE BOARD OF HEALTH

RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL

**PART 24, PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION
MACHINES IN THE HEALING ARTS**

Last amended 10/21/09, effective 07/01/2010

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

STATE BOARD OF HEALTH

**RADIATION CONTROL - PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION MACHINES
IN THE HEALING ARTS**

6 CCR 1007-1 Part 24

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

**PART 24: PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION MACHINES IN THE
HEALING ARTS**

PARTICLE ACCELERATORS AND THERAPEUTIC RADIATION MACHINES IN THE HEALING ARTS

24.1 Purpose and Scope.

24.1.1 Authority.

24.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

24.1.2 Basis and Purpose.

24.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

24.1.3 Scope.

24.1.3.1 This Part 24 establishes requirements for use of particle accelerators and therapeutic radiation machines in the healing arts.

24.1.4 Applicability.

24.1.4.1 The provisions of Part 24 are in addition to, and not in substitution for, other applicable provisions in Parts 1, 2, 4, 10 or other parts of these regulations.

24.1.4.2 The requirements and provisions of this part apply to each registrant or applicant for registration subject to this part unless specifically exempted, and also apply as appropriate to an equivalent licensee or applicant for a license.

24.1.5 Published Material Incorporated by Reference.

24.1.5.1 Published material incorporated in Part 24 by reference is available in accord with Part 1, Section 1.4.

24.2 Definitions.

As used in Part 24, these terms have the definitions set forth below.

“AAPM Report 46” means “Comprehensive QA for Radiation Oncology”, AAPM Report No. 46 by Task Group 40 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 21, Issue 4, April 1994, pp. 581-618).

“AAPM Report 47” means “AAPM Code of Practice for Radiotherapy Accelerators”, AAPM Report No. 47 by Task Group 45 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 21, Issue 7, July 1994, pp. 1093-1121).

“AAPM Report 82” means “Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT”, AAPM Report No. 82 by the IMRT Subcommittee of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 30, Issue 8, August 2003, pp. 2089-2115).

“AAPM Report 83” means “Quality Assurance for Computed-Tomography Simulators and the Computed Tomography-Simulation Process”, AAPM Report No. 83 by Task Group 66 of the Radiation Therapy Committee of the American Association of Physicists in Medicine (Medical Physics, Vol. 30, Issue 10, October 2003, pp. 2762-2792).

“ADCL” means a dosimetry calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM).

“Added filtration” means addition of a filter to the inherent filtration.

“Authorized user” means an individual who meets the requirements of Appendix 2K.

“Barrier”. See “protective barrier” .

“Beam axis” means, for purposes of Part 24, the axis of rotation of the beam-limiting device.

“Beam limiting device” means a field-defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

“Beam monitoring system” means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

“Beam scattering foil” means a thin piece of material (usually metallic) placed in the beam to spread out a beam of electrons to provide a more uniform electron distribution in the useful beam.

“Bent-beam linear accelerator” means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

“Central axis” means “beam axis” .

“Changeable filter” means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

“Collimator” means, for purposes of Part 24, a physical device that constrains the ionizing radiation.

“Contact therapy system” means a therapeutic radiation machine in which an external source of radiation is a short distance, usually less than five centimeters, from the skin.

“Conventional simulator” . See the first definition under “simulator” .

“Detector” . See “radiation detector” .

“Dose monitor unit” (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Electronic brachytherapy device" means the components of an electronic brachytherapy system that produce and deliver therapeutic radiation, including the x-ray tube, control mechanism, cooling system, and the power source.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"Electronic brachytherapy system" means a therapeutic radiation machine in which an x-ray source is used to irradiate tissue by intracavitory, intraluminal, interstitial, or similar application with the source in contact with, very close to, or at a distance usually less than five centimeters from the body surface.

"External beam radiation therapy system" means a therapeutic radiation machine in which the source of radiation is a certain distance, usually more than five centimeters, from the body.

"Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 24.7.

"Fluoroscopic simulator" . See the first definition under "simulator" .

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

"Half-value layer" (HVL) means the thickness of a specified material needed to reduce a radiation beam to one-half of its original intensity.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the housing assembly.

"Intensity Modulated Radiation Therapy" (IMRT) means radiation therapy using highly modulated spatially non-uniform radiation beam intensities that have been determined by computer-based optimization techniques.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry and collimator move through their full range of motion.

"Lead equivalent" means the thickness of a material that provides the same attenuation, under specified conditions, as lead.

"Leakage radiation" means the portion of ionizing radiation originating from the radiation therapy system that is not part of the useful beam. See "useful beam" .

"Light field" means the area illuminated by light, simulating the radiation field.

"Misadministration" . See "reportable medical event" .

"Mobile Electronic Brachytherapy Service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

"Monitor unit" (MU). See "dose monitor unit".

"Moving beam radiation therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other, while the beam is activated or with any planned change of absorbed dose distribution. It includes, but is not limited to, arc, skip, conformal, and rotational therapy.

"Nominal treatment distance" means:

- (1) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
- (2) For x-ray irradiation, the distance from the virtual source or target-to-isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Operator". See "therapeutic radiation machine operator".

"Patient", for purposes of Part 24, means a human individual or animal to whom machine-produced radiation is delivered for medical therapy.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Periodic quality assurance check" means a procedure performed periodically to ensure that a previous calibration continues to be valid.

"Prescribed dose" means the total dose and dose per fraction intended to a particular point or volume as documented in the written directive.

"Primary dose monitoring system" means a system that will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

"Primary protective barrier" (see "protective barrier").

"Protective barrier" means a barrier of radiation-absorbing material(s) used to reduce radiation exposure. The types of protective barriers include:

- (1) Primary protective barrier, which means the material, excluding filters, placed in the useful beam;
- (2) Secondary protective barrier, which means the material that attenuates stray radiation.

"QE(T)" means a qualified expert medical physicist designated for radiation therapy.

"Registered medical physicist" (RMP) for radiation therapy means an individual who meets the applicable requirements of Appendix 2B and has current Department approval to perform medical physics activities as a registered qualified expert for radiation therapy, designated QE(T), including to design shielding, measure ionizing radiation, and oversee radiation protection and quality assurance at radiation therapy and other medical facilities.

"Radiation detector" means a device that in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation field" . See "useful beam" .

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapist" means an individual who meets the requirements of Appendix 2L.

"Radiation therapy" means the therapeutic application of ionizing radiation to humans or animals for medical, research, or veterinary purposes.

"Radiation therapy physician" means a physician trained to use therapeutic radiation machines on humans.

"Radiation therapy veterinarian" means a veterinarian trained to use therapeutic radiation machines on animals.

"Radiographic simulator" . See the first definition under "simulator" .

"Radiotherapy" . See "radiation therapy" .

"Redundant beam monitoring system" means a combination of two dose-monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

"Reportable medical event" means an event that meets the criteria in 24.6. For purposes of Part 24, "misadministration" is an equivalent term.

"Scattered primary radiation" means radiation that has been deviated in direction only by materials irradiated by the useful beam.

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" . See "protective barrier" .

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"Simulator" (radiation therapy simulation system) means:

- (1) Any radiographic/fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing and reproducing the position and size of the therapeutic irradiation field (also known as a conventional simulator); or
- (2) A computed tomography system, which is used in conjunction with relevant software that recreates the treatment machine, and which allows import, manipulation, display and

storage of images from computed tomography and/or other imaging modalities (also known as a virtual simulator).

"Source-skin distance" (SSD). See "target-skin distance".

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Stray radiation" means the sum of leakage radiation and scattered radiation.

"Target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

"Target-skin distance" (TSD) means the distance measured along the beam axis from the center of the front surface of the x-ray target or the nominal position of the electron source to the surface of the irradiated object or patient.

"Tenth-value layer" (TVL) means the thickness of a specified material needed to reduce a radiation beam to one-tenth of its original intensity.

"Termination of irradiation" means the stopping of irradiation in a manner that will not permit continuance of irradiation without the resetting the operating condition(s) at the control panel.

"Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for radiation therapy, including external beam and electronic brachytherapy systems.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Useful beam" means the portion of ionizing radiation originating from the radiation head of the therapy system intended for therapeutic purposes. See "leakage radiation".

"Virtual simulator". See the second definition under "simulator".

"Virtual source" means a point from which radiation appears to originate.

"Wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam.

"Written directive" means an order in writing for the administration of radiation to a specific human patient or human research subject, in accord with the requirements of 24.6.

"X-ray tube" means any electron tube that is designed to be used primarily for the production of x-rays.

GENERAL REQUIREMENTS

24.3 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

24.3.1 Administrative Controls.

24.3.1.1 Each therapeutic radiation machine shall be registered with the Department.

24.3.1.2 The registrant shall be responsible for directing operation of the therapeutic radiation machine, including designation of each authorized user and/or machine operator.

24.3.1.3 The registrant or the registrant's agent shall ensure that all applicable requirements of Part 24 are met in the operation of the therapeutic radiation machine.

24.3.1.4 A therapeutic radiation machine that does not meet the requirements of Part 24 shall not be used to treat a patient.

24.3.1.5 For a therapeutic radiation machine used only for veterinary applications, the registrant may request exemption from a requirement of Part 24 that is not applicable to the practices of veterinary medicine.

24.3.2 Supervision of Use.

24.3.2.1 Human use of a therapeutic radiation machine shall be by, or under the general supervision of, an authorized user radiation therapy physician who has a current active State of Colorado license to practice the healing arts.

24.3.2.2 The use of a therapeutic radiation machine for veterinary applications shall be by, or under the general supervision of, a radiation therapy veterinarian who has a current active State of Colorado license to practice veterinary medicine.

24.3.3 Training for an Authorized User of a Therapeutic Radiation Machine.

24.3.3.1 The registrant for a therapeutic radiation machine subject to 24.7, 24.8 or 24.12 shall require each authorized user (radiation therapy physician) to meet the requirements of Appendix 2K.

24.3.4 Training for a Radiation Therapy Registered Medical Physicist.

24.3.4.1 The registrant for a therapeutic radiation machine subject to 24.7, 24.8 or 24.12 shall require each radiation therapy Registered Medical Physicist to be registered with the Department for approval as a radiation therapy qualified expert, designated QE(T), on the basis of training and experience in the clinical applications of radiation physics to radiation therapy.

24.3.5 Qualifications of a Therapeutic Radiation Machine Operator.

24.3.5.1 Each individual who will be operating a therapeutic radiation machine for human use shall be:

- (1) An authorized user who meets the requirements of Appendix 2K; or
- (2) An individual, designated by a facility authorized user, who meets the requirements of Appendix 2L, "Radiation Therapist (24.3.5) Adequate Radiation Safety Training and Experience".

24.3.5.2 Each individual who will be operating a therapeutic radiation machine for veterinary use shall meet qualification criteria specified by a radiation therapy veterinarian supervising as provided in 24.3.2.2.

24.3.5.3 The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility.

24.3.5.4 The name and training of each former operator shall be retained for a period of at least two (2) years beyond the last date the individual was authorized to operate a therapeutic radiation machine at that facility.

24.3.6 Written safety procedures and rules shall be developed by a Registered Medical Physicist.

24.3.6.1 These safety procedures and rules and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

24.3.6.2 The operator shall be able to demonstrate familiarity with these safety procedures and rules.

24.3.7 Operating procedures required by 24.7.18 and 24.8.18 shall specify how the Registered Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Registered Medical Physicist can be contacted.

24.3.8 No individual shall be exposed to the useful beam except for medical therapy purposes pursuant to a written directive by an authorized user.

24.3.8.1 Deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes is strictly prohibited.

24.3.9 Each individual associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program.

24.3.10 Record Maintenance and Retention.

24.3.10.1 The registrant shall maintain records, for inspection by the Department, in a separate file or location for each therapeutic radiation machine, including:

- (1) Reports of acceptance testing;
- (2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Part 24, as well as the name(s) of the person(s) who performed such activities;
- (3) Records of maintenance and/or modifications performed on the therapeutic radiation machine, as well as the name(s) of the person(s) who performed such services; and
- (4) Each authorization, in accordance with a written procedure approved by the Registered Medical Physicist, for the return to use of a therapeutic radiation machine after service, repair, or upgrade.

24.3.10.2 All records required by Part 24 shall be retained for a period of at least three (3) years from the date of completion in accordance with Section 2.6.3 of Part 2.

24.4 General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

24.4.1 Protection Surveys.

24.4.1.1 The registrant shall ensure that a radiation protection survey of each facility, new or existing, has been performed with an operable radiation measurement survey instrument calibrated in accordance with 24.11.

- (1) The radiation protection survey shall be performed by, or under the personal supervision of, a Registered Medical Physicist; and
- (2) The radiation protection survey shall verify, with the therapeutic radiation machine in a "BEAM-ON" condition and the machine parameters set to produce the maximum scattering and leakage conditions, that:
 - (a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 4.6.1; and
 - (b) Radiation levels in unrestricted areas do not exceed the limits specified in 4.14.1.

24.4.1.2 In addition to the requirements of 24.4.1.1, a radiation protection survey shall also be performed:

- (1) Prior to the first medical use of each therapeutic radiation machine;
- (2) After making any change in the treatment room shielding;
- (3) After making any change in the location of the therapeutic radiation machine within the treatment room;
- (4) After relocating the therapeutic radiation machine; or
- (5) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels, relative to the levels measured and documented in the last survey, in areas outside the radiation therapy treatment room.

24.4.1.3 The survey record shall indicate all instances where the facility, in the opinion of the Registered Medical Physicist, is in violation of applicable regulations. The survey record shall include:

- (1) The date of the measurement(s);
- (2) The reason the survey is required;
- (3) The name of the manufacturer of the therapeutic radiation machine;
- (4) The model number and serial number of the therapeutic radiation machine;
- (5) The instrument(s), with calibration details, used to measure radiation levels;
- (6) A map of the areas surrounding the treatment room that were surveyed;
- (7) The measured dose rate at several points in each area expressed in microsievert (or millirem) per hour;
- (8) The calculated maximum radiation dose (usually calculated week by week) over a period of one year for each restricted and unrestricted area; and
- (9) The signature of the individual performing or exercising personal supervision of the survey.

24.4.1.4 If the result of a survey required by 24.4.1.1 or 24.4.1.2 indicates any radiation level in excess of the respective limit specified in 24.4.1.1, the registrant shall lock the control in the "OFF" position and not use the unit:

- (1) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
- (2) Until the registrant has received a specific exemption from the Department.

24.4.2 Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program.

24.4.2.1 If the survey required by 24.4.1 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 4.14.1, before beginning the treatment program the registrant shall:

- (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 4.14.1;
- (2) Perform the survey required by 24.4.1 again; and
- (3) Include in the records required by 24.4.4 the results of the initial survey, a description of the modification made to comply with 24.4.2.1, and the results of the second survey; or
- (4) Request and receive an authorization under 4.14.3 allowing radiation levels in unrestricted areas greater than those permitted by 4.14.1.

24.4.3 Dosimetry Equipment.

24.4.3.1 The registrant shall have a calibrated dosimetry system available for use.

- (1) The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL);
- (2) The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration; and
- (3) The dosimetry system shall have been calibrated at an energy range appropriate for the radiation being measured.

24.4.3.2 The registrant shall have available for use a dosimetry system for quality assurance check measurements.

- (1) To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 24.4.3.1.
- (2) This comparison shall have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration.
- (3) The quality assurance check system may be the same system used to meet the requirement in 24.4.3.1.

24.4.3.3 The registrant shall maintain a record of each dosimetry system calibration or (inter)comparison for the duration of the license and/or registration, including for each calibration or (inter)comparison:

- (1) The date;
- (2) The model numbers and serial numbers of the instruments that were calibrated or (inter)compared as required by 24.4.3.1 and 24.4.3.2;
- (3) The correction factors that were determined;
- (4) The names of the individuals who performed the calibration or (inter)comparison; and
- (5) Evidence that:
 - (a) Calibration was performed by the Accredited Dosimetry Calibration Laboratory (ADCL); and / or
 - (b) Calibration or (inter)comparison was performed by, or under the personal supervision of, a Registered Medical Physicist.

24.4.4 Records of Radiation Therapy Surveys and Measurements.

24.4.4.1 The registrant for any therapeutic radiation machine subject to 24.7 or 24.8 shall maintain a copy of the records required in 24.4.1 and 24.4.2 for Department inspection in accordance with 2.6.

24.4.5 Shielding and Safety Design Requirements.

24.4.5.1 Each therapeutic radiation machine subject to 24.7 or 24.8 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 4.6 and 4.14.

24.4.5.2 Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall meet the minimum requirements of Appendix 24A and shall be submitted to a Department-approved qualified expert for radiation therapy for approval prior to actual installation of the therapeutic radiation machine.

24.5 Registered Medical Physicist Support.

24.5.1 In a facility having a therapeutic radiation machine, the Registered Medical Physicist shall perform the following:

- 24.5.1.1 Full calibration(s) required by 24.7.16 and 24.8.19;
- 24.5.1.2 Protection surveys required by 24.4.1;
- 24.5.1.3 Supervision and review of dosimetry;
- 24.5.1.4 Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
- 24.5.1.5 Surveys of residual radioactivity required by 24.8.17;

24.5.1.6 General supervision of quality assurance, including establishing written procedures and reviewing quality assurance checks as required by 24.7.17 and 24.8.20.

24.5.1.7 Consultation with the authorized user in treatment planning, as needed; and

24.5.1.8 Calculations/assessments regarding a reportable medical event.

24.5.2 The Registered Medical Physicist shall be available for problems or emergencies consistent with the procedure specified pursuant to 24.3.7.

24.6 Quality Management Program.

24.6.1 Each registrant or applicant subject to 24.7 or 24.8 shall develop, implement, and maintain a quality management program to ensure that radiation will be administered as directed by the authorized user.

24.6.2 The quality management program shall include provisions for written directives and procedures for administration of radiation.

24.6.2.1 A written directive:

- (1) Shall be dated and signed by a radiation therapy authorized user prior to the administration of radiation;
- (2) Shall contain the human patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions;
- (3) May be revised at the discretion of the authorized user, provided that the revision is written, dated and signed by the authorized user;
- (4) May be subject to oral revision, if because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, and provided that:
 - (a) The oral revision is documented as soon as possible in writing in the patient's record; and
 - (b) A revised written directive is signed by an authorized user within 48 hours of the oral revision; and
- (5) Shall be retained (a copy is acceptable) for 3 years.

24.6.2.2 The registrant shall develop, implement, and maintain written procedures to ensure that:

- (1) Prior to the administration of each course of radiation treatments, the human patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
- (2) Each administration is in accordance with the written directive;
- (3) Radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

- (a) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and
 - (b) Verifying that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units;
- (4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
 - (5) The registrant retains a copy of the treatment administration procedures for the duration of the registration.

24.6.3 Reports and Notifications of Reportable Medical Events.

- 24.6.3.1 A registrant shall report any event resulting from intervention of a human patient or human research subject in which the administration of any beam radiotherapy results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- 24.6.3.2 Other than events that result from intervention by a human patient or human research subject, a registrant shall report any event in which the delivered dose to the prescribed point or volume:
 - (1) Involved the wrong individual or the wrong treatment site; or
 - (2) Involved:
 - (a) A calculated administered dose that differs from the:
 - (i) Total prescribed dose by more than 10 percent of the total prescribed dose, for a total prescribed dose consisting of three (3) or fewer fractions; or
 - (ii) Total prescribed dose by more than 20 percent of the total prescribed dose; or
 - (iii) Weekly prescribed dose by more than 30 percent; and
 - (b) The event also involved:
 - (i) Malfunction or improper placement of any field definition or beam limiting device, including, but not limited to, a collimator, a mask, a diaphragm, a cone, or a block; or
 - (ii) Miscalculation of dose administered to the individual; or
 - (iii) Written facility radiotherapy procedures or protocols not being followed.
- 24.6.3.3 The registrant shall notify the Department by telephone no later than the next calendar day after discovery of the reportable medical event.
- 24.6.3.4 The registrant shall submit a written report to the Department within 15 calendar days after discovery of the reportable medical event pursuant to 24.6, to include:

- (1) The registrant or licensee's name;
- (2) The name of the authorized user who signed the written directive and/or who supervised delivery of the prescribed dose;
- (3) The name(s) of the Registered Medical Physicist(s);
- (4) The name(s) of the radiation therapist(s) (see Appendix 24D);
- (5) A brief description of the event;
- (6) Why the event occurred;
- (7) The room the event occurred in;
- (8) The type of radiotherapy equipment involved in the event;
- (9) Copies of written protocols;
- (10) The effect, if any, on the individual who received the dose;
- (11) Actions, if any, that have been taken, or are planned, to prevent recurrence; and
- (12) Certification that the registrant notified the individual who received the dose (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.

24.6.3.5 The report shall not contain the individual's name or any other information that could lead to identification of the individual who received the dose.

24.6.3.6 The registrant shall provide notification of the reportable medical event, no later than 24 hours after its discovery, to the authorized user (and to the referring physician if other than the authorized user).

24.6.3.7 The registrant shall notify the individual who is the subject of the reportable medical event no later than 24 hours after the reportable medical event is discovered, unless, based on medical judgment, the authorized user informs the registrant in writing that telling the individual would be harmful.

- (1) The registrant shall notify the affected individual as soon as possible if the affected individual cannot be reached within 24 hours.
- (2) The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the reportable medical event, because of any delay in notification.
- (3) To meet the requirements of this section, the notification of the individual who is the subject of the reportable medical event may be made instead to that individual's responsible relative or guardian.
- (4) If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

24.6.3.8 Aside from the notification requirement, nothing in this section affects any rights or duties of registrants, licensees, and physicians in relation to each other, to an individual affected by the reportable medical event, or to that individual's responsible relatives or guardians.

24.6.3.9 A registrant shall retain a record of a reportable medical event for 3 years, containing:

- (1) The registrant's or licensee's name;
- (2) The name of each individual involved;
- (3) The medical records number or equivalent means to identify the individual who is the subject of the reportable medical event;
- (4) A brief description of the event and why it occurred;
- (5) The effect, if any, on any individual who received the dose;
- (6) The actions, if any, taken, or planned, to prevent recurrence; and
- (7) Whether the registrant notified the individual (or the individual's responsible relative or guardian) or, if not, the reason notification was not provided.

24.6.3.10 A copy of the record required under 24.6.3.9 shall be provided to the authorized user(s), if other than the registrant or licensee, within 15 calendar days after discovery of the reportable medical event.

SPECIFIC REQUIREMENTS

24.7 Therapeutic Radiation Machines of Less Than 500 kV.

24.7.1 Leakage Radiation.

24.7.1.1 For each therapeutic radiation machine, the registrant shall determine for all systems the maximum leakage radiation at 5 centimeters from the tube housing assembly, and also at 1 meter from the target for systems > 50 to < 500 kV, or obtain equivalent measured and published data from the manufacturer or by other means acceptable to the Department.

24.7.1.2 When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate:

- (1) For systems 5 to 50 kV, shall not exceed 1 mGy (100 mrad) in any one hour, measured at any position 5 centimeters from the tube housing assembly.
- (2) For systems > 50 to < 500 kV, shall not exceed 1 cGy (1 rad) in any one hour, measured at a distance of 1 meter from the target in any direction.
 - (a) This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters.
 - (b) In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

24.7.1.3 Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

24.7.2 Permanent Beam Limiting Devices.

24.7.2.1 Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

24.7.3 Adjustable or Removable Beam Limiting Devices.

24.7.3.1 All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five (5) percent of the useful beam for the most penetrating beam used.

24.7.3.2 When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

24.7.4 Filter System.

24.7.4.1 The filter system shall be so designed that:

- (1) Filters cannot be accidentally displaced at any possible tube orientation;
- (2) An interlock system prevents irradiation if the proper filter is not in place;
- (3) The air kerma rate escaping from the filter slot shall not exceed 1 cGy (1 rad) per hour at one meter under any operating conditions; and
- (4) Each filter shall be marked as to its material of construction and its thickness.

24.7.5 Tube Immobilization.

24.7.5.1 The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

24.7.5.2 The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

24.7.6 Source Marking.

24.7.6.1 The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

24.7.7 Beam Block.

24.7.7.1 On contact therapy systems, a shield of at least 0.5 millimeters of lead equivalency at 100 kV shall be positioned over the entire useful beam exit port during periods when the tube is energized and the beam is not in use.

24.7.8 Timer.

24.7.8.1 A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

24.7.8.2 The timer required by 24.7.8.1 shall:

- (1) Have a display at the treatment control panel;
- (2) Have a pre-set time selector and an elapsed time or time remaining indicator;
- (3) Be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated;
- (4) Terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
- (5) Permit accurate pre-setting and determination of exposure times as short as one second;
- (6) Not permit an exposure if set at zero;
- (7) Not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
- (8) Be accurate to within one percent of the selected value or one second, whichever is greater.

24.7.9 Control Panel Functions.

24.7.9.1 The control panel, in addition to the displays required by other provisions in 24.7, shall have:

- (1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
- (2) An indication of whether x-rays are being produced;
- (3) A means for indicating x-ray tube potential and current;
- (4) A means for terminating an exposure at any time;
- (5) For therapeutic radiation machines installed after November 30, 1994, a locking device which will prevent unauthorized use of the therapeutic radiation machine; and
- (6) For therapeutic radiation machines manufactured after September 30, 1999, a positive display of specific filter(s) in the beam.

24.7.10 Multiple Tubes.

24.7.10.1 When a control panel may energize more than one x-ray tube:

- (1) Only one x-ray tube shall activate at any time;
- (2) The control panel shall have an indicator that identifies which x-ray tube is activated; and
- (3) An indicator at the tube housing assembly shall identify when that tube is energized.

24.7.11 Target-Skin Distance (TSD).

24.7.11.1 Means shall be provided to determine the central axis TSD to within one centimeter and to reproduce this measurement to within 2 millimeters thereafter.

24.7.12 Shutters.

24.7.12.1 Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds after turning "ON" the x-ray switch to energize the x-ray tube, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

- (1) In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel.
- (2) An indication of shutter position shall appear at the control panel.

24.7.13 Low Filtration X-ray Tubes.

24.7.13.1 Each therapeutic radiation machine equipped with a beryllium or other low-filtration window ($HVL < 0.1$ mm of Al) shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present.

24.7.14 Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV.

24.7.14.1 In addition to shielding adequate to meet requirements of 24.4.5, the treatment room shall meet the following design requirements:

- (1) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel, except for an intraoperative radiotherapy (IORT) room where the patient is under general anesthesia and no staff remain in the room.
- (2) Viewing Systems.
 - (a) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation.
 - (b) The viewing system shall be so located that the operator may observe the patient from the treatment control panel.
 - (b) The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

24.7.15 Additional Requirements.

24.7.15.1 Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

- (1) All protective barriers shall be fixed except for entrance doors or beam interceptors;

- (2) The control panel shall be located outside the treatment room or in a totally enclosed booth;
- (3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
- (4) When any door referred to in 24.7.15.1(3) is opened while the x-ray tube is activated, the air kerma rate in the useful beam at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

24.7.16 Full Calibration Measurements.

24.7.16.1 Full calibration of a therapeutic radiation machine subject to 24.7 shall be performed by, or under the personal supervision of, a Registered Medical Physicist:

- (1) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
- (2) At intervals not exceeding one year; and
- (3) Before medical use under the following conditions:
 - (a) Whenever quality assurance check measurements indicate that the radiation output differs by more than five (5) percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
 - (b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
- (4) Notwithstanding the requirements of 24.7.16.1(3):
 - (a) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - (b) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent use in treatments at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 24.7.16.1(3)(a).

24.7.16.2 To satisfy the requirement of 24.7.16.1, full calibration shall include all measurements recommended for annual calibration by AAPM Report 46, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 46 is not warranted for the clinical tasks for which the equipment will be used.

24.7.16.3 The registrant shall maintain a record of each calibration for the duration of the registration, to include:

- (1) The date of the calibration;

- (2) The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;
- (3) The manufacturer's name, model number and serial number for the instrument(s) used to calibrate the therapeutic radiation machine; and
- (4) The signature of the Registered Medical Physicist performing or exercising personal supervision of the calibration.

24.7.17 Periodic Quality Assurance Checks.

24.7.17.1 Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 24.7, which are capable of operation at greater than or equal to 50 kV.

24.7.17.2 To satisfy the requirement of 24.7.17.1, quality assurance checks shall meet the following requirements:

- (1) The registrant shall perform quality assurance checks in accordance with written procedures established by the Registered Medical Physicist; and
- (2) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed.
 - (a) The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 24.7.16.1.
 - (b) The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 24.7.16.1, shall be stated.

24.7.17.3 The cause for a parameter exceeding a tolerance set by the Registered Medical Physicist shall be investigated and corrected before the system is used for patient irradiation.

24.7.17.4 Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Registered Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in 24.7.16.1.

24.7.17.5 The registrant shall use the dosimetry system described in 24.4.3.2 to make the quality assurance check required in 24.7.17.2.

24.7.17.6 The registrant shall have the Registered Medical Physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed.

24.7.17.7 The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 24.7 are performed at intervals not to exceed one month.

24.7.17.8 Notwithstanding the requirements of 24.7.17.6 and 24.7.17.7, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 24.7.17.6 and 24.7.17.7 have been performed within the 30 day period immediately prior to said administration.

24.7.17.9 To satisfy the requirement of 24.7.17.7, safety quality assurance checks shall ensure proper operation of:

- (1) Electrical interlocks at each radiation therapy room entrance;
- (2) The "BEAM-ON" and termination switches;
- (3) If applicable, beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
- (4) Viewing systems; and
- (5) If applicable, electrically operated treatment room doors from inside and outside the treatment room.

24.7.17.10 The registrant shall maintain a record of each quality assurance check required by 24.7.17.1 and 24.7.17.7 for three (3) years, including:

- (1) The date of the quality assurance check;
- (2) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;
- (3) The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
- (4) The signature of the individual who performed the periodic quality assurance check.

24.7.18 Operating Procedures.

24.7.18.1 The therapeutic radiation machine shall not be used for irradiation of a patient unless the requirements of 24.7.16 and 24.7.17 have been met;

24.7.18.2 Therapeutic radiation machines shall not be left unattended unless secured pursuant to 24.7.9.1(5);

24.7.18.3 When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

24.7.18.4 The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV.

- (1) In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

24.7.18.5 A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

24.7.18.6 No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV.

24.7.18.7 At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 4.6.

24.8 Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).

24.8.1 Facility Design Requirements in Addition to Shielding Required by 24.4.5 and Appendix 24A.

24.8.1.1 All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

24.8.1.2 The control panel, in addition to other requirements specified in Part 24, shall:

- (1) Be located outside the treatment room;
- (2) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
- (3) Provide an indication of whether radiation is being produced; and
- (4) Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

24.8.1.3 Viewing Systems.

- (1) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation.
- (2) The viewing system shall be so located that the operator may observe the patient from the treatment control panel.
- (3) The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

24.8.1.4 Communication.

- (1) Provision shall be made for continuous two-way communication between the patient and the operator at the control panel.
- (2) The therapeutic radiation machine shall not be used for irradiation of a patient unless continuous two-way communication is possible.

24.8.1.5 Room Entrances.

- (1) Each treatment room entrance shall be provided with a warning light, in a readily observable position near the outside of each access door or entrance, that will indicate when the useful beam is "ON" and when it is "OFF".

24.8.1.6 Entrance Interlocks.

- (1) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continue.
- (2) If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

24.8.1.7 Beam Interceptor Interlocks.

- (1) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 4.14.1, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers.

24.8.1.8 Emergency Cutoff Switches.

- (1) At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 24.8.11.
- (2) All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

24.8.1.9 Safety Interlocks.

- (1) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

24.8.2 Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

24.8.2.1 The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

24.8.2.2 Except for the area defined in 24.8.2.1, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

24.8.2.3 For equipment manufactured after September 30, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission, Document 601-2-1, June 1998; and

24.8.2.4 For each therapeutic radiation machine, the registrant shall determine the leakage radiation existing at the positions specified in 24.8.2.1, 24.8.2.2 and 24.8.2.3 for the specified operating conditions, or obtain equivalent measured and published leakage radiation data from the manufacturer or by other means acceptable to the Department.

24.8.2.5 Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

24.8.3 Leakage Radiation Through Beam Limiting Devices.

24.8.3.1 Photon Radiation.

- (1) All adjustable or interchangeable beam limiting devices, excluding secondary custom blocks, shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two (2) percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field;

24.8.3.2 Electron Radiation.

- (1) All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:
 - (a) A maximum of two (2) percent and average of 0.5 percent of the absorbed dose, at dose maximum, on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 7 centimeters outside the periphery of the useful beam; and
 - (b) A maximum of ten (10) percent of the absorbed dose, at dose maximum, on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line 2 centimeters outside the periphery of the useful beam.

24.8.3.3 Measurement of Leakage Radiation.

- (1) Photon Radiation.
 - (a) Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth-value-layers (TVL) of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose.
 - (b) Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;
- (2) Electron Radiation.
 - (a) Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation that has been scattered from material beyond the radiation detector.
 - (b) Measurements shall be made using one centimeter of water equivalent build-up material.

24.8.4 Filters/Wedges.

- 24.8.4.1 Each wedge filter that is removable from the system shall be clearly marked with an identification number.
- 24.8.4.2 For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray).
- 24.8.4.3 If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be re-determined;
- 24.8.4.4 For equipment manufactured after September 30, 1999, which utilizes wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:
- (1) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
 - (2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position as selected by the operator or as required by the energy mode selected by the operator;
 - (3) A display shall be provided at the treatment control panel showing the wedge filter(s); and
 - (4) An interlock shall be provided to prevent irradiation if there is a mismatch between the filter and/or beam scattering foil selected by the operator or required for the energy/modality selected by the operator.

24.8.4.5 If the absorbed dose rate information required by 24.8.9 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such foil or filter shall be removable from the therapeutic radiation machine only by the use of tools;

24.8.5 Stray Radiation in the Useful Beam.

24.8.5.1 The registrant shall determine during acceptance testing, or obtain from the manufacturer or by other means acceptable to the Department, measured and published data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission, Document 601-2-1, June 1998, or equivalent criteria.

24.8.6 Beam Monitors.

24.8.6.1 All therapeutic radiation machines subject to 24.8 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

24.8.6.2 All therapeutic radiation machines subject to 24.8 shall be provided with at least two (2) independently powered integrating dose meters.

- (1) Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.
- (2) Equipment manufactured on or before September 30, 1999, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system.

24.8.6.3 The detector and the system into which that detector is incorporated shall meet the following requirements:

- (1) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
- (2) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
- (3) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and
- (4) The design of the beam monitoring systems shall ensure that the:
 - (a) Malfunctioning of one system shall not affect the correct functioning of the other systems; and
 - (b) Failure of either system shall terminate irradiation or prevent the initiation of radiation;
- (5) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after September 30, 1999, each display shall:
 - (a) Maintain a reading until intentionally reset;
 - (b) Have only one scale and no electrical or mechanical scale multiplying factors;
 - (c) Utilize a design such that increasing dose is displayed by increasing numbers; and
 - (d) In the event of power failure, the beam monitoring information required in 24.8.6.3(5)(c) displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

24.8.7 Beam Symmetry.

24.8.7.1 Bent-beam linear accelerators subject to 24.8 shall be provided with auxiliary device(s) to monitor beam symmetry;

24.8.7.2 The device(s) required in 24.8.7.1 shall be able to detect field asymmetry greater than ten (10) percent; and

24.8.7.3 The device(s) required in 24.8.7.1 shall be configured to terminate irradiation if the specifications in 24.8.7.2 cannot be maintained.

24.8.8 Selection and Display of Dose Monitor Units.

24.8.8.1 Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

24.8.8.2 The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

24.8.8.3 After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

24.8.8.4 For equipment manufactured after September 30, 1999, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

24.8.9 Air Kerma Rate/Absorbed Dose Rate.

24.8.9.1 For equipment manufactured after September 30, 1999, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in 24.8.6 may form part of this system.

24.8.9.2 In addition:

- (1) The dose monitor unit rate shall be displayed at the treatment control panel;
- (2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum;
- (3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and
- (4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer or by other means acceptable to the Department, the maximum value(s) specified in 24.8.9.2 and 24.8.9.3 for the specified operating conditions.

24.8.9.3 The following records shall be maintained at the installation for inspection by the Department:

- (1) The dose rate at which the irradiation will be terminated pursuant to 24.8.9.2(2); and
- (2) The maximum value(s) specified in 24.8.9.2(2) and 24.8.9.2(3).

24.8.10 Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

24.8.10.1 Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

24.8.10.2 If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen (15) percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

24.8.10.3 For equipment manufactured after September 30, 1999, an indicator on the control panel shall show which monitoring system has terminated irradiation.

24.8.11 Termination of Irradiation.

24.8.11.1 It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

24.8.12 Interruption of Irradiation.

24.8.12.1 If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel.

24.8.12.2 Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions.

24.8.12.3 If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

24.8.13 Timer.

24.8.13.1 A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

24.8.13.2 The timer shall:

- (1) Have a display at the treatment control panel;
- (2) Have a pre-set time selector and an elapsed time indicator;
- (3) Be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated;
- (4) Require that the elapsed time indicator be reset after irradiation is terminated and before irradiation can be reinitiated; and
- (5) Terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

24.8.14 Selection of Radiation Type.

24.8.14.1 Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

- (1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
- (2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;
- (3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;
- (4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

- (5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
- (6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

24.8.15 Selection of Energy.

24.8.15.1 Equipment capable of generating radiation beams of different energies shall meet the following requirements:

- (1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
- (2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
- (3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and
- (4) For equipment manufactured after September 30, 1999, the selection of energy shall be in compliance with International Electrotechnical Commission, Document 601-2-1, June 1998.

24.8.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy.

24.8.16.1 Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

- (1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
- (2) The mode of operation shall be displayed at the treatment control panel;
- (3) An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;
- (4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
- (5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement.
 - (a) For equipment manufactured after September 30, 1999:
 - (i) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one cm of linear motion differs by more than twenty (20) percent from the selected value;

- (ii) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five (5) percent from the dose monitor unit value selected;
 - (iii) An interlock shall be provided to prevent motion of more than five (5) degrees or one cm beyond the selected limits during moving beam radiation therapy;
 - (iv) An interlock shall be provided to require that a selection, verification, or display of direction of rotation be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy;
 - (v) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;
- (iv) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 24.8.10; and
- (b) For equipment manufactured after September 30, 1999, an interlock system shall be provided to terminate irradiation if movement:
 - (i) Occurs during stationary beam radiation therapy; or
 - (ii) Does not start or stop during moving beam radiation therapy unless such motion or stoppage is a pre-planned function.

24.8.17 Surveys for Residual Radiation.

24.8.17.1 Prior to machining, removing or working on a therapeutic radiation machine capable of generating photon and electron energies above 10 MV, a survey for residual activity of components that might have become activated due to photo-neutron production shall be conducted if the Registered Medical Physicist determines, consistent with 4.18.1.1, that 10% of the limits in 4.6 might be exceeded.

24.8.18 Operating Procedures.

24.8.18.1 No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

24.8.18.2 Therapeutic radiation machines shall not be made available for medical use unless the requirements of 24.4.1, 24.8.19 and 24.8.20 have been met;

24.8.18.3 Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

24.8.18.4 When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

24.8.18.5 If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

24.8.18.6 A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

24.8.19 Acceptance Testing, Commissioning and Full Calibration Measurements.

24.8.19.1 Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 24.8 shall be performed by, or under the personal supervision of, a Registered Medical Physicist.

24.8.19.2 Acceptance testing and commissioning shall be:

- (1) Performed in accordance with AAPM Report 47, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 47 is not warranted for the clinical tasks for which the equipment will be used; and
- (2) Conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

24.8.19.3 Full calibration shall include measurement of all parameters required by Table II of AAPM Report 46 and shall be performed in accordance with AAPM Report 47, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 46 and/or AAPM Report 47 is not warranted for the clinical tasks for which the equipment will be used.

- (1) Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding twelve (12) calendar months, unless a more frequent interval is required in Table II of AAPM Report 46.

24.8.19.4 All elements of a full calibration necessary to determine that all parameters are within acceptable limits shall be performed by, or under the personal supervision of, a Registered Medical Physicist:

- (1) Whenever quality assurance check measurements indicate that the radiation output differs by more than five (5) percent from the value obtained at the last full calibration and the difference cannot be reconciled.
 - (a) Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and
- (2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
 - (a) If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent use in treatments at the facility.
 - (b) The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 24.8.19.4(1).

24.8.19.5 The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include:

- (1) The date of the calibration;

- (2) The manufacturer's name, model number and serial number for the therapeutic radiation machine;
- (3) The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
- (4) The signature of the Registered Medical Physicist performing or exercising personal supervision of the calibration.

24.8.20 Periodic Quality Assurance Checks.

- 24.8.20.1 Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 24.8 at intervals not to exceed those specified in AAPM Report 46, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 46 is not warranted for the clinical tasks for which the equipment will be used;
- 24.8.20.2 To satisfy the requirement of 24.8.20.1, quality assurance checks shall include determination of central axis radiation output and periodic quality assurance checks contained in AAPM Report 46, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 46 is not warranted for the clinical tasks for which the equipment will be used;
- 24.8.20.3 The registrant shall use the dosimetry system described in 24.4.3.1, or a dosimetry system that has been inter-compared within the previous twelve (12) months with the dosimetry system consistent with 24.4.3.2, to make the periodic quality assurance checks required in 24.8.20.2;
- 24.8.20.4 The registrant shall perform periodic quality assurance checks required by 24.8.20.1 in accordance with procedures and frequencies established by the Registered Medical Physicist;
- 24.8.20.5 The registrant shall review the results of each periodic radiation output check according to the following procedures:
 - (1) The authorized user and/or Registered Medical Physicist shall be immediately notified if any radiation output parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Registered Medical Physicist has determined that all radiation output parameters are within their acceptable tolerances; and
 - (2) If all radiation output check parameters appear to be within their acceptable range, the radiation output check shall be reviewed and signed by either the authorized user or Registered Medical Physicist within three (3) days;
- 24.8.20.6 Safety quality assurance checks listed in AAPM Report 46 shall be performed for therapeutic radiation machines subject to 24.8, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 46 is not warranted for the clinical tasks for which the equipment will be used;
- 24.8.20.7 For therapeutic radiation machines not covered by AAPM Report 46, the following safety quality assurance checks, as applicable to the machines, shall be performed at intervals not to exceed one week:
 - (1) Electrical interlocks at each radiation therapy room entrance;

- (2) Proper operation of the "BEAM-ON" , interrupt and termination switches;
- (3) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
- (4) Viewing systems;
- (5) Electrically operated treatment room door(s) from inside and outside the treatment room; and
- (6) At least one emergency power cutoff switch.
 - (a) If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis.
 - (b) Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

24.8.20.8 The registrant shall promptly repair any system identified in 24.8.20.7 that is not operating properly; and

24.8.20.9 The registrant shall maintain a record of each quality assurance check required by 24.8.20.1 and 24.8.20.7 for three (3) years. The record shall include:

- (1) The date of the quality assurance check;
- (2) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;
- (3) The manufacturer's name, model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and
- (4) The signature of the individual who performed the periodic quality assurance check.

24.8.21 Quality Assurance Checks for Intensity Modulated Radiation Therapy (IMRT) shall:

24.8.21.1 Include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;

24.8.21.2 Be performed in accordance with AAPM Report 82, unless the Registered Medical Physicist determines that a particular recommendation of AAPM Report 82 is not warranted for the clinical tasks for which the equipment will be used; and

24.8.21.3 Be performed in accordance with the manufacturer's specifications.

24.9 Quality Assurance For Radiation Therapy Simulation Systems.

24.9.1 Quality assurance for a radiographic/fluoroscopic or virtual simulator shall include acceptance testing and periodic verification of system performance; and

24.9.2 Be performed (unless the Registered Medical Physicist determines that a particular recommendation is not warranted for the clinical task for which the equipment will be used) in accordance with:

24.9.2.1 AAPM Report 46, for a radiographic/fluoroscopic simulator; or

24.9.2.2 AAPM Report 83 for a virtual simulator.

24.10 Possession of Survey Instrument(s).

24.10.1 Each facility location authorized to use a therapeutic radiation machine in accordance with 24.7 or 24.8 shall possess appropriately calibrated portable radiation monitoring equipment, including:

24.10.1.1 At least one portable radiation measurement survey instrument that is:

- (1) Capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour;
- (2) Operable; and
- (3) Calibrated in accordance with 24.11.

24.11 Calibration of Survey Instruments.

24.11.1 The registrant shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, at intervals not to exceed twenty-four (24) months, and following repair.

24.11.2 To satisfy the requirements of 24.11.1, the registrant shall:

24.11.2.1 Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST); and

24.11.2.2 Calibrate at least two (2) points, at approximately 1/3 and 2/3 of full-scale, on each scale to be calibrated; and

24.11.3 To satisfy the requirements of 24.11.2, the registrant shall:

24.11.3.1 Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten (10) percent; or

24.11.3.2 Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty (20) percent if a correction factor or graph is conspicuously attached to the instrument.

24.11.4 The registrant may obtain the services of individuals licensed by the Department, NRC, an Agreement State, or a Licensing State to perform calibrations of survey instruments.

24.11.5 The registrant shall retain a record of each calibration required in 24.11.1 for three (3) years. The record shall include:

24.11.5.1 A description of the calibration procedure;

24.11.5.2 A description of the source used;

- 24.11.5.3 The certified dose rates from the source;
- 24.11.5.4 The rates indicated by the instrument being calibrated;
- 24.11.5.5 The correction factors deduced from the calibration data;
- 24.11.5.6 The signature of the individual who performed the calibration; and
- 24.11.5.7 The date of calibration.

24.12 Electronic Brachytherapy.

- 24.12.1 Electronic brachytherapy devices shall be subject to the requirements of 24.12, and shall be exempt for the requirements of 24.7.
 - 24.12.1.1 An electronic brachytherapy device that does not meet the requirements of 24.12 shall not be used for irradiation of patients; and
 - 24.12.1.2 An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).
- 24.12.2 Each facility location authorized to use an electronic brachytherapy device in accordance with 24.12 shall possess portable monitoring equipment in accord with 24.10 that is operable and calibrated in accordance with 24.11 for the applicable electronic brachytherapy source energy.
- 24.12.3 In addition to shielding adequate to meet requirements of 24.4.5, the treatment room shall meet the following design requirements:
 - 24.12.3.1 If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
 - 24.12.3.2 Access to the treatment room shall be controlled by a door at each entrance.
 - 24.12.3.3 Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation.
 - 24.12.3.4 For electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielded material around the treatment site.
 - 24.12.3.5 For electronic brachytherapy devices capable of operating at greater than 150 kV:
 - (1) The control panel shall be located outside the treatment room; and
 - (2) Electrical interlocks shall be provided for all door(s) to the treatment room that will:
 - (a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - (b) Cause the source to be shielded when an entrance door is opened; and

- (c) Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

24.12.4 Electrical Safety for Electronic Brachytherapy Devices.

- 24.12.4.1 The high voltage transformer shall be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.
- 24.12.4.2 The high voltage transformer shall be isolated from personnel (e.g., operator) and the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open.
- 24.12.4.3 The high voltage transformer shall have appropriate safety labels warning personnel of potential electrical shock and/or heat related injuries.
- 24.12.4.4 Equipment manufactured after shall be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:
 - (1) IEC 60601-1:1998+A1+A2:1995;
 - (2) IEC 60601-1-2:2001;
 - (3) IEC 60601-2-8:1999; and
 - (4) IEC 60601-2-17:2004.

24.12.5 The control panel, in addition to the displays required by other provisions in 24.12, shall:

- 24.12.5.1 Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
- 24.12.5.2 Provide an indication of whether x rays are being produced;
- 24.12.5.3 Provide a means for indicating electronic brachytherapy source potential and current;
- 24.12.5.4 Provide the means for terminating an exposure at any time; and
- 24.12.5.5 Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

24.12.6 A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

- 24.12.6.1 A timer shall be provided at the treatment control panel and shall indicate planned setting and the time elapsed or remaining;
- 24.12.6.2 The timer shall not permit an exposure if set at zero;
- 24.12.6.3 The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

24.12.6.4 The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

24.12.6.5 The timer shall permit setting of exposure times as short as 0.1 second; and

24.12.6.6 The timer shall be accurate to within one (1) percent of the selected value or 0.1 second, whichever is greater.

24.12.7 Registered Medical Physicist Support.

24.12.7.1 In each facility having an electronic brachytherapy device, a Registered Medical Physicist shall be responsible for:

- (1) Evaluation of the output from the electronic brachytherapy source;
- (2) Generation of the necessary dosimetric information;
- (3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;
- (4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in 24.12.11;
- (5) Consultation with the authorized user in treatment planning, as needed; and
- (6) Performing calculations/assessments regarding patient treatments that may constitute a reportable medical event as provided in 24.6.3.

24.12.7.2 The operating procedures required by 24.12.8 shall specify how the Registered Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Registered Medical Physicist is contacted.

24.12.8 Operating Procedures.

24.12.8.1 Only individuals approved by the authorized user, Radiation Safety Officer, or Registered Medical Physicist shall be present in the treatment room during treatment;

24.12.8.2 Electronic brachytherapy devices shall not be made available for medical use unless the requirements of 24.4.1, 24.12.10 and 24.12.11 have been met;

24.12.8.3 The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

24.12.8.4 During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;

- (1) The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed as provided in 24.12.3.3.

24.12.8.5 If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

24.12.8.6 Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation, including:

- (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
- (2) The names and telephone numbers of the authorized users, the Registered Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

24.12.8.7 A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console;

- (1) If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during device operation;

24.12.8.8 Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Registered Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally;

- (1) If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during device operation; and

24.12.8.9 If the patient suffers injury or dies, the Radiation Safety Officer, or RSO's designee, and an authorized user shall be notified as soon as possible.

24.12.9 Safety Precautions for Electronic Brachytherapy Devices.

24.12.9.1 A Registered Medical Physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

24.12.9.2 An authorized user and a Registered Medical Physicist shall be physically present during the initiation of all human patient treatments involving the electronic brachytherapy device;

24.12.9.3 A Registered Medical Physicist and either an authorized user or a physician or electronic brachytherapy device operator, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all human patient treatments involving the electronic brachytherapy device;

24.12.9.4 When shielding is required by 24.12.3.4, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment. Alternatively, a Registered Medical Physicist shall designate shield locations sufficient to meet the requirements of Part 4 of these regulations for any individual, other than the patient, in the treatment room; and

24.12.9.5 All personnel in the treatment room are required to remain behind shielding during treatment. A Registered Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

24.12.10 Electronic Brachytherapy Source Calibration Measurements.

24.12.10.1 Calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject to 24.12 shall be performed by, or under the direct supervision of, a Registered Medical Physicist;

24.12.10.2 Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

24.12.10.3 Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in 24.4.3.

24.12.10.4 Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

- (1) The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;
- (2) Timer accuracy and linearity over the typical range of use;
- (3) Proper operation of back-up exposure control devices;
- (4) Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and
- (5) Source positioning accuracy to within one (1) millimeter within the applicator;

24.12.10.5 Calibration of the x-ray source output required by 24.12.10.1 through 24.12.10.4 shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

24.12.10.6 The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration, including the:

- (1) Date of the calibration;
- (2) Manufacturer's name, model number and serial number for the electronic brachytherapy device;
- (3) Unique identifier for the corresponding electronic brachytherapy source;
- (4) Model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and
- (5) Name and signature of the Registered Medical Physicist responsible for performing the calibration.

24.12.11 Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.

24.12.11.1 Quality assurance checks shall be performed on each electronic brachytherapy device subject to 24.12:

- (1) At the beginning of each day of use;

- (2) Each time the device is moved to a new room or site; and
- (3) After each x-ray tube installation.

24.12.11.2 The registrant shall perform periodic quality assurance checks required by 24.12.11.1 in accordance with procedures established by the Registered Medical Physicist;

24.12.11.3 To satisfy the requirements of 24.12.11.1, radiation output quality assurance checks shall include as a minimum:

- (1) Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:
 - (a) Output as a function of time, or
 - (b) Output as a function of setting on a monitor chamber.
- (2) Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by 24.12.10.; and
- (3) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one (1) mm; and

24.12.11.4 The registrant shall use a dosimetry system that has been intercompared within the previous twelve (12) months with the dosimetry system described in 24.4.3.1 to make the quality assurance checks required in 24.12.11.3.

24.12.11.5 The registrant shall review the results of each radiation output quality assurance check according to the following procedures:

- (1) An authorized user and Registered Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Registered Medical Physicist has determined that all parameters are within their acceptable tolerances;
- (2) If all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Registered Medical Physicist within two (2) days; and
- (3) The Registered Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed thirty (30) days.

24.12.11.6 To satisfy the requirements of 24.12.11.1 safety device quality assurance checks shall, at a minimum, assure:

- (1) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
- (2) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
- (3) Proper operation of radiation monitors, if applicable;

- (4) The integrity of all cables, catheters or parts of the device that carry high voltages; and
- (5) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

24.12.11.7 If the results of the safety device quality assurance checks required in 24.12.11.6 indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

24.12.11.8 The registrant shall maintain a record of each quality assurance check required by 24.12.11.3 and 24.12.11.7 in an auditable form for three (3) years.

- (1) The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Registered Medical Physicist who reviewed the quality assurance check;
- (2) For radiation output quality assurance checks required by 24.12.11.3, the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the electronic brachytherapy device.

24.12.12 Therapy-Related Computer Systems.

24.12.12.1 The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available).

- (1) In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

24.12.12.2 Acceptance testing shall be performed by, or under the direct supervision of, a Registered Medical Physicist and shall include at a minimum, as applicable, verification of:

- (1) The source-specific input parameters required by the dose calculation algorithm;
- (2) The accuracy of dose, dwell time, and treatment time calculations at representative points;
- (3) The accuracy of isodose plots and graphic displays;
- (4) The accuracy of the software used to determine radiation source positions from radiographic images; and
- (5) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

24.12.12.3 The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

24.12.12.4 Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the authorized user and the Registered Medical Physicist for correctness through means independent of that used for the determination of the parameters.

24.12.13 A registrant providing mobile electronic brachytherapy service shall, as a minimum:

24.12.13.1 Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.

24.12.13.2 Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.

24.12.13.3 Perform, at each location on each day of use, all of the required quality assurance checks specified in 24.12.11 to assure proper operation of the device.

PART 24, APPENDIX 24A:

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

24A.1 All Therapeutic Radiation Machines.

24A.1.1 Basic facility information including: name, telephone number and facility registration number; registration number of the individual preparing the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

24A.1.2 All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

24A.1.3 Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

24A.2 Therapeutic Radiation Machines Up To 150 kV (photons only).

In addition to the requirements listed in 24A.1 above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

24A.2.1 Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

24A.2.2 Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time or monitor units (MU) per day or week, the average treatment time or monitor units (MU) per patient, along with the anticipated number of patients to be treated per day or week;

24A.2.3 A facility drawing to scale indicating: the direction of North; normal location of the therapeutic radiation machine's radiation port(s); each port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 4.6;

- 24A.2.4 The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- 24A.2.5 The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and
- 24A.2.6 At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry doors) and shielding material in the facility:
- (1) If commercial software is used to generate shielding requirements, the software used and the version/ revision date shall be identified; or
 - (2) If the software used to generate shielding requirements is not in the open literature or commercially available, quality control sample calculations to verify the result obtained with the software shall be identified.
- 24A.3 Therapeutic Radiation Machines Over 150 kV.**
- In addition to the requirements listed in 24A.1 above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:
- 24A.3.1 Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (photon, electron). The target to isocenter distance shall be specified;
- 24A.3.2 Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- 24A.3.3 Facility drawing to scale [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze;
- 24A.3.4 The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- 24A.3.5 The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and
- 24A.3.6 At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility:
- (1) If commercial software is used to generate shielding requirements, identify the software used and the version/ revision date; or
 - (2) If the software used to generate shielding requirements is not in the open literature or commercially available, submit quality control sample calculations to verify the result obtained with the software.

24A.4 Neutron Shielding

In addition to the requirements listed in 24A.3 above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

- 24A.4.1 The structural composition, thickness, minimum density and location of all neutron shielding material;
- 24A.4.2 Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;
- 24A.4.3 At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e.: restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility:
 - (1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; or
 - (2) If the software used to generate shielding requirements is not in the open literature or commercially available, submit quality control sample calculations to verify the result obtained with the software; and
- 24A.4.4 The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

Editor's Notes

6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

History

[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]



Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

6 CCR 1011-1, Chapter III

**STATE BOARD OF HEALTH
GENERAL BUILDING AND FIRE SAFETY
(Last Amended April 17, 1996, effective June 30, 1996)**

CHAPTER III

CHAPTER III - GENERAL BUILDING AND FIRE SAFETY

1. CONSTRUCTION STANDARDS. All buildings housing health facilities licensed by the Colorado Department of Public Health And Environment shall conform to the standards listed herein.
2. SITE. All-weather roads and walks shall be provided within the lot lines to the main, service, and ambulance entrances.

The site of any health facility should be reasonably accessible to the population served. Public transportation should be available, especially if an outpatient service is to be maintained.

The site should not be near insect breeding areas, industrial developments, airports, railways, or highways producing noise, nuisance or air pollution, or other objectional facilities or businesses.
3. PARKING. Parking space shall be conveniently available for staff, visitors, and service vehicles.

A ratio of two parking spaces per patient bed is recommended.
4. CODES AND REGULATIONS. The following codes and regulations (on file at the Colorado Department of Public Health and Environment, Health Facilities Division) must be observed insofar as they are not in conflict with the other sections of these standards: 1) National Fire Protection Association. Building Exit Code 1963, excluding paragraphs 2350 to 2376. 2) International Conference of Building Officials, Uniform Building Code, Vol. 1, 1964. 3.) USPHS, Public Health Service Regulations, Part 53, Pertaining to the Construction and Modernization of Hospitals and Medical Facilities, "Sub-part N" (Appendix A), Dec. 29, 1964; 4)

National Fire Protective Association:
Bulletin No. 10 - Portable Extinguishers, 1962

 - 14 - Standpipe-Hose Systems, 1952
 - 30 - Flammable Liquids Code, 1963
 - 31 - Oil Burning Equipment, 1964
 - 37 - Combustion Engines, 1963
 - 55 - Gas Shut-off, 1924
 - 56 - Flammable Anesthetics, 1962
 - 565 - Nonflammable Medical Gases, 1962
 - 58 - L. P. Gas Storage, Use, 1963
 - 70 - National Electrical Code, 1962
 - 71 - Central Station Signal, 1962
 - 72 - Proprietary Signal System, 1962
 - 72C - Remote Station Systems, 1962
 - 76 - Hospital Electrical Service, 1962
 - 82 - Incinerators, 1960
 - 82A - Rubbish, 1948
 - 90A - Air Conditioning System, 1962
 - 96 - Ventilation Restaurant Cooking Equipment, 1964
 - 241 - Building Construction Operation, 1958
 - 255 - Flamespread Tests, 1961

Colorado Department of Health: Technical Plumbing Code, amended 1961, Restaurant Sanitation Code, amended 1959. 6) Colorado State Industrial Commission Boiler Code, amended 1961, 7) National Bureau of Standards: Handbook 73, Protection Against Radiations from Sealed Gamma Sources, 1960; Handbook 76, Medical X-ray Protection Up to Three Million Volts, 1961. 8) All other applicable local codes and regulations.
5. NEW CONSTRUCTION, ADDITIONS, CONVERSIONS.
 - 5.1 Buildings erected after the adoption date of these standards, and additions thereto, shall comply with all requirements for new buildings.

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- 5.2 Each addition to a new or an existing building converted to health facility use, shall be such that the entire resulting building conforms to all requirements of these standards.
- 5.3 No building shall be converted to a health facility unless it complies with all requirements for new buildings and meets specified standards for patient services to be rendered.
6. **OCCUPANCY.** Occupancies not essential to the functions of a health facility are prohibited therein, with the exception of residence facilities for personnel required to live in the building.
7. **LOCATION ON PROPERTY.** Fire protection requirements for exterior walls and wall openings, based on the location on the property, shall be as specified in section 504 of the Uniform Building Code.
8. **AREAS OF BUILDINGS.** Floor areas of buildings for fire separation shall be specified in Sections 505 and 506 of the Uniform Building Code.
9. **FOUNDATIONS.** Foundations shall rest on natural solid ground and shall be carried to a depth of not less than one foot below the estimated frost line or shall rest on leveled rock or load-bearing piles, when solid ground is not encountered.* Footings, piers, and foundation walls shall be adequately protected against deterioration from the action of ground water. Proper bearing values for the soil shall be established in accordance with recognized standards.
10. **DESIGN.**
 - 10.1 General. The buildings and all parts thereof shall be of sufficient strength to support all dead, live, and lateral loads without exceeding the working stresses permitted for the materials of their construction in the applicable code.
 - 10.2 Special. Special provision shall be made for machine or apparatus loads which would cause a greater stress than that produced by the specified minimum live load, with due consideration of vibration or impact resulting from operation of such equipment (e.g., some portable x-ray machines weigh as much as 1,000 pounds). Consideration shall be given to structural members and connections of structures which may be subject to hurricanes, tornadoes, and earthquakes. Suitable allowance shall be made for future partition changes.
 - 10.3 Live Loads. The following unit live loads shall be taken as the minimum uniformly distributed live loads for the occupancies listed: 1) Patient bedrooms and all adjoining service rooms which comprise a typical patient care unit (except solaria and corridors) - 40 p.s.f.; 2) Solaria, corridors above the first floor, operating suites, examination and treatment rooms, laboratories, toilets, and locker rooms - 60 p.s.f.; 3) Corridors on first floor, waiting rooms and similar public areas, offices, conference room, library, kitchen and radiographic room - 80 p.s.f.; 4) Stairways, laundry, large rooms used for dining, recreation or assembly purposes, work shops - 100 p.s.f.; 5) Records, file room, storage, supply - 125 p.s.f.; 6) Mechanical equipment room (unless actual equipment loads are accurately determined) 150 p.s.f.; 7) Roofs (except use increased value where snow and ice may occur) - 20 p.s.f.; 8) Wind - as required by local conditions, but not less than 15 p.s.f.

*Not required for existing facilities

11. **FIRE RESISTIVE CONSTRUCTION.**
 - 11.1 Where one-hour fire resistive construction throughout is required by these standards, an approved automatic fire-extinguishing system may not be substituted.
 - 11.2 One-story buildings shall be constructed of not less than one-hour fire resistive construction throughout, except that if used to house or treat mentally retarded or mentally ill patients, one-story buildings shall in addition be constructed of noncombustible materials.
 - 11.3 Buildings more than one-story in height shall be constructed of noncombustible materials, using a structural framework of reinforced concrete or structural steel except that load-bearing masonry walls and piers may be used in buildings up to and including three stories. Basements shall be counted a story if the finished floor level directly above a basement or cellar is more than six feet above grade. Grade (ground level) is the average of the finished ground level at the center of all walls of a building. If walls are parallel to and within five (5) feet of a sidewalk, alley or other public way, the above ground levels shall be measured at the elevation of the sidewalk, alley or public way.
 - 11.4 Interior non-load bearing partitions, other than those enclosing corridors and vertical shafts, may be of noncombustible construction without a fire-resistive rating.

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- 11.5 All walls enclosing stairways, elevators, laundry and trash chutes, and other vertical shafts, in buildings of more than one-story, and all boiler rooms and rooms used for the storage of combustible materials shall be of two-hour fire resistive noncombustible construction.
- 12 EXITS.
- 12.1 All exit facilities shall be in accordance with the Building Exits Code. (Except paragraphs 2350 50 2376 inclusive, Existing Hospitals and Nursing Homes).
- 12.2 In new construction, only the following types of exits will be permitted: 1) Doors; 2) Stairs and smokeproof towers; 3) Ramps; 4) Horizontal exits. In existing buildings, fire escape stairs, Class A or B, in addition to the above types of exits, will be permitted.
- 12.3 At least two exits of the above type, remote from each other, shall be provided for each floor or fire section shall be of type 1 or 2 as listed above. In new buildings, stairs must be class A. See Building Exits Code, par. 3311). Class A stairways must be forty-four (44) inches wide. The width shall be measured between handrails when handrails project more than 3-1/2 inches.
- 12.4 Basements used only for service to the building, and every boiler room and every room containing and incinerator or L.P. gas or liquid fuel-fired equipment, shall have at least two means of egress, one of which may be a ladder.
- 12.5 Basement exits for patients shall discharge directly outdoors without the necessity for use of interior stairs connecting with the story above.
- 12.6 Elevators, if for patient use, must have a platform size of 5'4"x8'. Door openings must be 3' 10" wide.
- 12.7 Every patient room shall have a doorway opening directly to a patient corridor.
- 12.8 Corridors and passageways to be used as a means of exit, or part of a means of exit, shall be unobstructed and shall not lead through any room or space used for a purpose that may obstruct free passage.
- 12.9 Exits shall be so placed that the entrance door of every patient room, day rooms, dormitories, dining rooms and other areas shall be not more than one hundred (100) feet (along line of travel) from the nearest exit. In buildings completely protected by a standard automatic sprinkler system, the distance may be one hundred and fifty (150) feet.
- 12.10 Corridor widths.
- 12.10.1 Corridors located in areas housing bed patients, and providing egress therefrom, shall be eight(8) feet in clear width. This width may be narrowed to 7'6" by corridor railings or other projections. A greater width should be provided at elevator entrances.
- 12.10.2 Horizontal exits and smoke stop doors at least forty-four (44) inches in width are permitted in corridors.
- 12.10.3 New buildings shall be so designed that all patient beds can be rolled into exits.
- 12.10.4 In existing buildings, corridors in areas housing bedridden patients, and providing egress therefrom, shall be at least five (5) feet wide.
- 12.11 Dead Ends. Exits shall be so arranged that there are no pockets or dead ends exceeding thirty (30) feet in which occupants may be trapped.
- 12.12 No door shall swing into a corridor except closet doors.
- 12.13 Door widths shall be 3'8" clear widths (4'0" preferable) at all: 1) Bedrooms; 2) Treatment rooms; 3) Operating rooms; 4) X-ray therapy rooms; 5) Delivery rooms; 6) Solariums; 7) X-ray rooms; 8) Physical therapy rooms; 9) Labor rooms. In existing buildings exit doorways and doorways to the above areas shall be at least thirty-two (32) inches in clear width. Exit doors so located as not to be subject to use by patients may not be less than twenty-eight (28) inches wide.
- 12.14 Horizontal Exits. Horizontal exits shall be in accordance with Section 30 or the Building Exits Code and shall be at least forty-four (44) inches in clear width. Doors need not swing with exit travel. In existing buildings, wall of one-hour fire-resistive construction may be used in connection with horizontal exits.
13. PROTECTION

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- 13.1 Each floor used for sleeping rooms for more than thirty (30) patients, unless provided with a horizontal exit, shall be divided into at least two fire sections by a smoke stop partition having at least a one-hour fire-resistance rating. (A one-half hour fire resistance rating is permitted for existing buildings.) Such a partition shall be continuous through any concealed space such as between the ceiling and the floor or roof above.
- 13.2 Openings in smoke stop partitions shall have three-quarter hour fire doors (metal, metal covered, or approved treated wood construction). Smoke stop doors shall be so installed that they may be left in open position but will close automatically in case of fire by arrangements which are in accordance with Section 3209 of the Building Exits Code or by heat sensitive releases, and may be released manually to self-closing action. Such doors need not swing with exit travel.
- 13.3 Any openings in smoke stop partitions or doors shall be protected by fixed wire glass panels, or by rated louvers.
- 13.4 In unsprinkled buildings, no more than one hundred and fifty (150) feet of corridor without horizontal exit or smoke stop doors shall be permitted.
- 13.5 Glass on corridors, except directly to the outside, must be one-fourth inch wire glass set in approved metal stops.
- 13.6 Doors opening on corridors must be wood solid core, or better.
- 13.7 Protection of Vertical Openings. All stairways, elevator shafts, chutes and other openings between different stories or floor levels shall be enclosed or protected to prevent the spread of fire or smoke (See Section 11.5).
- 13.8 Doors in stairway enclosures shall be one and one-half hour B label, fire rated doors, and shall be self-closing and shall be kept in closed position except as otherwise permitted by Section 3209 of the Building Exits Code.
- 13.9 No laundry, trash, or other chute, or incinerator flue shall open directly on any exit, or corridor to an exit. A separate room or closet separated from the exit or corridor by an approved self-closing fire door shall be used.* Laundry chutes, where used, must be 2'0" minimum diameter.*

*Not required in existing facilities.

- 13.10 All incinerator flues, rubbish chutes, and linen or laundry chutes shall be of standard type properly designed and maintained for fire safety according to N.F.P.A. Standard No. 82, Incinerators, 1960. (This standard applies to rubbish, linen and laundry chutes).
- 13.11 In new construction, all chutes other than incinerator chutes shall be provided with automatic sprinkler protection.
14. X-RAY PROTECTION.
 - 14.1 X-ray rooms, surgeries, cystoscopic rooms and other areas containing x-ray producing equipment, other than mobile equipment, shall have ray protection as recommended by Handbooks No. 73 and 76 of the National Bureau of Standards.
 - 14.2 All Radioisotopes. Rooms or areas where radioisotopes are used or stored, shall have the ray protection necessary to limit the radiation in occupied areas to those levels required by the Atomic Energy Commission. The methods for determining radiation barriers shall be those established in the applicable handbook of the National Bureau of Standards.
 - 14.3 X-ray Equipment. X-ray equipment and installation shall comply with recommendations contained in the National Electrical Code and Handbooks, Nos. 73 and 76 of the National Bureau of Standards.
15. WINDOWS.
 - 15.1 For patient rooms customarily used by patients or personnel shall have windows or be supplied by mechanical ventilation as required by Section 19.4, Chapter IV or these standards.
 - 15.2 For patient room windows see Section 19.4, Chapter IV of these standards.
 - 15.3 For purposes of evacuation, the window sills of one-story buildings constructed of other than noncombustible materials shall be not more than six feet above ground level.
16. INTERIOR FINISHES.

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- 16.1 Floors. The floors of the following areas shall have smooth, waterproof surfaces which are wear resistant: 1) Toilets; 2) Baths; 3) Bedpan rooms; 4) Floor pantries; 5) Utility rooms; 6) Treatment rooms; 7) Sterilizing rooms; 8) Janitor's closets; 9) Elevators; 10) Chute anterooms; 11) Central supply rooms; 12) Clean or soiled linen storage rooms; 13) Storage in patient areas; 14) Lobbies; 15) Waiting rooms; 16) Corridors; 17) Nurses' station; 18) Patient rooms; 19) Medicine preparation room; 20) X-ray suite; 21) Operating suite; 22) Delivery suite; 23) Emergency suite; 24) Nursery suite; 25) Dining rooms; 26) meeting rooms.
- 16.2 Carpeting may be used in administrative areas and other areas as approved by the state Health Department.
- 16.3 The floors of the following areas shall be waterproof, greaseproof, smooth and resistant to heavy wear: 1) Kitchens; 2) Butcher rooms; 3) Food preparation; 4) Formula rooms; 5) Dishwashing rooms.
- 16.4 Floors in anesthetizing areas and in rooms used for storage of flammable anesthetic agents in surgical areas shall be conductive as required by the N.F.P.A. no. 56, Code for Use of Flammable Anesthetics, 1962.
- 16.5 The walls of the following areas shall have a smooth or smooth textured surface with painted or equal washable finish. At the base they shall be waterproof and free from spaces which may harbor insects or dirt: 1) Patient rooms; 2) Corridors; 3) Nurses' station; 4) X-ray room; 5) Clean storage areas.
- 16.6 The walls of the following areas shall have waterproof painted, glazed or similar finishes. At the base they shall be free from spaces which may harbor insects or dirt: 1) Kitchens; 2) Pantries; 3) Utility rooms; 4) Toilets; 5) Baths; 6) Showers; 7) Dishwashing rooms; 8) Janitor's closets; 9) Sterilizing rooms; 10) Spaces with sinks; 11) Treatment rooms; 12) Delivery suite; 13) Operating suite; 14) Nursery suite; 15) Emergency suite; 16) Dark rooms; 17) Chute anterooms; 18) Central supply rooms; 19) Medicine preparation rooms; 20) Soiled linen holding rooms; 21) Laboratories; 22) Autopsy rooms.
- 16.7 Ceilings. The ceilings of the following areas shall be painted with waterproof paint. The first three shall have a surface that is unbroken except for lighting, ventilation, or other necessary services: 1) Operating rooms; 2) Delivery rooms; 3) Emergency rooms; 4) All rooms where food and drink is prepared; 5) Dishwash room; 6) Toilets; 7) Baths; 8) Showers; 9) Janitor closets; 10) Patient rooms; 11) Central anterooms; 12) Clinical examination and treatment rooms; 13) Nursery suite; 14) Medicine preparation area; 15) Darkrooms; 16) Radiological suite; 17) Chute anterooms; 18) Clean holding areas; 19) Soiled holding areas; 20) Laboratories; 21) Autopsy rooms; 22) Clean storage areas; 23) Surgical suite; 24) Delivery suite; 25) Emergency suite; 26) Laundry rooms.
- 16.8 The ceilings of the following areas shall be acoustically treated: 1) Corridors in patient areas; 2) Nurses stations; 3) Labor rooms; 4) Floor pantries.
17. FLAME SPREAD.
- 17.1 Interior finish of all exit ways, storage rooms and all areas of unusual fire hazard shall have a flame spread rating of less than 20.
- 17.2 Interior finish of patient rooms, patient day rooms and other areas occupied by patients shall have a flame spread rating of less than 75.
- 17.3 Interior finish of other areas shall have a flame spread rating of less than 75 except that ten percent of the aggregate wall and ceiling areas of any space may have a flame spread rating up to 200.
- 17.4 Interior finish materials shall be classified in accordance with their average flame spread rating on the basis of tests conducted in accordance with ASTM Standard No. E84.
18. CEILING HEIGHTS AND CEILING INSULATION.
- 18.1 Ceiling heights and ceiling insulation for all health facilities shall be as specified in the Public Health Service Regulations, Sub-part N. Par. 53.160 with the following exceptions:
- Ceiling heights specified above for boiler rooms, laundry rooms, and kitchens, are required only in new hospitals.
 - Boiler room ceilings must be at least 5 feet higher than the top of any boiler unit.
 - Kitchen ceiling heights may be no less than 9'0".
19. UTILITIES.

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- 19.1 Requirements for the following categories shall be as specified in the Public Health Service Regulations, Sub-part N, Par. 53.163 or elsewhere in these standards: 1) Heating; 2) Ventilation; 3) Plumbing; 4) Plumbing fixtures and fittings; 5) Water supply; 6) Drainage; 7) Gas piping and appliances; 8) Oxygen systems; 9) Sterilizers; 10) Electrical installations; 11) Elevators and Dumbwaiters; 12) Refrigerators; 13) Kitchen equipment; 14) Laundry.
- 19.2 Ventilation. Exhaust air shall be discharged from the building remote from fresh air intakes.
- 19.3 Water Supply. The water supply system shall be from a municipal water supply system or other system approved by the State Health Department as meeting the Standards for the Quality of Water Supplied to the Public, published by the Colorado Department of Health.
- 19.4 Chemical properties of the water should be such as to prevent caking of deposits in and corrosion of the plumbing system and undesirable depositing of salts from water evaporation.
- 19.5 Electrical Service. The provisions of N.F.P.A. standard No. 76, Essential Hospital Electrical Service, shall be complied with as follows:
 - a. The Emergency Electrical System shall be Type I as defined in the Building exits Code No. 101, Sec. 52.
 - b. The Critical Electrical System I (Automatic Restoration) shall include the recommended areas and functions.
 - c. Critical Electrical System II (Delayed Automatic Restoration) shall include the recommended areas and functions and partial use of elevators and vertical conveyors.
20. FIRE PREVENTION AND DRILLS.
There shall be a written program of Fire Prevention, Fire Exit Drill, and Evacuation for all Health Facilities. The program shall define policies, procedures, and the responsibilities and duties of personnel. All personnel shall be instructed and trained concerning their duties under the program. Fire Exit Drills shall be conducted at regular intervals.
21. SUBMISSION AND APPROVAL OF BUILDING PLANS AND SPECIFICATIONS.
Plans and drawings for all buildings to be built, added to, or altered, to house facilities licensed by the Department of Public Health And Environment shall be submitted to the department for approval in the following sequence prior to the start of construction:
 - 21.1 A written program describing the objectives of the sponsoring organization, and the type and size of service or services to be provided in the proposed facility.
 - 21.2 Preliminary drawings showing the proposed general location, boundaries, approaches to and physical features of the site, other buildings on the site, means or water supply, sewage disposal, and other utilities to the site. The preliminary drawings shall also show the proposed layout of each floor of the facility with each room labeled as to its use, and a general cross section of the structure indicating type of construction.
 - 21.3 Outline specifications indicating important electrical, mechanical, and other features not shown on drawings.
 - 21.4 Final working drawings and specifications. These must be approved before construction is begun, and should not be commenced before detail plans.

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CHAPTER III
GENERAL BUILDING AND FIRE SAFETY

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OCR PRIVACY BRIEF

SUMMARY OF THE HIPAA PRIVACY RULE



HIPAA Compliance Assistance

SUMMARY OF THE HIPAA PRIVACY RULE

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SUMMARY OF THE HIPAA PRIVACY RULE

Introduction	<p>The <i>Standards for Privacy of Individually Identifiable Health Information</i> (“Privacy Rule”) establishes, for the first time, a set of national standards for the protection of certain health information. The U.S. Department of Health and Human Services (“HHS”) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).¹ The Privacy Rule standards address the use and disclosure of individuals’ health information—called “protected health information” by organizations subject to the Privacy Rule — called “covered entities,” as well as standards for individuals’ privacy rights to understand and control how their health information is used. Within HHS, the Office for Civil Rights (“OCR”) has responsibility for implementing and enforcing the Privacy Rule with respect to voluntary compliance activities and civil money penalties.</p> <p>A major goal of the Privacy Rule is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being. The Rule strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing. Given that the health care marketplace is diverse, the Rule is designed to be flexible and comprehensive to cover the variety of uses and disclosures that need to be addressed.</p> <p>This is a summary of key elements of the Privacy Rule and not a complete or comprehensive guide to compliance. Entities regulated by the Rule are obligated to comply with all of its applicable requirements and should not rely on this summary as a source of legal information or advice. To make it easier for entities to review the complete requirements of the Rule, provisions of the Rule referenced in this summary are cited in notes at the end of this document. To view the entire Rule, and for other additional helpful information about how it applies, see the OCR website: http://www.hhs.gov/ocr/hipaa. In the event of a conflict between this summary and the Rule, the Rule governs.</p> <p>Links to the OCR Guidance Document are provided throughout this paper. Provisions of the Rule referenced in this summary are cited in endnotes at the end of this document. To review the entire Rule itself, and for other additional helpful information about how it applies, see the OCR website: http://www.hhs.gov/ocr/hipaa.</p>
Statutory & Regulatory Background	<p>The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. Sections 261 through 264 of HIPAA require the Secretary of HHS to publicize standards for the electronic exchange, privacy and security of health information. Collectively these are known as the <i>Administrative Simplification</i> provisions.</p> <p>HIPAA required the Secretary to issue privacy regulations governing individually identifiable health information, if Congress did not enact privacy legislation within</p>

	<p>three years of the passage of HIPAA. Because Congress did not enact privacy legislation, HHS developed a proposed rule and released it for public comment on November 3, 1999. The Department received over 52,000 public comments. The final regulation, the Privacy Rule, was published December 28, 2000.²</p> <p>In March 2002, the Department proposed and released for public comment modifications to the Privacy Rule. The Department received over 11,000 comments. The final modifications were published in final form on August 14, 2002.³ A text combining the final regulation and the modifications can be found at 45 CFR Part 160 and Part 164, Subparts A and E on the OCR website: http://www.hhs.gov/ocr/hipaa.</p>
Who is Covered by the Privacy Rule	<p>The Privacy Rule, as well as all the Administrative Simplification rules, apply to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA (the “covered entities”). For help in determining whether you are covered, use the decision tool at: http://www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp.</p> <p>Health Plans. Individual and group plans that provide or pay the cost of medical care are covered entities.⁴ Health plans include health, dental, vision, and prescription drug insurers, health maintenance organizations (“HMOs”), Medicare, Medicaid, Medicare+Choice and Medicare supplement insurers, and long-term care insurers (excluding nursing home fixed-indemnity policies). Health plans also include employer-sponsored group health plans, government and church-sponsored health plans, and multi-employer health plans. There are exceptions—a group health plan with less than 50 participants that is administered solely by the employer that established and maintains the plan is not a covered entity. Two types of government-funded programs are not health plans: (1) those whose principal purpose is not providing or paying the cost of health care, such as the food stamps program; and (2) those programs whose principal activity is directly providing health care, such as a community health center,⁵ or the making of grants to fund the direct provision of health care. Certain types of insurance entities are also not health plans, including entities providing only workers’ compensation, automobile insurance, and property and casualty insurance.</p> <p>Health Care Providers. Every health care provider, regardless of size, who electronically transmits health information in connection with certain transactions, is a covered entity. These transactions include claims, benefit eligibility inquiries, referral authorization requests, or other transactions for which HHS has established standards under the HIPAA Transactions Rule.⁶ Using electronic technology, such as email, does not mean a health care provider is a covered entity; the transmission must be in connection with a standard transaction. The Privacy Rule covers a health care provider whether it electronically transmits these transactions directly or uses a billing service or other third party to do so on its behalf. Health care providers include all “providers of services” (e.g., institutional providers such as hospitals) and “providers of medical or health services” (e.g., non-institutional providers such as physicians, dentists and other practitioners) as defined by Medicare, and any other person or organization that furnishes, bills, or is paid for health care.</p>

	<p>Health Care Clearinghouses. <i>Health care clearinghouses</i> are entities that process nonstandard information they receive from another entity into a standard (i.e., standard format or data content), or vice versa.⁷ In most instances, health care clearinghouses will receive individually identifiable health information only when they are providing these processing services to a health plan or health care provider as a business associate. In such instances, only certain provisions of the Privacy Rule are applicable to the health care clearinghouse's uses and disclosures of protected health information.⁸ Health care clearinghouses include billing services, repricing companies, community health management information systems, and value-added networks and switches if these entities perform clearinghouse functions.</p>
Business Associates	<p>Business Associate Defined. In general, a business associate is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing.⁹ Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. However, persons or organizations are not considered business associates if their functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all. A covered entity can be the business associate of another covered entity.</p> <p>Business Associate Contract. When a covered entity uses a contractor or other non-workforce member to perform "<i>business associate</i>" services or activities, the Rule requires that the covered entity include certain protections for the information in a business associate agreement (in certain circumstances governmental entities may use alternative means to achieve the same protections). In the business associate contract, a covered entity must impose specified written safeguards on the individually identifiable health information used or disclosed by its business associates.¹⁰ Moreover, a covered entity may not contractually authorize its business associate to make any use or disclosure of protected health information that would violate the Rule. Covered entities that have an existing written contract or agreement with business associates prior to October 15, 2002, which is not renewed or modified prior to April 14, 2003, are permitted to continue to operate under that contract until they renew the contract or April 14, 2004, whichever is first.¹¹ Sample business associate contract language is available on the OCR website at: http://www.hhs.gov/ocr/hipaa/contractprov.html. Also see OCR "Business Associate" Guidance.</p>
What Information is Protected	<p>Protected Health Information. The Privacy Rule protects all "<i>individually identifiable health information</i>" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "<i>protected health information (PHI)</i>".¹²</p>

	<p><i>"Individually identifiable health information"</i> is information, including demographic data, that relates to:</p> <ul style="list-style-type: none"> • the individual's past, present or future physical or mental health or condition, • the provision of health care to the individual, or • the past, present, or future payment for the provision of health care to the individual, <p>and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.¹³ Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).</p> <p>The Privacy Rule excludes from protected health information employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g.</p> <p>De-Identified Health Information. There are no restrictions on the use or disclosure of de-identified health information.¹⁴ De-identified health information neither identifies nor provides a reasonable basis to identify an individual. There are two ways to de-identify information; either: 1) a formal determination by a qualified statistician; or 2) the removal of specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.¹⁵</p>
<h3>General Principle for Uses and Disclosures</h3>	<p>Basic Principle. A major purpose of the Privacy Rule is to define and limit the circumstances in which an individual's protected health information may be used or disclosed by covered entities. A covered entity may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.¹⁶</p> <p>Required Disclosures. A covered entity must disclose protected health information in only two situations: (a) to individuals (or their personal representatives) specifically when they request access to, or an accounting of disclosures of, their protected health information; and (b) to HHS when it is undertaking a compliance investigation or review or enforcement action.¹⁷ See OCR "Government Access" Guidance.</p>
<h3>Permitted Uses and Disclosures</h3>	<p>Permitted Uses and Disclosures. A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) To the Individual (unless required for access or accounting of disclosures); (2) Treatment, Payment, and Health Care Operations; (3) Opportunity to Agree or Object; (4) Incident to an otherwise permitted use and disclosure; (5) Public Interest and Benefit Activities; and</p>

	<p>(6) Limited Data Set for the purposes of research, public health or health care operations.¹⁸ Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.</p> <p>(1) To the Individual. A covered entity may disclose protected health information to the individual who is the subject of the information.</p> <p>(2) Treatment, Payment, Health Care Operations. A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities.¹⁹ A covered entity also may disclose protected health information for the treatment activities of any health care provider, the payment activities of another covered entity and of any health care provider, or the health care operations of another covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if both covered entities have or had a relationship with the individual and the protected health information pertains to the relationship. See OCR “Treatment, Payment, Health Care Operations” Guidance.</p> <p>Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another.²⁰</p> <p>Payment encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual²¹ and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual.</p> <p>Health care operations are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity.²²</p> <p>Most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations purposes require an authorization as described below.²³</p> <p>Obtaining “consent” (written permission from individuals to use and disclose their protected health information for treatment, payment, and health care operations) is optional under the Privacy Rule for all covered entities.²⁴ The content of a consent form, and the process for obtaining consent, are at the discretion of the covered entity electing to seek consent.</p>
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	<p>(3) Uses and Disclosures with Opportunity to Agree or Object. Informal permission may be obtained by asking the individual outright, or by circumstances that clearly give the individual the opportunity to agree, acquiesce, or object. Where the individual is incapacitated, in an emergency situation, or not available, covered entities generally may make such uses and disclosures, if in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual.</p> <p>Facility Directories. It is a common practice in many health care facilities, such as hospitals, to maintain a directory of patient contact information. A covered health care provider may rely on an individual's informal permission to list in its facility directory the individual's name, general condition, religious affiliation, and location in the provider's facility.²⁵ The provider may then disclose the individual's condition and location in the facility to anyone asking for the individual by name, and also may disclose religious affiliation to clergy. Members of the clergy are not required to ask for the individual by name when inquiring about patient religious affiliation.</p> <p>For Notification and Other Purposes. A covered entity also may rely on an individual's informal permission to disclose to the individual's family, relatives, or friends, or to other persons whom the individual identifies, protected health information directly relevant to that person's involvement in the individual's care or payment for care.²⁶ This provision, for example, allows a pharmacist to dispense filled prescriptions to a person acting on behalf of the patient. Similarly, a covered entity may rely on an individual's informal permission to use or disclose protected health information for the purpose of notifying (including identifying or locating) family members, personal representatives, or others responsible for the individual's care or the individual's location, general condition, or death. In addition, protected health information may be disclosed for notification purposes to public or private entities authorized by law or charter to assist in disaster relief efforts.</p> <p>(4) Incidental Use and Disclosure. The Privacy Rule does not require that every risk of an incidental use or disclosure of protected health information be eliminated. A use or disclosure of this information that occurs as a result of, or as "incident to," an otherwise permitted use or disclosure is permitted as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information being shared was limited to the "minimum necessary," as required by the Privacy Rule.²⁷ See OCR "Incidental Uses and Disclosures" Guidance.</p> <p>(5) Public Interest and Benefit Activities. The Privacy Rule permits use and disclosure of protected health information, without an individual's authorization or permission, for 12 national priority purposes.²⁸ These disclosures are permitted, although not required, by the Rule in recognition of the important uses made of health information outside of the health care context. Specific conditions or limitations apply to each public interest purpose, striking the balance between the individual privacy interest and the public interest need for this information.</p> <p>Required by Law. Covered entities may use and disclose protected health information without individual authorization as <i>required by law</i> (including by</p>
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	<p>statute, regulation, or court orders).²⁹</p> <p>Public Health Activities. Covered entities may disclose protected health information to: (1) public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect; (2) entities subject to FDA regulation regarding FDA regulated products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance; (3) individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law; and (4) employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with the Occupational Safety and Health Administration (OHS), the Mine Safety and Health Administration (MHSA), or similar state law.³⁰ See OCR “Public Health” Guidance; CDC Public Health and HIPAA Guidance.</p> <p>Victims of Abuse, Neglect or Domestic Violence. In certain circumstances, covered entities may disclose protected health information to appropriate government authorities regarding victims of abuse, neglect, or domestic violence.³¹</p> <p>Health Oversight Activities. Covered entities may disclose protected health information to health oversight agencies (as defined in the Rule) for purposes of legally authorized health oversight activities, such as audits and investigations necessary for oversight of the health care system and government benefit programs.³²</p> <p>Judicial and Administrative Proceedings. Covered entities may disclose protected health information in a judicial or administrative proceeding if the request for the information is through an order from a court or administrative tribunal. Such information may also be disclosed in response to a subpoena or other lawful process if certain assurances regarding notice to the individual or a protective order are provided.³³</p> <p>Law Enforcement Purposes. Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following six circumstances, and subject to specified conditions: (1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; (2) to identify or locate a suspect, fugitive, material witness, or missing person; (3) in response to a law enforcement official’s request for information about a victim or suspected victim of a crime; (4) to alert law enforcement of a person’s death, if the covered entity suspects that criminal activity caused the death; (5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises; and (6) by a covered health care provider in a medical emergency not occurring on its premises, when necessary to inform law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime.³⁴</p>
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Decedents. Covered entities may disclose protected health information to funeral directors as needed, and to coroners or medical examiners to identify a deceased person, determine the cause of death, and perform other functions authorized by law.³⁵

Cadaveric Organ, Eye, or Tissue Donation. Covered entities may use or disclose protected health information to facilitate the donation and transplantation of cadaveric organs, eyes, and tissue.³⁶

Research. “Research” is any systematic investigation designed to develop or contribute to generalizable knowledge.³⁷ The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, without an individual’s authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals’ authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought.³⁸ A covered entity also may use or disclose, without an individuals’ authorization, a limited data set of protected health information for research purposes (see discussion below).³⁹ See [OCR “Research” Guidance](#); [NIH Protecting PHI in Research](#).

Serious Threat to Health or Safety. Covered entities may disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal.⁴⁰

Essential Government Functions. An authorization is not required to use or disclose protected health information for certain essential government functions. Such functions include: assuring proper execution of a military mission, conducting intelligence and national security activities that are authorized by law, providing protective services to the President, making medical suitability determinations for U.S. State Department employees, protecting the health and safety of inmates or employees in a correctional institution, and determining eligibility for or conducting enrollment in certain government benefit programs.⁴¹

	<p>Workers' Compensation. Covered entities may disclose protected health information as authorized by, and to comply with, workers' compensation laws and other similar programs providing benefits for work-related injuries or illnesses.⁴² See OCR "Workers' Compensation" Guidance.</p> <p>(6) Limited Data Set. A limited data set is protected health information from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed.⁴³ A limited data set may be used and disclosed for research, health care operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the protected health information within the limited data set.</p>
Authorized Uses and Disclosures	<p>Authorization. A covered entity must obtain the individual's written authorization for any use or disclosure of protected health information that is not for treatment, payment or health care operations or otherwise permitted or required by the Privacy Rule.⁴⁴ A covered entity may not condition treatment, payment, enrollment, or benefits eligibility on an individual granting an authorization, except in limited circumstances.⁴⁵</p> <p>An authorization must be written in specific terms. It may allow use and disclosure of protected health information by the covered entity seeking the authorization, or by a third party. Examples of disclosures that would require an individual's authorization include disclosures to a life insurer for coverage purposes, disclosures to an employer of the results of a pre-employment physical or lab test, or disclosures to a pharmaceutical firm for their own marketing purposes.</p> <p>All authorizations must be in plain language, and contain specific information regarding the information to be disclosed or used, the person(s) disclosing and receiving the information, expiration, right to revoke in writing, and other data. The Privacy Rule contains transition provisions applicable to authorizations and other express legal permissions obtained prior to April 14, 2003.⁴⁶</p> <p>Psychotherapy Notes⁴⁷. A covered entity must obtain an individual's authorization to use or disclose psychotherapy notes with the following exceptions⁴⁸:</p> <ul style="list-style-type: none"> • The covered entity who originated the notes may use them for treatment. • A covered entity may use or disclose, without an individual's authorization, the psychotherapy notes, for its own training, and to defend itself in legal proceedings brought by the individual, for HHS to investigate or determine the covered entity's compliance with the Privacy Rules, to avert a serious and imminent threat to public health or safety, to a health oversight agency for lawful oversight of the originator of the psychotherapy notes, for the lawful activities of a coroner or medical examiner or as required by law. <p>Marketing. Marketing is any communication about a product or service that encourages recipients to purchase or use the product or service.⁴⁹ The Privacy Rule carves out the following health-related activities from this definition of marketing:</p> <ul style="list-style-type: none"> • Communications to describe health-related products or services, or payment

	<p>for them, provided by or included in a benefit plan of the covered entity making the communication;</p> <ul style="list-style-type: none"> • Communications about participating providers in a provider or health plan network, replacement of or enhancements to a health plan, and health-related products or services available only to a health plan's enrollees that add value to, but are not part of, the benefits plan; • Communications for treatment of the individual; and • Communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or care settings to the individual. <p>Marketing also is an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information, in exchange for direct or indirect remuneration, for the other entity to communicate about its own products or services encouraging the use or purchase of those products or services. A covered entity must obtain an authorization to use or disclose protected health information for marketing, except for face-to-face marketing communications between a covered entity and an individual, and for a covered entity's provision of promotional gifts of nominal value. No authorization is needed, however, to make a communication that falls within one of the exceptions to the marketing definition. An authorization for marketing that involves the covered entity's receipt of direct or indirect remuneration from a third party must reveal that fact. See OCR "Marketing" Guidance.</p>
Limiting Uses and Disclosures to the Minimum Necessary	<p>Minimum Necessary. A central aspect of the Privacy Rule is the principle of "minimum necessary" use and disclosure. A covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of protected health information needed to accomplish the intended purpose of the use, disclosure, or request.⁵⁰ A covered entity must develop and implement policies and procedures to reasonably limit uses and disclosures to the minimum necessary. When the minimum necessary standard applies to a use or disclosure, a covered entity may not use, disclose, or request the entire medical record for a particular purpose, unless it can specifically justify the whole record as the amount reasonably needed for the purpose. See OCR "Minimum Necessary" Guidance.</p> <p>The minimum necessary requirement is not imposed in any of the following circumstances: (a) disclosure to or a request by a health care provider for treatment; (b) disclosure to an individual who is the subject of the information, or the individual's personal representative; (c) use or disclosure made pursuant to an authorization; (d) disclosure to HHS for complaint investigation, compliance review or enforcement; (e) use or disclosure that is required by law; or (f) use or disclosure required for compliance with the HIPAA Transactions Rule or other HIPAA Administrative Simplification Rules.</p> <p>Access and Uses. For internal uses, a covered entity must develop and implement policies and procedures that restrict access and uses of protected health information based on the specific roles of the members of their workforce. These policies and procedures must identify the persons, or classes of persons, in the workforce who need access to protected health information to carry out their duties, the categories of</p>

	<p>protected health information to which access is needed, and any conditions under which they need the information to do their jobs.</p> <p>Disclosures and Requests for Disclosures. Covered entities must establish and implement policies and procedures (which may be standard protocols) for <i>routine, recurring disclosures, or requests for disclosures</i>, that limits the protected health information disclosed to that which is the minimum amount reasonably necessary to achieve the purpose of the disclosure. Individual review of each disclosure is not required. For non-routine, non-recurring disclosures, or requests for disclosures that it makes, covered entities must develop criteria designed to limit disclosures to the information reasonably necessary to accomplish the purpose of the disclosure and review each of these requests individually in accordance with the established criteria.</p> <p>Reasonable Reliance. If another covered entity makes a request for protected health information, a covered entity may rely, if reasonable under the circumstances, on the request as complying with this minimum necessary standard. Similarly, a covered entity may rely upon requests as being the minimum necessary protected health information from: (a) a public official, (b) a professional (such as an attorney or accountant) who is the covered entity's business associate, seeking the information to provide services to or for the covered entity; or (c) a researcher who provides the documentation or representation required by the Privacy Rule for research.</p>
<h3>Notice and Other Individual Rights</h3>	<p>Privacy Practices Notice. Each covered entity, with certain exceptions, must provide a notice of its privacy practices.⁵¹ The Privacy Rule requires that the notice contain certain elements. The notice must describe the ways in which the covered entity may use and disclose protected health information. The notice must state the covered entity's duties to protect privacy, provide a notice of privacy practices, and abide by the terms of the current notice. The notice must describe individuals' rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated. The notice must include a point of contact for further information and for making complaints to the covered entity. Covered entities must act in accordance with their notices. The Rule also contains specific distribution requirements for direct treatment providers, all other health care providers, and health plans. See OCR "Notice" Guidance.</p> <ul style="list-style-type: none"> • Notice Distribution. A covered health care provider with a <i>direct treatment relationship</i> with individuals must deliver a privacy practices notice to patients starting April 14, 2003 as follows: <ul style="list-style-type: none"> ○ Not later than the first service encounter by personal delivery (for patient visits), by automatic and contemporaneous electronic response (for electronic service delivery), and by prompt mailing (for telephonic service delivery); ○ By posting the notice at each service delivery site in a clear and prominent place where people seeking service may reasonably be expected to be able to read the notice; and ○ In emergency treatment situations, the provider must furnish its notice as soon as practicable after the emergency abates.

	<p>Covered entities, whether <i>direct treatment providers</i> or <i>indirect treatment providers</i> (such as laboratories) or <i>health plans</i> must supply notice to anyone on request.⁵² A covered entity must also make its notice electronically available on any web site it maintains for customer service or benefits information.</p> <p>The covered entities in an <i>organized health care arrangement</i> may use a joint privacy practices notice, as long as each agrees to abide by the notice content with respect to the protected health information created or received in connection with participation in the arrangement.⁵³ Distribution of a joint notice by any covered entity participating in the organized health care arrangement at the first point that an OHCA member has an obligation to provide notice satisfies the distribution obligation of the other participants in the organized health care arrangement.</p> <p>A health plan must distribute its privacy practices notice to each of its enrollees by its Privacy Rule compliance date. Thereafter, the health plan must give its notice to each new enrollee at enrollment, and send a reminder to every enrollee at least once every three years that the notice is available upon request. A health plan satisfies its distribution obligation by furnishing the notice to the “named insured,” that is, the subscriber for coverage that also applies to spouses and dependents.</p> <ul style="list-style-type: none"> • Acknowledgement of Notice Receipt. A covered health care provider with a direct treatment relationship with individuals must make a good faith effort to obtain written acknowledgement from patients of receipt of the privacy practices notice.⁵⁴ The Privacy Rule does not prescribe any particular content for the acknowledgement. The provider must document the reason for any failure to obtain the patient’s written acknowledgement. The provider is relieved of the need to request acknowledgement in an emergency treatment situation. <p>Access. Except in certain circumstances, individuals have the right to review and obtain a copy of their protected health information in a covered entity’s <i>designated record set</i>.⁵⁵ The “designated record set” is that group of records maintained by or for a covered entity that is used, in whole or part, to make decisions about individuals, or that is a provider’s medical and billing records about individuals or a health plan’s enrollment, payment, claims adjudication, and case or medical management record systems.⁵⁶ The Rule excepts from the right of access the following protected health information: psychotherapy notes, information compiled for legal proceedings, laboratory results to which the Clinical Laboratory Improvement Act (CLIA) prohibits access, or information held by certain research laboratories. For information included within the right of access, covered entities may deny an individual access in certain specified situations, such as when a health care professional believes access could cause harm to the individual or another. In such situations, the individual must be given the right to have such denials reviewed by a licensed health care professional for a second opinion.⁵⁷ Covered entities may impose reasonable, cost-based fees for the cost of copying and postage.</p> <p>Amendment. The Rule gives individuals the right to have covered entities amend their protected health information in a designated record set when that information is</p>
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	<p>inaccurate or incomplete.⁵⁸ If a covered entity accepts an amendment request, it must make reasonable efforts to provide the amendment to persons that the individual has identified as needing it, and to persons that the covered entity knows might rely on the information to the individual's detriment.⁵⁹ If the request is denied, covered entities must provide the individual with a written denial and allow the individual to submit a statement of disagreement for inclusion in the record. The Rule specifies processes for requesting and responding to a request for amendment. A covered entity must amend protected health information in its designated record set upon receipt of notice to amend from another covered entity.</p> <p>Disclosure Accounting. Individuals have a right to an accounting of the disclosures of their protected health information by a covered entity or the covered entity's business associates.⁶⁰ The maximum disclosure accounting period is the six years immediately preceding the accounting request, except a covered entity is not obligated to account for any disclosure made before its Privacy Rule compliance date. The Privacy Rule does not require accounting for disclosures: (a) for treatment, payment, or health care operations; (b) to the individual or the individual's personal representative; (c) for notification of or to persons involved in an individual's health care or payment for health care, for disaster relief, or for facility directories; (d) pursuant to an authorization; (e) of a limited data set; (f) for national security or intelligence purposes; (g) to correctional institutions or law enforcement officials for certain purposes regarding inmates or individuals in lawful custody; or (h) incident to otherwise permitted or required uses or disclosures. Accounting for disclosures to health oversight agencies and law enforcement officials must be temporarily suspended on their written representation that an accounting would likely impede their activities.</p> <p>Restriction Request. Individuals have the right to request that a covered entity restrict use or disclosure of protected health information for treatment, payment or health care operations, disclosure to persons involved in the individual's health care or payment for health care, or disclosure to notify family members or others about the individual's general condition, location, or death.⁶¹ A covered entity is under no obligation to agree to requests for restrictions. A covered entity that does agree must comply with the agreed restrictions, except for purposes of treating the individual in a medical emergency.⁶²</p> <p>Confidential Communications Requirements. Health plans and covered health care providers must permit individuals to request an alternative means or location for receiving communications of protected health information by means other than those that the covered entity typically employs.⁶³ For example, an individual may request that the provider communicate with the individual through a designated address or phone number. Similarly, an individual may request that the provider send communications in a closed envelope rather than a post card.</p> <p>Health plans must accommodate reasonable requests if the individual indicates that the disclosure of all or part of the protected health information could endanger the individual. The health plan may not question the individual's statement of endangerment. Any covered entity may condition compliance with a confidential communication request on the individual specifying an alternative address or method of contact and explaining how any payment will be handled.</p>
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Administrative Requirements

HHS recognizes that covered entities range from the smallest provider to the largest, multi-state health plan. Therefore the flexibility and scalability of the Rule are intended to allow covered entities to analyze their own needs and implement solutions appropriate for their own environment. What is appropriate for a particular covered entity will depend on the nature of the covered entity's business, as well as the covered entity's size and resources.

Privacy Policies and Procedures. A covered entity must develop and implement written privacy policies and procedures that are consistent with the Privacy Rule.⁶⁴

Privacy Personnel. A covered entity must designate a privacy official responsible for developing and implementing its privacy policies and procedures, and a contact person or contact office responsible for receiving complaints and providing individuals with information on the covered entity's privacy practices.⁶⁵

Workforce Training and Management. Workforce members include employees, volunteers, trainees, and may also include other persons whose conduct is under the direct control of the entity (whether or not they are paid by the entity).⁶⁶ A covered entity must train all workforce members on its privacy policies and procedures, as necessary and appropriate for them to carry out their functions.⁶⁷ A covered entity must have and apply appropriate sanctions against workforce members who violate its privacy policies and procedures or the Privacy Rule.⁶⁸

Mitigation. A covered entity must mitigate, to the extent practicable, any harmful effect it learns was caused by use or disclosure of protected health information by its workforce or its business associates in violation of its privacy policies and procedures or the Privacy Rule.⁶⁹

Data Safeguards. A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure.⁷⁰ For example, such safeguards might include shredding documents containing protected health information before discarding them, securing medical records with lock and key or pass code, and limiting access to keys or pass codes. See [OCR "Incidental Uses and Disclosures" Guidance](#).

Complaints. A covered entity must have procedures for individuals to complain about its compliance with its privacy policies and procedures and the Privacy Rule.⁷¹ The covered entity must explain those procedures in its privacy practices notice.⁷²

Among other things, the covered entity must identify to whom individuals can submit complaints to at the covered entity and advise that complaints also can be submitted to the Secretary of HHS.

Retaliation and Waiver. A covered entity may not retaliate against a person for exercising rights provided by the Privacy Rule, for assisting in an investigation by HHS or another appropriate authority, or for opposing an act or practice that the person believes in good faith violates the Privacy Rule.⁷³ A covered entity may not

	<p>require an individual to waive any right under the Privacy Rule as a condition for obtaining treatment, payment, and enrollment or benefits eligibility.⁷⁴</p> <p>Documentation and Record Retention. A covered entity must maintain, until six years after the later of the date of their creation or last effective date, its privacy policies and procedures, its privacy practices notices, disposition of complaints, and other actions, activities, and designations that the Privacy Rule requires to be documented.⁷⁵</p> <p>Fully-Insured Group Health Plan Exception. The only administrative obligations with which a fully-insured group health plan that has no more than enrollment data and summary health information is required to comply are the (1) ban on retaliatory acts and waiver of individual rights, and (2) documentation requirements with respect to plan documents if such documents are amended to provide for the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO that services the group health plan.⁷⁶</p>
Organizational Options	<p>The Rule contains provisions that address a variety of organizational issues that may affect the operation of the privacy protections.</p> <p>Hybrid Entity. The Privacy Rule permits a covered entity that is a single legal entity and that conducts both covered and non-covered functions to elect to be a “hybrid entity.”⁷⁷ (The activities that make a person or organization a covered entity are its “covered functions.”⁷⁸) To be a hybrid entity, the covered entity must designate in writing its operations that perform covered functions as one or more “health care components.” After making this designation, most of the requirements of the Privacy Rule will apply only to the health care components. A covered entity that does not make this designation is subject in its entirety to the Privacy Rule.</p> <p>Affiliated Covered Entity. Legally separate covered entities that are affiliated by common ownership or control may designate themselves (including their health care components) as a single covered entity for Privacy Rule compliance.⁷⁹ The designation must be in writing. An affiliated covered entity that performs multiple covered functions must operate its different covered functions in compliance with the Privacy Rule provisions applicable to those covered functions.</p> <p>Organized Health Care Arrangement. The Privacy Rule identifies relationships in which participating covered entities share protected health information to manage and benefit their common enterprise as “organized health care arrangements.”⁸⁰ Covered entities in an organized health care arrangement can share protected health information with each other for the arrangement’s joint health care operations.⁸¹</p> <p>Covered Entities With Multiple Covered Functions. A covered entity that performs multiple covered functions must operate its different covered functions in compliance with the Privacy Rule provisions applicable to those covered functions.⁸² The covered entity may not use or disclose the protected health information of an individual who receives services from one covered function (e.g., health care provider) for another covered function (e.g., health plan) if the individual is not involved with the other function.</p>

	<p>Group Health Plan disclosures to Plan Sponsors. A group health plan and the health insurer or HMO offered by the plan may disclose the following protected health information to the “plan sponsor”—the employer, union, or other employee organization that sponsors and maintains the group health plan⁸³:</p> <ul style="list-style-type: none"> • Enrollment or disenrollment information with respect to the group health plan or a health insurer or HMO offered by the plan. • If requested by the plan sponsor, summary health information for the plan sponsor to use to obtain premium bids for providing health insurance coverage through the group health plan, or to modify, amend, or terminate the group health plan. “Summary health information” is information that summarizes claims history, claims expenses, or types of claims experience of the individuals for whom the plan sponsor has provided health benefits through the group health plan, and that is stripped of all individual identifiers other than five digit zip code (though it need not qualify as de-identified protected health information). • Protected health information of the group health plan’s enrollees for the plan sponsor to perform plan administration functions. The plan must receive certification from the plan sponsor that the group health plan document has been amended to impose restrictions on the plan sponsor’s use and disclosure of the protected health information. These restrictions must include the representation that the plan sponsor will not use or disclose the protected health information for any employment-related action or decision or in connection with any other benefit plan.
Other Provisions: Personal Representatives and Minors	<p>Personal Representatives. The Privacy Rule requires a covered entity to treat a “personal representative” the same as the individual, with respect to uses and disclosures of the individual’s protected health information, as well as the individual’s rights under the Rule.⁸⁴ A personal representative is a person legally authorized to make health care decisions on an individual’s behalf or to act for a deceased individual or the estate. The Privacy Rule permits an exception when a covered entity has a reasonable belief that the personal representative may be abusing or neglecting the individual, or that treating the person as the personal representative could otherwise endanger the individual.</p> <p>Special case: Minors. In most cases, parents are the personal representatives for their minor children. Therefore, in most cases, parents can exercise individual rights, such as access to the medical record, on behalf of their minor children. In certain exceptional cases, the parent is not considered the personal representative. In these situations, the Privacy Rule defers to State and other law to determine the rights of parents to access and control the protected health information of their minor children. If State and other law is silent concerning parental access to the minor’s protected health information, a covered entity has discretion to provide or deny a parent access to the minor’s health information, provided the decision is made by a licensed health care professional in the exercise of professional judgment. See OCR “Personal Representatives” Guidance.</p>

<h2>State Law</h2>	<p>Preemption. In general, State laws that are contrary to the Privacy Rule are preempted by the federal requirements, which means that the federal requirements will apply.⁸⁵ “Contrary” means that it would be impossible for a covered entity to comply with both the State and federal requirements, or that the provision of State law is an obstacle to accomplishing the full purposes and objectives of the Administrative Simplification provisions of HIPAA.⁸⁶ The Privacy Rule provides exceptions to the general rule of federal preemption for contrary State laws that (1) relate to the privacy of individually identifiable health information and provide greater privacy protections or privacy rights with respect to such information, (2) provide for the reporting of disease or injury, child abuse, birth, or death, or for public health surveillance, investigation, or intervention, or (3) require certain health plan reporting, such as for management or financial audits.</p> <p>Exception Determination. In addition, preemption of a contrary State law will not occur if HHS determines, in response to a request from a State or other entity or person, that the State law:</p> <ul style="list-style-type: none"> • Is necessary to prevent fraud and abuse related to the provision of or payment for health care, • Is necessary to ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation, • Is necessary for State reporting on health care delivery or costs, • Is necessary for purposes of serving a compelling public health, safety, or welfare need, and, if a Privacy Rule provision is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or • Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.
<h2>Enforcement and Penalties for Noncompliance</h2>	<p>Compliance. Consistent with the principles for achieving compliance provided in the Rule, HHS will seek the cooperation of covered entities and may provide technical assistance to help them comply voluntarily with the Rule.⁸⁷ The Rule provides processes for persons to file complaints with HHS, describes the responsibilities of covered entities to provide records and compliance reports and to cooperate with, and permit access to information for, investigations and compliance reviews.</p> <p>Civil Money Penalties. HHS may impose civil money penalties on a covered entity of \$100 per failure to comply with a Privacy Rule requirement.⁸⁸ That penalty may not exceed \$25,000 per year for multiple violations of the identical Privacy Rule requirement in a calendar year. HHS may not impose a civil money penalty under specific circumstances, such as when a violation is due to reasonable cause and did not involve willful neglect and the covered entity corrected the violation within 30 days of when it knew or should have known of the violation.</p>

	<p>Criminal Penalties. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA faces a fine of \$50,000 and up to one-year imprisonment.⁸⁹ The criminal penalties increase to \$100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to ten years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. Criminal sanctions will be enforced by the Department of Justice.</p>
Compliance Dates	<p>Compliance Schedule. All covered entities, except “small health plans,” must be compliant with the Privacy Rule by April 14, 2003.⁹⁰ Small health plans, however, have until April 14, 2004 to comply.</p> <p>Small Health Plans. A health plan with annual receipts of not more than \$5 million is a small health plan.⁹¹ Health plans that file certain federal tax returns and report receipts on those returns should use the guidance provided by the Small Business Administration at 13 Code of Federal Regulations (CFR) 121.104 to calculate annual receipts. Health plans that do not report receipts to the Internal Revenue Service (IRS), for example, group health plans regulated by the Employee Retirement Income Security Act 1974 (ERISA) that are exempt from filing income tax returns, should use proxy measures to determine their annual receipts.⁹² See What constitutes a small health plan?</p>
Copies of the Rule & Related Materials	The entire Privacy Rule, as well as guidance and additional materials, may be found on our website, http://www.hhs.gov/ocr/hipaa .

End Notes

¹ Pub. L. 104-191.

² 65 FR 82462.

³ 67 FR 53182.

⁴ 45 C.F.R. §§ 160.102, 160.103.

⁵ Even if an entity, such as a community health center, does not meet the definition of a health plan, it may, nonetheless, meet the definition of a health care provider, and, if it transmits health information in electronic form in connection with the transactions for which the Secretary of HHS has adopted standards under HIPAA, may still be a covered entity.

⁶ 45 C.F.R. §§ 160.102, 160.103; *see* Social Security Act § 1172(a)(3), 42 U.S.C. § 1320d-1(a)(3). The transaction standards are established by the HIPAA Transactions Rule at 45 C.F.R. Part 162.

⁷ 45 C.F.R. § 160.103.

⁸ 45 C.F.R. § 164.500(b).

⁹ 45 C.F.R. § 160.103.

¹⁰ 45 C.F.R. §§ 164.502(e), 164.504(e).

¹¹ 45 C.F.R. § 164.532

¹² 45 C.F.R. § 160.103.

¹³ 45 C.F.R. § 160.103

¹⁴ 45 C.F.R. §§ 164.502(d)(2), 164.514(a) and (b).

¹⁵ The following identifiers of the individual or of relatives, employers, or household members of the individual must be removed to achieve the “safe harbor” method of de-identification: (A) Names; (B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census (1) the geographic units formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000; (C) All elements of dates (except year) for dates directly related to the individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; (D) Telephone numbers; (E) Fax numbers; (F) Electronic mail addresses; (G) Social security numbers; (H) Medical record numbers; (I) Health plan beneficiary numbers; (J) Account numbers; (K) Certificate/license numbers; (L) Vehicle identifiers and serial numbers, including license plate numbers; (M) Device identifiers and serial numbers; (N) Web Universal Resource Locators (URLs); (O) Internet Protocol (IP) address numbers; (P) Biometric identifiers, including finger and voice prints; (Q) Full face photographic images and any comparable images; and ® any other unique identifying number, characteristic, or code, except as permitted for re-identification purposes provided certain conditions are met. In addition to the removal of the above-stated identifiers, the covered entity may not have actual knowledge that the remaining information could be used alone or in combination with any other information to identify an individual who is subject of the information. 45 C.F.R. § 164.514(b).

¹⁶ 45 C.F.R. § 164.502(a).

¹⁷ 45 C.F.R. § 164.502(a)(2).

¹⁸ 45 C.F.R. § 164.502(a)(1).

¹⁹ 45 C.F.R. § 164.506(c).

²⁰ 45 C.F.R. § 164.501.

²¹ 45 C.F.R. § 164.501.

²² 45 C.F.R. § 164.501.

²³ 45 C.F.R. § 164.508(a)(2)

²⁴ 45 C.F.R. § 164.506(b).

²⁵ 45 C.F.R. § 164.510(a).

²⁶ 45 C.F.R. § 164.510(b).

²⁷ 45 C.F.R. §§ 164.502(a)(1)(iii).

²⁸ See 45 C.F.R. § 164.512.

²⁹ 45 C.F.R. § 164.512(a).

³⁰ 45 C.F.R. § 164.512(b).

³¹ 45 C.F.R. § 164.512(a), (c).

³² 45 C.F.R. § 164.512(d).

³³ 45 C.F.R. § 164.512(e).

³⁴ 45 C.F.R. § 164.512(f).

³⁵ 45 C.F.R. § 164.512(g).

³⁶ 45 C.F.R. § 164.512(h).

³⁷ The Privacy Rule defines research as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 C.F.R. § 164.501.

³⁸ 45 C.F.R. § 164.512(i).

³⁹ 45 CFR § 164.514(e).

⁴⁰ 45 C.F.R. § 164.512(j).

⁴¹ 45 C.F.R. § 164.512(k).

⁴² 45 C.F.R. § 164.512(l).

⁴³ 45 C.F.R. § 164.514(e). A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; (xvi) Full face photographic images and any comparable images. 45 C.F.R. § 164.514(e)(2).

⁴⁴ 45 C.F.R. § 164.508.

⁴⁵ A covered entity may condition the provision of health care solely to generate protected health information for disclosure to a third party on the individual giving authorization to disclose the

information to the third party. For example, a covered entity physician may condition the provision of a physical examination to be paid for by a life insurance issuer on an individual's authorization to disclose the results of that examination to the life insurance issuer. A health plan may condition enrollment or benefits eligibility on the individual giving authorization, requested before the individual's enrollment, to obtain protected health information (other than psychotherapy notes) to determine the individual's eligibility or enrollment or for underwriting or risk rating. A covered health care provider may condition treatment related to research (e.g., clinical trials) on the individual giving authorization to use or disclose the individual's protected health information for the research. 45 C.F.R. 508(b)(4).

⁴⁶ 45 CFR § 164.532.

⁴⁷ "Psychotherapy notes" means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. 45 C.F.R. § 164.501.

⁴⁸ 45 C.F.R. § 164.508(a)(2).

⁴⁹ 45 C.F.R. §§ 164.501 and 164.508(a)(3).

⁵⁰ 45 C.F.R. §§ 164.502(b) and 164.514 (d).

⁵¹ 45 C.F.R. §§ 164.520(a) and (b). A group health plan, or a health insurer or HMO with respect to the group health plan, that intends to disclose protected health information (including enrollment data or summary health information) to the plan sponsor, must state that fact in the notice. Special statements are also required in the notice if a covered entity intends to contact individuals about health-related benefits or services, treatment alternatives, or appointment reminders, or for the covered entity's own fundraising.

⁵² 45 C.F.R. § 164.520(c).

⁵³ 45 C.F.R. § 164.520(d).

⁵⁴ 45 C.F.R. § 164.520(c).

⁵⁵ 45 C.F.R. § 164.524.

⁵⁶ 45 C.F.R. § 164.501.

⁵⁷ A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed by a licensed health care professional (who is designated by the covered entity and who did not participate in the original decision to deny), when a licensed health care professional has determined, in the exercise of professional judgment, that: (a) the access requested is reasonably likely to endanger the life or physical safety of the individual or another person; (b) the protected health information makes reference to another person (unless such other person is a health care provider) and the access requested is reasonably likely to cause substantial harm to such other person; or (c) the request for access is made by the individual's personal representative and the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

A covered entity may deny access to individuals, without providing the individual an opportunity for review, in the following protected situations: (a) the protected health information falls under an exception to the right of access; (b) an inmate request for protected health information under certain circumstances; (c) information that a provider creates or obtains in the course of research that includes treatment for which the individual has agreed not to have access as part of consenting

to participate in the research (as long as access to the information is restored upon completion of the research); (d) for records subject to the Privacy Act, information to which access may be denied under the Privacy Act, 5 U.S.C. § 552a; and (e) information obtained under a promise of confidentiality from a source other than a health care provider, if granting access would likely reveal the source. 45 C.F.R. § 164.524.

⁵⁸ 45 C.F.R. § 164.526.

⁵⁹ Covered entities may deny an individual's request for amendment only under specified circumstances. A covered entity may deny the request if it: (a) may exclude the information from access by the individual; (b) did not create the information (unless the individual provides a reasonable basis to believe the originator is no longer available); (c) determines that the information is accurate and complete; or (d) does not hold the information in its designated record set. 164.526(a)(2).

⁶⁰ 45 C.F.R. § 164.528.

⁶¹ 45 C.F.R. § 164.522(a).

⁶² 45 C.F.R. § 164.522(a). In addition, a restriction agreed to by a covered entity is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502(a)(2)(ii), 164.510(a) or 164.512.

⁶³ 45 C.F.R. § 164.522(b).

⁶⁴ 45 C.F.R. § 164.530(i).

⁶⁵ 45 C.F.R. § 164.530(a).

⁶⁶ 45 C.F.R. § 160.103.

⁶⁷ 45 C.F.R. § 164.530(b).

⁶⁸ 45 C.F.R. § 164.530(e).

⁶⁹ 45 C.F.R. § 164.530(f).

⁷⁰ 45 C.F.R. § 164.530(c).

⁷¹ 45 C.F.R. § 164.530(d).

⁷² 45 C.F.R. § 164.520(b)(1)(vi).

⁷³ 45 C.F.R. § 164.530(g).

⁷⁴ 45 C.F.R. § 164.530(h).

⁷⁵ 45 C.F.R. § 164.530(j).

⁷⁶ 45 C.F.R. § 164.530(k).

⁷⁷ 45 C.F.R. §§ 164.103, 164.105.

⁷⁸ 45 C.F.R. § 164.103.

⁷⁹ 45 C.F.R. § 164.105. Common ownership exists if an entity possesses an ownership or equity interest of five percent or more in another entity; common control exists if an entity has the direct or indirect power significantly to influence or direct the actions or policies of another entity. 45 C.F.R. §§ 164.103.

⁸⁰ The Privacy Rule at 45 C.F.R. § 160.103 identifies five types of organized health care arrangements:

- A clinically-integrated setting where individuals typically receive health care from more than one provider.
- An organized system of health care in which the participating covered entities hold themselves out to the public as part of a joint arrangement and jointly engage in

utilization review, quality assessment and improvement activities, or risk-sharing payment activities.

- A group health plan and the health insurer or HMO that insures the plan's benefits, with respect to protected health information created or received by the insurer or HMO that relates to individuals who are or have been participants or beneficiaries of the group health plan.
- All group health plans maintained by the same plan sponsor.
- All group health plans maintained by the same plan sponsor and all health insurers and HMOs that insure the plans' benefits, with respect to protected health information created or received by the insurers or HMOs that relates to individuals who are or have been participants or beneficiaries in the group health plans.

⁸¹ 45 C.F.R. § 164.506(c)(5).

⁸² 45 C.F.R. § 164.504(g).

⁸³ 45 C.F.R. § 164.504(f).

⁸⁴ 45 C.F.R. § 164.502(g).

⁸⁵ 45 C.F.R. § 160.203.

⁸⁶ 45 C.F.R. § 160.202.

⁸⁷ 45 C.F.R. § 160.304

⁸⁸ Pub. L. 104-191; 42 U.S.C. §1320d-5.

⁸⁹ Pub. L. 104-191; 42 U.S.C. §1320d-6.

⁹⁰ 45 C.F.R. § 164.534.

⁹¹ 45 C.F.R. § 160.103.

⁹² Fully insured health plans should use the amount of total premiums that they paid for health insurance benefits during the plan's last full fiscal year. Self-insured plans, both funded and unfunded, should use the total amount paid for health care claims by the employer, plan sponsor or benefit fund, as applicable to their circumstances, on behalf of the plan during the plan's last full fiscal year. Those plans that provide health benefits through a mix of purchased insurance and self-insurance should combine proxy measures to determine their total annual receipts.

HIPAA Notice of Privacy Practices

Effective as of March 1/2010

CREEKSIDE CANCER CARE, L.L.C.
ALPINE RADIATION ONCOLOGY SERVICES, P.L.L.C.
CENTENNIAL RADIATION ONCOLOGY, P.C.

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This Notice of Privacy Practices describes how we may use and disclose your protected health information (PHI) to carry out treatment, payment or health care operations (TPO) and for other purposes that are permitted or required by law. It also describes your rights to access and control your protected health information. "Protected health information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health condition and related health care services.

USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

Your protected health information may be used and disclosed by your physician, our office staff and others outside of our office that are involved in your care and treatment for the purpose of providing health care services to you, to pay your health care bills, to support the operation of the physician's practice, and any other use required by law.

Treatment: We will use and disclose your protected health information to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with a third party. For example, your protected health information may be provided to a physician to whom you have been referred to ensure that the physician has the necessary information to diagnose or treat you.

Payment: Your protected health information will be used, as needed, to obtain payment for your health care services. For example, obtaining approval for a hospital stay may require that your relevant protected health information be disclosed to the health plan to obtain approval for the hospital admission.

Healthcare Operations: We may use or disclose, as-needed, your protected health information in order to support the business activities of your physician's practice. These activities include, but are not limited to, quality assessment, employee review, training of medical students, licensing, fundraising, and conducting or arranging for other business activities. For example, we may disclose your protected health information to medical school students that see patients at our office. In addition, we may use a sign-in sheet at the registration desk where you will be asked to sign your name and indicate your physician. We may also call you by name in the waiting room when your physician is ready to see you. We may use or disclose your protected health information, as necessary, to contact you to remind you of your appointment, and inform you about treatment alternatives or other health-related benefits and services that may be of interest to you.

We may use or disclose your protected health information in the following situations without your authorization. These situations include: as required by law, public health issues as required by law, communicable diseases, health oversight, abuse or neglect, food and drug administration requirements, legal proceedings, law enforcement, coroners, funeral directors, organ donation, research, criminal activity, military activity and national security, workers' compensation, inmates, and other required uses and disclosures. Under the law, we must make disclosures to you upon your request. Under the law, we must also disclose your protected health information when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements under Section 164.500.

Other Permitted and Required Uses and Disclosures will be made only with your consent, **authorization or opportunity to object unless required by law**. **You may revoke the authorization**, at any time, in writing, except to the extent that your physician or the physician's practice has taken an action in reliance on the use or disclosure indicated in the authorization.

YOUR RIGHTS

The following are statements of your rights with respect to your protected health information.

You have the right to inspect and copy your protected health information (fees may apply) – Under federal law, however, you may not inspect or copy the following records: Psychotherapy notes, information compiled in reasonable anticipation of, or used in, a civil, criminal, or administrative action or proceeding, protected health information restricted by law, information that is related to medical research in which you have agreed to participate, information whose disclosure may result in harm or injury to you or to another person, or information that was obtained under a promise of confidentiality.

You have the right to request a restriction of your protected health information – This means you may ask us not to use or disclose any part of your protected health information and by law we must comply when the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full. You may also request that any part of your protected health information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this Notice of Privacy Practices. Your request must state the specific restriction requested and to whom you want the restriction to apply. By law, you may not request that we restrict the disclosure of your PHI for treatment purposes.

You have the right to request to receive confidential communications – You have the right to request confidential communication from us by alternative means or at an alternative location. You have the right to obtain a paper copy of this notice from us, upon request, even if you have agreed to accept this notice alternatively i.e. electronically.

You have the right to request an amendment to your protected health information – If we deny your request for amendment, you have the right to file a statement of disagreement with us and we may prepare a rebuttal to your statement and will provide you with a copy of any such rebuttal.

You have the right to receive an accounting of certain disclosures – You have the right to receive an accounting of all disclosures except for disclosures: pursuant to an authorization, for purposes of treatment, payment, healthcare operations; required by law, that occurred prior to April 14, 2003, or six years prior to the date of this request.

You have the right to obtain a paper copy of this notice from us even if you have agreed to receive the notice electronically. We reserve the right to change the terms of this notice and we will notify you of such changes on the following appointment. We will also make available copies of our new notice if you wish to obtain one.

COMPLAINTS

You may complain to us or to the Secretary of Health and Human Services if you believe your privacy rights have been violated by us. You may file a complaint with us by notifying our Compliance Officer of your complaint. **We will not retaliate against you for filing a complaint.**

We are required by law to maintain the privacy of, and provide individuals with, this notice of our legal duties and privacy practices with respect to protected health information. We are also required to abide by the terms of the notice currently in effect. If you have any questions in reference to this form, please ask to speak with our HIPAA Compliance Officer in person or by phone at our main phone number.

Please sign the accompanying "Acknowledgment" form. Please note that by signing the Acknowledgment form you are only acknowledging that you have received or been given the opportunity to receive a copy of our Notice of Privacy Practices.