RADIATION SAFETY MANUAL FOR DUKE UNIVERSITY AND DUKE UNIVERSITY MEDICAL CENTER

Radiation Safety Division
Occupational And Environmental Safety Office
Duke University
Durham, North Carolina

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I. INTRODUCTION

The policies outlined in the *Radiation Safety Manual for Duke University and Duke University Medical Center* are intended to ensure that the use of radioactive material and radiation producing machines is in accordance with applicable state and federal regulations and accepted standards for the protection of health and the minimization of hazard to life or property. This manual is an overview of the organization of the radiation safety programs, and the responsibilities of entities and individuals within Duke University and the Duke University Health System (DUHS). Certain operational policies and procedures are briefly described in the manual and the applicable policy/procedure documents incorporated by reference.

Although the safe use of lasers is an area of oversight by the Committees, complete coverage is provided in the Duke Laser Safety Policy. Specific information on the organization, policies, procedures and training programs of the Laser Safety Program may be obtained by contacting the Radiation Safety Division.

The definitions of terms and abbreviations used in this Manual may be found in Appendix A: *Terms and Abbreviations*.

Applicability of Federal and State Regulations

All activities employing radioactive material or radiation-producing machines on the campus of Duke University, Duke University Medical Center (DUMC) and other specified locations are strictly governed by (a) the policies and procedures in this Manual, and (b) other policies and procedures approved by the Duke Radiation Safety Committees (RSCs). The statutory guidance for the Duke University Radiation Safety Program includes, but is not limited to the following titles and parts of the North Carolina Administrative Code and the Code of Federal Regulations (CFR):

- 10A NCAC 15: *North Carolina Regulations For Protection Against Radiation*
- 10 CFR 20: *Standards For Protection Against Radiation*
- 10 CFR 35: *Medical Use Of Byproduct Material*
- 10 CFR 37: *Physical Protection Of Category 1 And Category 2 Quantities Of Radioactive Material*
- 21 CFR 361.1: *Radioactive Drugs For Certain Research Uses*
- 45 CFR 46: *Federal Policy for the Protection of Human Subjects* ("Common Rule")
- Conditions of the radioactive material and accelerator licenses Duke holds with the State of North Carolina, as amended

Although Duke University must comply with all federal and state regulations and the conditions of its licenses, some of the policies that have been approved by the RSCs are more restrictive than the regulations. In no case may citation of federal or state regulation be used as justification for non-compliance with these policies.

A. ORGANIZATION OF RADIATION SAFETY PROGRAMS AT DUKE UNIVERSITY

The organization of the radiation safety program at Duke University reflects the intent of North Carolina and federal regulations regarding the administration of radiation protection programs.

The Administration of Duke University appoints two RSCs, one to provide radiation protection oversight to the Medical Center, the School of Medicine (SOM) and selected DUHS entities, and another for the University accelerator facilities and laboratories. The Radiation Safety Officer (RSO) reports to both Committees. The policies of the Committees are executed by the RSO through the Radiation Safety Division of the Occupational and Environmental Safety Office (OESO), hereinafter referred to as the "Radiation Safety Division" (RSD). The RSD, in turn, provides guidance and oversight to Authorized Users (AUs) of radiation producing devices and radioactive material. In addition, the RSD provides support to the Radioactive Material Waste Program of OESO's Environmental Programs Division (EPD) and provides oversight for the Laser Safety Program. The organization of Duke radiation safety programs and the chain of regulatory and administrative oversight are summarized below and shown in Figures 1 and 2. Specific areas of responsibility and authority are presented in Chapter II.

Figure 1. Organizational Chart of Duke University Radiation Safety Programs

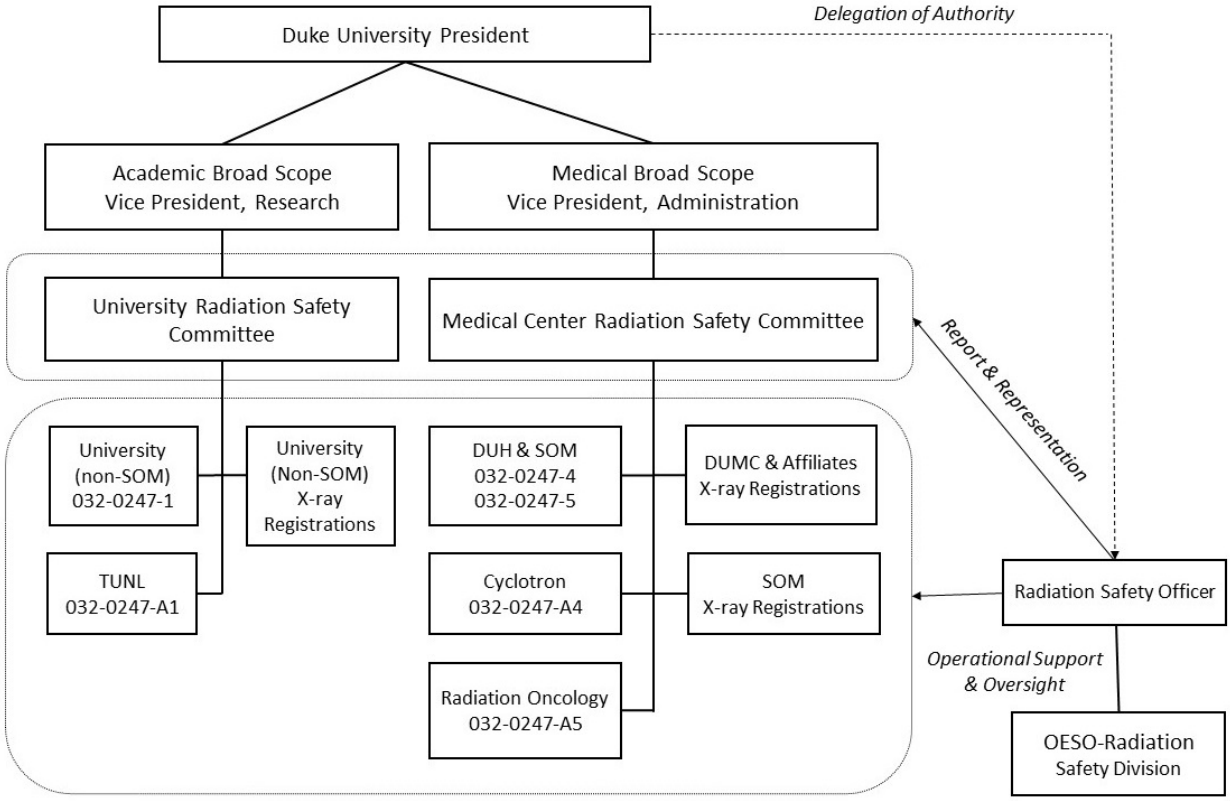
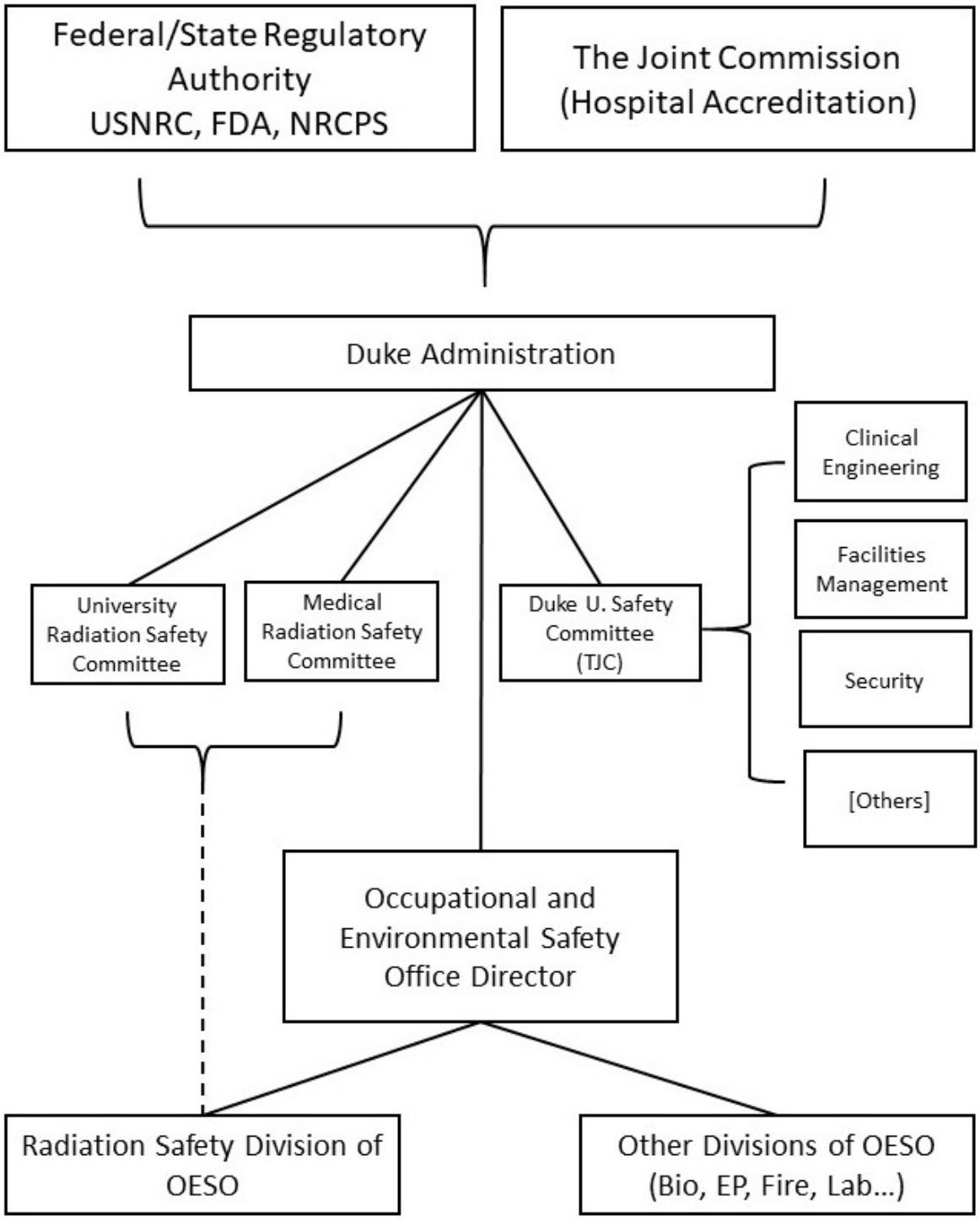


Figure 2. Organization of Duke University Safety Committees and OESO



1. *Administration:* The Duke University administration works through the Committees and the RSO to provide institutional oversight of radiation safety programs.

2. *Committees:* The Duke University Committee on Radiological Safety ("University Committee"), the DUMC Radiation Control and Radioactive Drug Research Committee ("Medical Center Committee"), and the Accelerator RSCs are responsible for establishing and enforcing policies and procedures for the procurement, use and disposal of radioactive material, devices emitting ionizing radiation, and lasers.

3. *Radiation Safety Officer (RSO):* A person, appointed by the Administration, who serves as the operational representative of the University and Medical Center Committees for providing information and assistance on radiation safety matters, and to assure adherence to regulations issued by the Committees and state or federal agencies. This includes the authority to halt operations involving radioactive material or radiation producing machines that compromise safety or regulatory compliance. For specific areas of authority of the RSO, See Section II.C.1.

4. *Accelerator Director:* A person who oversees the operations of a specific campus accelerator facility.

5. *Authorized User (AU):* A person authorized by the University or Medical Center Committee to use or supervise the use of radioactive material and/or devices producing ionizing radiation.

6. *Radiation Worker:* A person utilizing ionizing radiation under the supervision of an AU.

B. THE PRINCIPLE OF "ALARA"

Every employee of Duke University and its affiliated institutions is protected from unnecessary exposure to ionizing radiation by federal and state law. Accordingly, every Duke radiation worker is informed about protective practices that can reduce exposure through education and training.

Federal and state regulations prescribe "maximum permissible dose limits" for individuals who are exposed to radioactive material or radiation sources consequential to their employment (See Table 1). These limits, which have been recommended by various governmental and private advisory organizations, are believed to represent exposure levels that should not result in harm to the worker or his or her offspring during their lifetime.

"Occupational dose" refers to the radiation dose received by an individual consequential to their employment and the accompanying assigned duties. Occupational dose does not

include the dose received from background radiation, as a patient or human research subject or as a member of the general public.

In view of the uncertainty of the effects of low-level radiation, it is prudent to keep all radiation exposures and releases of radioactive material to the environment to the lowest feasible levels. This is the philosophy underlying the concept of "As Low As Reasonably Achievable", or ALARA. This principle is incorporated in state and federal regulations which require licensees to implement policies and procedures so that environmental releases and occupational doses are in accordance with ALARA, and not simply meeting published regulatory limits.

Table 1. Annual Occupational Dose Limits for Adult Radiation Workers

Body Part Exposed	Annual Occupational Limit
Whole body (head, trunk, gonads, arms above elbows, legs above knees)	5 rem (50 mSv)
Lens of the eye	15 rem (150 mSv)
Single organ other than the lens of the eye	50 rem (500 mSv)
Skin of whole body, skin of the extremities	50 rem (500 mSv)
Embryo/Fetus of a declared pregnant worker (see Note below)	0.5 rem (5 mSv) during entire pregnancy

Note on Fetal Radiation Dose: Guidance from the National Council on Radiation Protection and Measurements recommends that fetal dose be limited to 50 millirem (0.5 mSv) per month, with proration of the unmonitored period between conception and declaration of 50 millirem per month.

Note on Workers under the Age of 18 and Members of the Public: The annual limits for minor radiation workers are 10% of the applicable adult worker limits. The annual limit (effective dose equivalent) for any member of the public is 100 millirem (1 mSv).

II. FUNCTIONS AND RESPONSIBILITIES

Each component of the Duke University Radiation Safety chain of organization has specific responsibilities concerning the safe use of radioactive material and radiation sources. The functions, responsibilities, and enforcement duties of the major components are as follows.

A. ADMINISTRATION

The Duke University Administration is responsible for:

1. Establishment of a formal radiation safety structure that includes Radiation Safety Committees (RSCs) for Duke University and Duke University Medical Center (DUMC) and the appointment of a Radiation Safety Officer (RSO)

2. Institutional oversight for specific accelerator licenses at Duke University/Medical Center through the Committees and the RSO.

3. Ensure that adequate resources are provided for the radiation safety program, including support for the RSCs and RSO.

B. COMMITTEES

The Medical Center and University Committees and each local Accelerator RSC, in collaboration with the RSO and the Radiation Safety Division (RSD), shall:

1. Provide guidance and information on the radiation safety program to Administration, ensure that adequate resources are provided and assist the RSO in the development, implementation and maintenance of the radiation safety program.

2. Meet at least four times a year, or at a frequency determined by the RSO, to review radiation safety issues and receive a status report on such issues from the RSO. The Chairs of the Committees have the authority to make temporary policy decisions when a formal Committee meeting cannot be scheduled in a timely fashion. Such temporary policy decisions are subject to a full review by the Committee at its next meeting.

3. Meet at the call of the Chair to resolve matters of an emergency nature relating to health and safety arising from the use of radiation.

C. RADIATION SAFETY OFFICER AND DIVISION

1. The RSO shall:

    a. Determine compliance with policies issued by the Committees and by federal, state and local agencies.

    b. Supervise radiation control activities.

    c. Review all proposals for the use of radionuclides and radiation-producing devices and conditions of their use and transmit such proposals to the Committees with recommendations for approval or disapproval. This includes proposals for the investigational use of radioactive drugs in humans, as a member of the Radioactive Drug Research Committee.

    d. Have the authority to halt operations involving radioactive material or radiation machines if unsafe or unacceptable conditions exist.

    e. Control acquisition and transfers of radionuclides to individuals on and off campus and ensure that individual and institutional possession limits are not exceeded.

    f. Implement institutional accelerator safety policies and regulations, as determined by the Committees.

    g. Through the Laser Safety Manager, implement the policies and procedures of the Laser Safety Committees.

    h. Prepare an annual report for the radiation safety program.

    i. Prepare license amendments and maintain timely renewals of licenses.

    j. Determine if incidents involving the clinical use of radioactive material or accelerators constitute medical events as defined in state and federal regulations, report such incidents to North Carolina regulators where applicable, and assist the Authorized Users (AU) in formulating corrective actions.

2. The RSD, under the supervision of the RSO, shall:

    a. Maintain radiation dosimetry records of all persons issued personnel monitors and maintain records of bioassay results.

    b. Maintain a registry of all campus facilities subject to the radiation safety program.

    c. Maintain records of radioactive material procurement and disposal in a form suitable for timely retrieval and reporting to regulatory agencies.

d. Assist AUs in the storage, use and disposal of radioactive material at the laboratory level.

e. Audit clinical and research laboratories and accelerator facilities through meetings with AUs and/or their designees and periodic inspection of operations, reporting any issues of non-compliance to the RSO.

f. Monitor the AUs' procurement, transportation, storage, use and disposal of radioactive materials to ensure compliance with the State of North Carolina licenses, the institutional ALARA program and applicable United States Department of Transportation (USDOT) and Environmental Protection Administration (EPA) regulations.

g. Coordinate a radioactive waste management program for waste to be disposed of outside the laboratory setting in conjunction with the Environmental Protection Division of the Duke Office of Occupational and Environmental Safety Office. This includes receipt of waste, decay-in-storage, burial, incineration and disposal through commercial vendors.

h. Provide operational support to the Laser Safety Manager.

i. Calibrate and/or perform operational checks of radiation survey instruments for AUs when required.

j. Perform leak tests on sealed sources as required by state regulations.

k. Receive, inspect and distribute incoming shipments of radioactive material as required by North Carolina and USDOT regulations.

l. Conduct educational programs in the safe use of radionuclides and radiation-producing machines through formal courses and electronic media.

m. Conduct an environmental monitoring program to ensure regulatory compliance.

n. Investigate incidents involving radioactive material and radiation-producing machines or violations of regulations.

o. Respond to emergencies and supervise decontamination operations by the AUs as required.

p. Monitor inpatient therapies utilizing unsealed or sealed radioactive material as required, and assist in determining when appropriate discharge criteria have been met.

D. ACCELERATOR FACILITIES

1. Each Accelerator Director shall:

    a. Establish a local Accelerator RSC structure that includes appointing local Committee members and a local Radiation Safety Manager, per all applicable program and license requirements.

    b. Provide an operational budget and necessary personnel support for the management of the accelerator radiation safety program.

    c. Function as a representative of the Duke Administration in the local Accelerator RSC meetings.

    d. Commit to the ALARA program.

    e. Be authorized to terminate immediately any project or operation that is found to be a threat to the health of employees and/or members of the public, or to the property or environment of the University and local community. Such operational decisions are subject to full review by the institutional Committees and the institutional RSO.

    f. Execute established radiation safety policies and ensure compliance with the applicable license conditions.

    g. Supervise radiation control activities.

E. AUTHORIZED USER

1. Each Authorized User shall:

    a. Develop written procedures for the use of radiation sources or radioactive material as appropriate for the intensity and scope of the activities covered in the AU's laboratory and commensurate with good radiation protection practices.

    b. Furnish all information requested by the Committee or RSO concerning their qualifications, facilities, equipment and safety procedures.

    c. Maintain records as required by this Manual.

    d. Ensure that receipt and transportation of radioactive material in any amount is compliant with the policies and procedures of the RSD, and applicable regulations in any other jurisdictions.

e. Designate an alternate AU to provide oversight of their laboratory operations during out of contact exceeding thirty days, and to transmit this information to the RSO.

f. Ensure that each radiation worker under their supervision has received radiation safety training appropriate to such use, including information for pregnant women or women of child-bearing potential as set forth in Chapter VIII, Reproductive Health.

g. Notify the RSO of any changes in Authorization status.

h. Notify the RSO of intention to terminate the Authorization, no later than thirty days prior to the proposed termination.

i. Ensure that (a) survey instruments in their laboratory are not used unless calibrated or operationally checked (as appropriate) by the RSD within the past 12 months, and (b) contact the RSD when obtaining new survey instruments, or if an instrument requiring calibration or an operational check is discovered.

F. RADIATION WORKER

1. Each Radiation Worker shall:

a. Understand and implement the appropriate radiation safety precautions for the specific radioactive material being used.

b. Conduct radiation-related operations under the supervision of their AU, in adherence to all applicable radiation safety program requirements, including training, personnel monitoring, bioassay performance and surveys for radioactive contamination.

III. ESCALATED ENFORCEMENT

A. PURPOSE

This section outlines the key elements involved in the notification and resolution of items of non-compliance to the radiation safety program requirements.

B. ENFORCEMENT PROCESS

Upon discovery of a radiation safety issue, from either a routine safety audit or a non-routine finding:

1. Unsafe activities must be stopped immediately by the Authorized User (AU). Certain serious safety issues may warrant immediate actions beyond the stoppage of the unsafe activities themselves. The Radiation Safety Officer (RSO) may order additional safeguards such as the temporary suspension of radiation use by specific radiation workers or at specific facilities, and the temporary confiscation of radioactive materials. Significant issues and actions shall be reported by the RSO to the applicable RSC for further actions.

2. The Radiation Safety Division (RSD) will provide the AU written notification of any items of non-compliance. Upon receipt of the notification, the AU is responsible for investigating and resolving the cited issues immediately. The notification will specify if a written response is required from the AU regarding corrective measures for any items of non-compliance cited. If required, the AU written response shall be provided within two weeks unless otherwise specified.

3. For repeat violations (i.e. same item cited on the previous audit) or other patterns of violations, the AU must respond in writing, within one week of notification unless otherwise specified, with at least the following items:

    a. what caused the item(s) of non-compliance; and

    b. corrective actions the AU has taken or will take to prevent recurrence.

If compliance still cannot be achieved, for the effective resolution of the radiation safety issues, the RSO may escalate the issue to key leadership-level individuals, including but not limited to: the Chair of the applicable RSC, the Occupational and Environmental Safety director, the AU's Departmental Chair, Dean, Vice Provost, and the Duke Compliance Officer.

IV. RADIOACTIVE MATERIAL

A. AUTHORIZATION

The possession and use of any licensable quantity of radioactive material are subject to institutional radioactive material authorization and must be conducted in compliance with all applicable regulatory requirements. In addition, shipboard use associated with the Duke University Marine Laboratory (DUML) must be covered under either the Duke University license or a license issued by the United States Nuclear Regulatory Commission (USNRC), an Agreement State, or other recognized licensing agency.

1. Types of Authorizations

The two types of Authorizations to use radioactive material at Duke University and the Medical Center are:

a. Authorization for radioactive material use in scientific research or other applications that do not involve human subjects; and

b. Authorization for radioactive material use in medicine or scientific research in humans.

2. Status of Authorizations

a. Active: The Authorized User (AU) is authorized by the Committees to use, purchase and possess radioactive material in any form. An Authorization must remain classified as "active" if it has any active radioactive materials inventory.

b. Inactive: An inactive AU has chosen not to perform experiments utilizing unsealed radioactive material for an extended period of time. An inactive user shall have no radioactive material (including radioactive waste) in their possession. An AU who wishes to change to inactive status must notify the Radiation Safety Officer (RSO) in writing of this decision. Inactive users who have equipment containing sealed sources must either (a) have the sealed sources removed and transferred to the custody of the RSO, (b) transfer them to an active AU or (c) dispose of them prior to requesting "inactive" status. “Inactive” status is confirmed only upon a close-out audit of the Authorization conducted by the Radiation Safety Division (RSD). If an inactive user desires to reinstate their "active" status, they must notify the RSO in writing and fulfill "Active" status training requirements.

c. Terminated: The AU is no longer employed by Duke University or has terminated, either by their own choice or by the direction of the Committees, their Authorization to use, order or possess radioactive material including equipment containing sealed sources, irradiators, or radiation producing machines. This person has no radioactive material, equipment containing radioactive material, or radiation producing equipment. A "terminated status" AU shall have completed (either prior to termination or in absentia) a "close-out" procedure, in which the inventory of radioactive material under the Authorization has been disposed or transferred, radioactive waste has been removed, and rooms and facilities have been surveyed and determined to be free of radioactive contamination. Documentation of the "close-out" will be maintained by the RSD.

B. GENERAL RADIATION SAFETY POLICIES FOR RADIOACTIVE MATERIAL

The Committees of Duke University and Duke University Medical Center have adopted a number of policies and procedures to ensure the proper procurement, distribution, use and disposal of radioactive material and radiation-producing equipment. This chapter outlines important general radiation safety practices and procedures that must be implemented by all AUs.

1. Basic Laboratory Radiation Safety Policies

All AUs are responsible for strict adherence to standard radiation safety practices and procedures in their individual laboratories and clinical areas. The RSD will assist AUs in developing satisfactory written procedures pertinent to their specific requirements. In general, the following guidelines regarding the safe storage, control, and use of radioactive material will apply.

a. Radioactive Material Use and Storage Areas

(i) Take the necessary precautions to prevent contamination from radioactive material that has been removed from stock and used in experiments. This is accomplished by training personnel in the proper handling of radioactive material to prevent ingestion, the use of hoods when working with materials that may become airborne, the proper performance of radiation surveys, and the application of proper techniques for decontamination of laboratory areas should contamination occur.

(ii) Instruct all individuals working in or frequenting any portion of an area where radioactive material is used or stored regarding Duke University's reproductive health policy and the requirements of Chapter VIII of this Manual.

(iii) Ensure that stock solutions of radioactive material and sealed sources containing radioactive material are stored in a locked room, locked cabinet, locked freezer/refrigerator or lock-box when not in use. If locking the individual storage unit is not feasible, then the laboratory room containing the storage area must be locked whenever the area is not under supervision or direct surveillance. Material in use need not be locked up provided it is kept under surveillance at all times. Users shall not permit radioactive material to be left unattended on desks, tables or laboratory benches. All unauthorized individuals shall be excluded from radioactive material use areas. The AU shall enlist the aid of the Duke University Police Department to enforce the exclusion of unauthorized personnel, if necessary.

(iv) Ensure that any entryway providing access from public areas into areas where radioactive material is used or stored or where radiation-emitting devices are used are posted with the appropriate official "Caution" signs. Assistance in obtaining official signs and their posting may be obtained from the RSD.

(v) Ensure radioactive material use areas, equipment, fixtures (e.g. sinks and hoods), etc. are clearly indicated as potentially contaminated (e.g. with "Caution - Radioactive Material" labels).

(vi) Prohibit eating, drinking, smoking, and/or application of cosmetics within that area of the laboratory where radioactive material is stored or used. Prohibit food storage in refrigerators where radioactive material is stored. Ensure that each person handling unsealed radioactive material washes their hands thoroughly before eating, smoking, or leaving the work area.

(vii) Enforce wearing appropriate personal protective equipment, including disposable protective gloves, laboratory coats, eye protection and so forth when handling unsealed radioactive material. Disposable gloves worn in radioactive use areas shall not be worn into areas not designated for radioactive material use, and shall be disposed of as radioactive waste before leaving the radioactive material area. Laboratory coats should be left in the laboratory rooms.

(viii) Prohibit operation of pipettes or siphons by mouth suction.

(ix) Maintain exposure of personnel and release of radioactive material to ALARA levels.

(x) Submit an Authorization amendment request in advance whenever the location of radioactive material use (building and/or rooms) is to be changed from that identified on the current Authorization.

(xi) Perform thyroid bioassays for each individual handling radioiodine in quantities and in operations described in Chapter VII.D. Intake of radioiodine shall be computed using the appropriate on-line application on the RSD web site and compared to applicable action levels. If the AU is not equipped to perform the measurements, they must schedule bioassay measurements through the RSD.

(xii) Instruct all individuals in the proper use and maintenance of proper detection instrumentation in the lab to ensure the absence of radioactive contamination in the lab and on personnel.

(xiii) Ensure that appropriate measures, such as filters and traps, are placed between apparatus containing radioactive material and the house vacuum system, in order to prevent the entry of radioactive material into the vacuum system.

2. Termination of Laboratory Operations (Close-Out)

When an AU ends their affiliation with Duke University or desires to terminate their radiation Authorization, any laboratory space controlled by that user must be decommissioned (cleaned out by the AU and closed out by the RSD) before the area can be returned to non-radiation use or occupied by another AU. Any AU who anticipates terminating their Authorization shall submit an amendment request notifying the RSO of the termination no less than thirty (30) days prior to the anticipated date of termination.

3. Removable Contamination Surveys

The specific contamination survey requirements for each laboratory are outlined in the authorization documentation of the responsible AU. Laboratories using low-energy beta emitting radionuclides or other nuclides as specified by the RSO must perform periodic surveys for removable contamination (“wipe tests”). Records of these surveys shall be made available for review by RSD personnel. The frequency of the wipe surveys will depend upon the materials being used in the individual laboratories, as specified in the written procedures for each laboratory and approved by the RSD.

The responsible AU must ensure that areas producing wipe test results in excess of the action limits specified in Table 2 are decontaminated. Documenting wipe test results in net counts per minute (CPM) and decontaminating areas producing greater than 100 net CPM per wipe will ensure compliance with the Table 2 limits. Alternatively wipe test results may be documented in disintegrations per minutes (DPM) using an appropriate conversion factor and compared directly to the Table 2 limits.

Table 2. Wipe Test Decontamination Action Levels

Net DPM on Wipe*		Action to be Taken by Laboratory Personnel
Alpha, gamma and high energy (>250 keV) beta emitting radionuclides (e.g. I-131, P-32, Cr-51, Ac-225)	Low energy (< 250 keV) beta emitting radionuclides (e.g. H-3, C-14, S-35)	
Less than 220	Less than 2,200	No action required
220 – 11,000	2,200 – 11,000	Clean area (see "Decontamination" below); repeat wipe(s)
11,000 – 110,000		Clean area, repeat wipe(s); notify RSD to verify clean-up
> 110,000		Cease radioactive material use and notify RSD. Commence immediate cleanup under RSD supervision

* Wipe area 100 cm^2 minimum.

4. Decontamination

Preparations for decontamination shall begin promptly. The user will determine the extent and hazard of contamination prior to commencing clean up. The individual responsible for the contamination is expected to perform the necessary

clean up. The AU shall inform the RSD of all contamination incidents exceeding the notification level specified in Table 2 above. The RSD will oversee the associated decontamination process.

See the applicable parts of Chapter XI. RADIOLOGICAL EMERGENCY PROCEDURES for more details.

5. Sealed Sources

a. The RSO shall ensure that leak tests and physical inventories are performed on those sealed sources specified and at the intervals specified in the applicable radioactive material license conditions or regulations.

b. The responsible AU shall ensure that:

(i) the RSO is notified prior to the acquisition, transfer, relocation, destruction or disposal of any sealed source;

(ii) the RSO is notified immediately upon the loss or suspected theft of any sealed source (see section XI.D, Loss or Theft of Radioactive Material), or any damage to or breach of a source or accelerator target that may lead to significant spread of radioactive contamination;

(iii) all sealed sources under the AU's control are secured against unauthorized access or removal;

(iv) a complete inventory of all sealed sources under the AU's control is maintained and kept available for inspection by RSD staff.

6. Airborne Radioactive Material

Procedures that might produce airborne radioactivity shall be conducted in a fume hood, glove box, or other suitable closed system. Such airborne radioactivity fume hoods must have an annual certification of airflow by Duke Facilities Management or other qualified service providers.

The air concentrations of radioactive material due to potential discharges from fume hoods or the accelerator facilities will be evaluated by the RSD. Where indicated, appropriate control methods such as activated charcoal filters will be employed to ensure regulatory compliance.

7. Research Animals

a. Approval

The administration of radioactive material to research animals and the irradiation of research animals must be approved by the Institutional Animal Care and Use Committee and the RSD.

b. General Policies

(i) Injection of radioactive material into animals, where appropriate, shall be performed in trays lined with absorbent material.

(ii) Cages must be labeled as to radionuclide, quantity of radionuclide administered per animal, date of administration, and authorized user.

(iii) Special procedures shall be developed relative to the collection and disposition of the animal's excreta and carcass.

(iv) Any live animal containing radioactive material being returned to the Vivarium shall have prior approval of the Division of Laboratory Animal Resources and the RSD.

8. Ordering, Receipt, Inventory, Transport, And Disposal

a. Ordering Radioactive Material

Radioactive material orders originating from research laboratories shall be approved by the RSD and may be submitted using an appropriate web-based ordering application. Fax and email orders are also acceptable. Clinical areas including Radiation Oncology and Nuclear Medicine and Radiotheranostics (NMRT) may order directly from the supplier.

b. Receipt of Radioactive Material

All shipments of radioactive material, except as specifically exempted by the RSO or designee, shall be addressed to and received at the locations specified in the applicable Duke radioactive material licenses. The RSD shall be contacted if anyone other than RSD personnel delivers radioactive packages to a biomedical research laboratory. The RSD will accept in-coming radioactive material shipments at its office location only during normal business hours. An AU requiring radioactive material delivery outside of regular hours must contact the RSD in advance to make special arrangements.

Clinical areas (Radiation Oncology, NMRT and Radiopharmacy) may receive radioactive material directly from the supplier, as long as the required package-receipt procedure, per applicable regulations, is strictly followed.

Following acceptance of a shipment at its office location, RSD personnel will document surface dose rates, inspect the package for leakage or other signs of damage, determine if surface contamination exists and document

the results of the inspection for regulatory compliance purposes. For deliveries of radioactive material to Radiation Oncology or to the Radiopharmacy for clinical use, the RSO may delegate this "check-in" procedure to qualified on-site personnel. For non-clinical labs, RSD personnel will deliver radioactive material only to the requesting AU or designee, and only if that designee is trained to accept radioactive material shipments. Upon receipt, the AU is responsible for ensuring completion of the following tasks:

(i) inspection of the inner contents of the package and report discrepancies to the RSD.

(ii) storage of the material in a secure location.

c. Inventory of Radioactive Material

AUs shall complete their radioactive material inventory reports within the intervals specified by the RSO. The inventory reports must also include estimates of the amount(s) of radioactive material discharged into the sanitary sewer, if any.

Inventory reports shall be submitted to the RSD using an on-line Radioactive Materials Inventory Reporting application that is maintained by the Occupational and Environmental Safety Office (OESO). Radioactive material shipments will be entered into the Inventory Reporting System by RSD personnel upon delivery. AUs will be responsible for using the on-line reporting application to periodically update their holdings. Failure to update holdings within the maximum time intervals specified by the RSO may result in suspension of ordering privileges or withholding of material. In general, inventory reports are to be submitted at least once each month for unsealed material. Because it is impractical to maintain inventory records for very short-lived radionuclides, radionuclides with half-lives less than three (3) days are exempted from inventory reporting requirements.

d. Transfer of Radioactive Material

(i) Transfer of radioactive material between Duke AUs is subject to approval by the RSO or designee. The decision will be based on safety and compliance with institutional license conditions and all other applicable regulatory requirements.

(ii) Routine transfers from Duke facilities that produce or supply radioactive material (e.g. Cyclotron Facility, NMRT, Radiopharmacy) to on-campus AUs may be eligible for procedural preapproval by the RSO. If the transferring facility uses their own inventory tracking system (e.g. NMIS^{TM}) then they may be exempt

from additional documentation of the transfer. The recipient must still document the transfer using a Radioactive Material Transfer Form.

(iii) Any radioactive material with a half-life greater than 3 days that is transferred to a Duke AU must be added to the recipient's radioactive material inventory. It is the responsibility of the recipient to provide the RSD with an accurate copy of the Radioactive Material Transfer Form so that their inventory can be properly updated.

(iv) Transfer of radioactive material to an external entity is subject to approval by the RSO or designee. The decision will be based on safety and compliance with institutional license conditions and all other applicable regulatory requirements for both Duke and the recipient.

e. Relocation, Transportation or Shipment of Radioactive Material

The transportation or shipment of radioactive material on campus and to other institutions, including the DUML, Duke laboratories in the Research Triangle Park and the Durham Veterans Affairs Medical Center, must comply with both State of North Carolina and United States Department of Transportation (USDOT) regulations. All such shipments and transport within or from Duke University shall be subject to prior approval from the RSD. In addition:

(i) Transport of radioactive material off-campus by Duke personnel as checked baggage on public conveyances is prohibited.

(ii) Radiation sources such as equipment containing sealed sources of radioactive material (such as liquid scintillation/gamma counters, gas chromatograph electron capture detectors, moisture content gauges, etc.) shall not be relocated, transferred, donated, sold, discarded or otherwise disposed without approval by the RSO.

f. Disposal of Radioactive Waste

The Environmental Programs Division (EPD) of OESO is responsible for radioactive waste management at Duke University and Medical Center. AUs are responsible for ensuring that all their personnel working with isotopes understand the waste segregation and packaging procedures set forth by the EPD. Radioactive material, in any amount, must be disposed of as radioactive waste and not placed in the normal solid waste stream. Small amounts of residual radioactivity may be discharged into the sanitary sewer (e.g. sink drain, toilet, etc.) in the course of cleaning

glassware and laboratory apparatus. However, discharge to the sewer shall not be used as a primary means of radioactive waste disposal, except as authorized by the RSO. Instead, liquid waste should be handled as specified by the EPD. AUs shall record, via their monthly inventory report, estimates of their discharge of radioactive material into the wastewater stream. Any such discharges to the sanitary sewer must be in accordance with the Laboratory-specific Standard Operating Procedure. While radioactive waste is in the lab, all waste containers must be clearly labeled with the radionuclide(s) contained within and a "Radioactive Material" label. In addition, each non-empty waste barrel provided by the EPD must have a waste disposal sheet on or near the waste barrel, and the sheet must list the nuclide(s) and activity in the waste barrel. Specific requirements for the disposal and collection of radioactive waste are available on the EPD website.

AUs may seek special authorization by the RSO to conduct decay-in-storage clearance for isotopes with a physical half-life of shorter than 15 days. Once authorized, the laboratory may clear decay-in-storage wastes as non-radioactive only if:

1. The radioactivity cannot be distinguished from the background radiation level, at all sides of the container, with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
2. All radiation labels are removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as waste of other hazards; and
3. All key aspects of the clearance (e.g. material cleared, instrument used, radiation level measured, date of clearance, etc.) are properly documented using the “Decay-In-Storage Form”, which can be found on the Radiation Safety section of the OESO website under “Forms”. The documentation is retained for at least 3 years.

Once the DIS waste is cleared as non-radioactive, it may require further management or disposal consideration for other hazards, if applicable.

C. NON-HUMAN RESEARCH USE OF RADIOACTIVE MATERIAL

1. Qualifications

a. Full-time Duke Faculty

An applicant for non-human use of radioactive material shall be a full-time member of the faculty and have both training and experience commensurate with the types and quantities of radioactive material for which application is being made (see Appendix B: *Faculty Positions Qualifying for Authorized User Status*).

b. Adjunct Duke Faculty with Primary Academic Appointments at Other Institutions

(i) An applicant with an "Adjunct" faculty appointment at Duke who has a primary appointment at another institution may qualify for non-clinical AU status provided the following conditions are met:

(ii) The applicant has both training and experience commensurate with the types and quantities of radioactive material for which application is being made;

(iii) The applicant holds a full-time primary academic appointment at the other institution which carries a faculty rank of Assistant Professor or higher, as defined in (a) above; and

(iv) The applicant's salary is supported in part by Duke University.

c. Waiving of Faculty Status Requirement for Certain Authorizations

The qualifications of non-faculty individuals as AUs may be accepted for those Authorizations that are solely operational in function.

(i) "Operational" means that the radioactivity possessed under the Authorization is not used for biomedical or basic science research purposes, but for storage or analytical applications not related to research. Examples include the oversight of radioactive waste for decay in storage and off-site transfer, or the use of lead content analyzers for industrial hygiene purposes, and so forth.

(ii) Operational Authorizations are subject to the approval of and oversight by the applicable RSC.

2. Development of Written Standard Operating Procedures

Recognizing that the types of clinical and laboratory operations encompassed by the programs at Duke vary greatly, the Committees require that each AU develop a set of written procedures that are specific to their laboratory.

Each AU's written procedures should contain the following information, based upon the general requirements of the Duke Radiation Safety Program:

a. The types of radioactive material and/or radiation producing machines present in the laboratory.

b. General safety issues that address the proper handling of radioactive material, use of fume hoods, wearing of personal protective equipment, etc.

c. Laboratory-specific procedures for ordering, receiving, storing and disposing of radioactive material.

d. Laboratory-specific procedures for conducting surveys for detection of contamination (wipe test locations, frequencies, etc.).

e. Description of laboratory-specific record-keeping procedures. As an aid to formulating these laboratory-specific written procedures, the RSD will supply any current or prospective AU with a template electronic document that is based on the radionuclides included in the AU's authorization.

3. Amending the Authorization

If the AU wishes to alter the conditions of the Authorization (such as by adding or deleting permitted radionuclides, changing locations of use, or changing possession limits), they shall fill out an “Amendment Request for Radioactive Material Authorization” form and submit it to the RSD for review and provisional approval by the RSO. The review will consider factors including but not limited to the appropriateness of the training, procedure, equipment, shielding, monitoring. All amendments to Authorizations are subject to formal approval by the appropriate RSC.

D. AUTHORIZATION FOR MEDICAL USE OF RADIOACTIVE MATERIAL IN HUMANS: PHYSICIANS, MEDICAL PHYSICISTS AND NUCLEAR PHARMACISTS

The administration of radioactive material or therapeutic radiation to patients or research subjects at DUMC is regulated by the USNRC, the US Food and Drug Administration (FDA), the State of North Carolina and the Medical Center Committee. In order to participate in the human use of radioactive material or accelerators, applicants must provide evidence of training and experience that reflect those set forth in the applicable federal and state regulations. These requirements generally involve (1) training in basic radioactivity handling techniques, (2) supervised clinical training in an institutional radiology, nuclear medicine or radiation oncology program, and (3) relevant experience. Details of the process for attaining AU physician, Authorized Medical Physicist or

Authorized Nuclear Pharmacist are set forth in Appendix C: *Human-Use Authorized User, Authorized Medical Physicist and Authorized Nuclear Pharmacist: Qualifications and Process.* The general qualifications and application process is summarized as follows:

> (1) Application shall be made through the administration of the clinical department in which the physician, physicist or pharmacist will be employed. The application shall specify the uses of radioactive material, as set forth in federal regulations, that are required for the applicant to fulfill their responsibilities to the clinical department.
>
> (2) Physician and Nuclear Pharmacist applicants must hold an active and unrestricted practice license from the applicable North Carolina Board.
>
> (3) All applicants shall provide evidence of training, experience and licensure (if applicable) to the General Secretary of the Duke RSCs. A "Human Use Subcommittee" will review the credentials of the applicants and provide the membership of the Medical Center Committee with a recommendation for approval. Final approval is contingent upon a majority vote of the Medical Center Committee membership.
>
> (4) If approved, the authorization for clinical use of radioactive material is limited to DUMC's license of broad scope. Authorization by the Committee does not imply authorization at those entities of the Duke University Health System that hold specific hospital licenses.

E. BASIC HUMAN RESEARCH AND THE RADIOACTIVE DRUG RESEARCH COMMITTEE

"Basic human research" means research intended to obtain basic information regarding the metabolism (including kinetics, distribution and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology or biochemistry; but not intended for immediate therapeutic, diagnostic or similar benefit. For such studies, application must be made to the DUMC Radioactive Drug Research Committee (RDRC). The RDRC reports to the FDA. Investigators who wish to conduct basic human research on radioactive drugs shall make an application to the RDRC, consistent with the requirements of 21 CFR 361. RDRC approval does not relieve the applicant of obtaining the approval of other entities, including the Duke Institutional Review Board (IRB), prior to conducting research in humans.

F. PROCEDURES INVOLVING IONIZING RADIATION, MRI AND LASERS IN CLINICAL INVESTIGATIONS

Investigators supervising clinical trials that are subject to oversight by the Duke IRB must inform research subjects of any exposure to ionizing radiation consequential to participation in a clinical study where the exposure exceeds the standard of care for the condition that is the subject of the study. The IRB requires that such protocols undergo "Specialty Committee" review and approval. The Medical Center Committee or its designated member(s) acts as the Specialty Committee for protocols involving ionizing radiation ("Radiation Safety Specialty Committee"). Information about incorporating the use of ionizing and non-ionizing radiation in clinical studies is available on the Duke IRB web site.

V. CAMPUS AND MEDICAL CENTER ACCELERATOR FACILITIES

The particle accelerator facilities on campus, which include the Triangle Universities Nuclear Laboratory, the Free Electron Laser Laboratory, the Medical Center Cyclotron Facility and the Radiation Oncology Department's clinical linear accelerators, present special issues in regard to radiation safety. The potential for high external radiation levels and the radioactive byproducts generated during operation of these machines require a high level of awareness of the potential hazards. Detailed information on the specific radiation safety-related policies and procedures for each facility is provided in the facility-specific Radiation Safety Manual or clinical Quality Management Program. For accelerator use on human patients or research subjects, refer to IV.D for information about the specific authorization requirements.

Basic accelerator safety considerations are as follows.

- With the exception of patients or human research subjects irradiated for therapeutic purposes, exposure of individuals to the direct beam or secondary radiation from bombarded targets is prohibited.
- All operations shall be conducted in accordance with applicable state and federal regulations, and facility-specific licensing conditions, policies and procedures. Personnel shall be trained in the appropriate operating procedures, alarm systems, safety interlocks and emergency procedures.
- Handling of activated accelerator components shall be conducted in accordance with specific radiation protection policies and procedures.

- Research accelerator personnel shall be trained in the safe handling of radioactive material produced by the accelerators, and to submit to bioassays for internal contamination if warranted.

VI. X-RAY DEVICES

A. Authorization

The acquisition, possession and use of any system, device, subsystem, or machine component that may generate by electronic means x-rays above 5 keV, unless licensed as a particle accelerator (see Chapter V), are subject to institutional x-ray authorization and must be conducted in compliance with all applicable regulatory requirements.

1. Types of X-Ray Authorizations

The two types of X-ray Authorizations at Duke University and the Medical Center are:

a. Authorization for non-human use (See Section VI.C for non-human research and operations other than veterinary medicine and Section VI. D for veterinary medicine); and

b. Authorization for human use (See Section VI.E for research involving human subjects).

2. Status of X-Ray Authorizations

a. *Active:* The X-ray Authorized User (XAU) is authorized to use, purchase and possess x-ray devices. A person must remain classified as "active" if they are in possession of and are actively using x-ray devices.

b. *Inactive:* An XAU who wishes to change to inactive status must notify the Radiation Safety Officer (RSO)in writing of this decision. The “Inactive” status XAU has chosen not to use x-ray devices for an extended period of time. An inactive XAU shall have either (1) no x-ray devices; or (2) all their x-ray devices classified as “Not in Use”. The Radiation Safety Division (RSD) shall update the corresponding x-ray registration(s) in a timely manner. “Inactive” status is confirmed only upon a close-out audit of the Authorization conducted by the RSD. If an inactive XAU desires to reinstate their "Active" status, they must notify the RSO in writing and fulfill "Active" status training requirements. For each x-ray device returning to use, a satisfactory radiation safety evaluation conducted by the RSD, including a radiation survey, will be required.

c. *Terminated:* The XAU is no longer employed by Duke University in a qualified capacity (see section below) or has terminated, either by their own choice or by the direction of the applicable RSC, their Authorization

to use x-ray devices. The "Terminated" status requires that the XAU shall have completed (conducted either prior to termination or in absentia) a "close-out" procedure, in which all x-ray devices under the Authorization have been disposed of or transferred and the devices' information removed from the registration(s).

B. PURCHASING, RECEIPT, INSTALLATION, RELOCATION AND DISPOSAL

The acquisition, safe use and disposal of x-ray producing equipment is regulated by the State of North Carolina and the US Food and Drug Administration (FDA). "X-ray producing equipment" includes, but is not limited to, x-ray devices manufactured for clinical use (and/or used for non-clinical or veterinary purposes), x-ray diffraction analytical equipment, baggage/personnel screening and custom-built units. Duke policies incorporate the regulations by reference.

1. Purchasing X-Ray Devices

North Carolina regulations require all commercial vendors and installers of x-ray devices be registered service providers with the state of North Carolina. Duke entities desiring to acquire x-ray devices shall contact the RSD and Duke Clinical Engineering (if clinical equipment) in advance of procurement for consultation on radiation safety and regulatory compliance. Some x-ray devices may require a facility construction project for shielding installations.

2. Receipt & Installation of X-Ray Devices

a. *Installation*: XAUs shall notify the RSD upon receipt or installation of an x-ray device. Installation of clinical equipment must be performed by a service provider who is registered with the North Carolina Radiation Protection Section (NCRPS) and who is required to complete an FDA Form 2579. The XAU shall obtain and maintain all records of installation/receipt (i.e. FDA forms, installation reports etc.) from the registered service provider.

b. *Registration:* X-ray devices are required to be registered with the state in accordance with the state regulations. The XAU shall provide all applicable materials and facility access to the RSD to ensure timely registration.

c. *Radiation Surveys:* Surveys of clinical installations shall be performed by the RSD prior to first clinical use. For non-clinical applications, surveys shall be performed within 30 days of first use.

The clinical devices may be subject to additional radiation output and image quality testing by Clinical Engineering and/or the Clinical Imaging Physics Group.

3. Relocation of X-Ray Devices

Each XAU or the XAU's departmental representative shall notify the RSD prior to relocating their x-ray devices. Changes of location require registration with the State. A radiation survey of the device in its new location must be performed by the RSD prior to being put to routine use. Relocation of clinical devices that requires disassembly and reassembly shall be done by a registered service provider who will complete a new FDA Form 2579 following reassembly. This includes devices originally installed for human use but subsequently transferred to non-clinical uses.

4. Disposal of X-Ray Devices

There are three ways in which an XAU can dispose of their x-ray devices:

a. Return to the manufacturer.

b. Transfer to another facility. If the facility is within the Duke University Health System (DUHS) XAUs shall ensure that the individual receiving the device is an approved XAU.

c. Render the device inoperable and dispose of it via Duke Surplus.

The XAU shall notify the RSD of the disposal and provide confirmation of transfer/disposal.

C. X-RAY USE IN NON-HUMAN RESEARCH AND OPERATIONS OTHER THAN VETERINARY MEDICINE

1. X-Ray Authorized User Qualifications

a. *Full-time Duke Faculty:* An applicant for non-human use of x-ray devices shall be a full-time member of the faculty and have both training and experience commensurate with the x-ray modalities for which the application is being made (see Appendix B for eligible faculty ranks).

b. *Adjunct Duke Faculty with Primary Academic Appointments at Other Institutions* : An applicant with an "Adjunct" faculty appointment at Duke who has a primary appointment at another institution may qualify for non-clinical XAU status provided the following conditions are met:

(i) The applicant has both training and experience commensurate with the x-ray modalities for which application is being made;

(ii) The applicant holds a full-time primary academic appointment at the other institution which carries a faculty rank of Assistant Professor or higher, as defined in (a) above; and

(iii) The applicant's salary is supported in part by Duke University.

c. *Waiving of Faculty Status Requirements for Certain Authorizations:* At the discretion of the RSC, non-faculty individuals may also qualify for XAU status for those x-ray Authorizations that are solely operational in function (e.g. baggage scanners at security check points).

2. Amending the Authorization

Modifications such as adding devices, new radiation procedures or changes in authorization conditions to an XAU's authorization shall be requested in writing for review and approval by the RSO or designee.

3. Radiation Safety Policies for Research Laboratories

This section outlines important general radiation safety practices and procedures that must be implemented by all research-use XAUs.

a. Development of Written Radiation Safety Programs

North Carolina regulations require that each x-ray licensee or registrant develop, document, and implement a Written Radiation Safety Program (WRSP). Each XAU is required to develop a set of written procedures that are specific to their x-ray facility. The RSD will assist XAUs in developing satisfactory written procedures pertinent to their specific requirements. The WRSP determines the day-to-day conduct of radiation protection procedures in the facility, based upon the nature of use.

Each XAUs WRSPs should contain the following information, based upon the general requirements of the Duke Radiation Safety Program and the North Carolina Radiation Protection Regulations:

(i) The modalities of each x-ray device used in the laboratory such as x-ray cabinets, x-ray diffraction, x-ray fluorescence and medical equipment (c-arms, radiographic x-ray units, etc.).

(ii) Specific instructions in safe work practices for the use of the x-ray devices.

(iii) Equipment control measures in place to prevent unauthorized use or removal of device.

(iv) Purposes and functions of all protective devices employed.

b. X-Ray Device Use

Each XAU shall:

(i) Ensure all laboratory personnel (a) follow the X-ray Authorization conditions and the WRSP and (b) complete radiation safety training.

(ii) Instruct all individuals working in or frequenting any portion of an area where x-ray devices are employed regarding Duke University's reproductive health policy and the requirements of Chapter VIII of this Manual.

(iii) Ensure that any entryway providing access from public areas into areas where x-ray devices are used are posted with the appropriate official "Caution" signage. Assistance in obtaining appropriate signage and their posting may be obtained from the RSD.

(iv) Take the necessary precautions to prevent unauthorized use or removal of their x-ray devices.

(v) Enlist the aid of the Duke University Police Department to enforce the exclusion of unauthorized personnel, if necessary.

(vi) Enforce wearing appropriate x-ray shielding personal protective equipment (XPPE), including x-ray shielding aprons, eyewear and protective gloves if applicable. See Section F of this chapter for more information on the XPPE standards and requirements.

(vii) Maintain personnel radiation exposure ALARA.

(viii) Ensure dosimeters are used appropriately and exchanged on time.

(ix) Maintain records of device history, specific training on use of device and WRSPs.

c. Termination of Laboratory Operations

When an XAU ends their affiliation with Duke University or desires to terminate their X-ray Authorization, they shall submit an amendment request notifying the RSO of the termination no less than thirty (30) days prior to the anticipated date of termination. All x-ray devices must be disposed of or transferred. For transfers within Duke, the XAU shall ensure devices are transferred to other XAUs before leaving the premises.

For transfer, sale, donation or disposal of x-ray devices outside Duke University (including to other entities within DUHS), the XAU shall provide to the RSD all pertinent information regarding the disposal or transfer (i.e. written confirmation of disposal or external transfer. This shall include the name and address of the recipient organization).

d. Animal Research

All research protocols involving the research use of x-rays on animals must be approved by the Duke Institutional Animal Care and Use Committee (IACUC) and the RSD. Researchers must describe the type of device, exposure doses, and procedures for handling animals in their applications to IACUC. The following general policies shall apply:

(i) Supporting or restraining devices shall be used to hold animals in position during radiographic exposures.

(ii) If a human holder is required during x-ray procedure, they shall wear appropriate XPPE, with strict adherence to the following additional requirements:

(a) No personnel shall be routinely used to hold animals during x-ray procedures;

(b) Pregnant workers or individuals under 18 years of age are not allowed to support or hold animals during x-ray procedures.

See Section F of this chapter for more information on the XPPE standards and requirements.

D. X-RAY USE IN VETERINARY MEDICINE

The use of x-ray devices in veterinary medicine is limited to licensed veterinarians or those trained and directly supervised by them. The staff veterinarian shall be the XAU for these facilities. The use of x-ray devices and personnel radiation safety are reviewed similar to the research laboratory radiation safety programs.

The following policies shall be included in the WRSP:

1. Only personnel required for the x-ray procedure shall be in the x-ray room during the exposure.

2. Mechanical supporting or restraining devices shall be used when an animal must be held during x-ray exposures.

3. If a human holder is required during exposure, the personnel holding the animal shall wear appropriate XPPE, with strict adherence to the following additional requirements:

a. No personnel shall be routinely used to hold animals during x-ray procedures.

b. Pregnant workers or individuals under 18 years of age are not allowed to support or hold animals during x-ray procedures.

See Section F of this chapter for more information on the XPPE standards and requirements.

E. X-RAY USE IN MEDICINE AND RESEARCH INVOLVING HUMAN RESEARCH SUBJECTS

All diagnostic, interventional and therapeutic use of x-rays shall only be ordered by licensed practitioners in medicine based on sufficient clinical justification and conducted by qualified x-ray operators with procedures and settings for the optimized care of the patients.

Healing arts mass screenings, such as breast cancer screening by mammography, do not require a specific order by a licensed practitioner, but shall still be conducted by qualified x-ray operators with procedures and settings for the optimized care of the patients.

The x-ray use in human research subjects, other than standard-of-care procedures, must be conducted under an approved IRB protocol, in which the human x-ray use is specifically ordered by a licensed practitioner who is a co-investigator on the protocol.

1. X-Ray Authorized User Qualifications

At a clinical facility, the XAU will typically be the clinical director or department chair. The XAU shall have appropriate training and experience and is responsible for the x-ray radiation safety program operations at the facility.

2. Radiation Safety Policies for Clinical X-Ray Departments

a. Written Radiation Safety Programs

Each clinical department shall develop, document, and implement a WRSP. These written procedures shall provide operator specific instructions in safe work practices and in safe operating procedures, for the use of clinical x-ray devices. The procedures shall include, but not limited to:

(i) X-ray operator certification or credentialing requirements, with reference to applicable regulations or departmental policies.

(ii) Procedures for each x-ray based imaging modality used at the facility.

(iii) Exposure techniques or protocols for the different exams performed.

(iv) Policies on ancillary personnel.

(v) Procedures in place to minimize personnel radiation exposure.

(vi) Procedures for pregnant patients.

(vii) Control measures in place to prevent unauthorized use or device removal.

b. Guidelines for the Safe Use of X-Rays in Healing Arts and Clinical Research

The following guidance pertains to the safe use of clinical x-ray devices. Such devices include, but are not limited to, digital and fixed plain-film radiographic equipment, bone densitometers, mobile (portable) units, CT scanners and fluoroscopy units. Other provisions set forth in pertinent subsections of the North Carolina Administrative Code shall also apply.

(i) Individuals who will be operating the x-ray devices shall be trained in the safe operating procedures and use of the equipment, and demonstrate an understanding of such procedures.

(ii) WRSPs shall be made available to each individual who operates x-ray devices and shall be reviewed annually. In lieu of a physical document, the WRSP may be reviewed by completing the designated OESO as an on-line module, “Medical X-ray Safety Program”.

(iii) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. “Ancillary personnel” may include parents of pediatric patients assisting with x-ray procedures for the purpose of avoiding sedation.

(iv) Mechanical holding devices shall be used whenever medical circumstances permit. If a human holder is required:

(a) XPPE shall be worn to protect the hand or other parts of the body that might be exposed to the primary beam.

(b) No individual shall be used routinely to hold patients or digital cassettes.

(c) Pregnant women and minors shall not hold patients or digital cassettes during exposures.

See Section F of this chapter for more information on the XPPE standards and requirements.

(v) No individual shall be exposed to the useful beam for purposes of education, demonstration, training, research or any other purpose not related to the healing arts, unless the individual is participating in clinical research approved by the Duke Institutional Review Board, with radiation safety specialty committee approval.

F. X-RAY SHIELDING PERSONAL PROTECTIVE EQUIPMENT

To minimize personnel radiation exposure during x-ray procedures in both clinical and research settings, appropriate radiation shielding is required for individuals exposed to an x-ray equipment's primary beam or the direct scatter. In lieu of fixed or mobile protective radiation shields, such shielding requirements are often fulfilled by x-ray shielding personal protective equipment (XPPE). The following summarizes how managers, x-ray operators and other users who are working in the x-ray environment can obtain, use, inspect and dispose of their XPPE.

1. Obtaining XPPE: Obtain your XPPE from a supplier whose manufacturing quality management system is compliant with ISO 9001:2008 or later. Contact the RSD for assistance.
2. Using and Storing XPPE: Complete the training module "X-Ray Aprons: Handling, Storage and Documentation" as directed by the RSO. X-ray equipment operators and ancillary personnel must wear XPPE having a lead equivalent of no less than 0.25 mm. Operators must not place any part of the body into the primary x-ray beam unless they are wearing XPPE having a lead equivalent of no less than 0.5 mm. For vest/skirt combination garments, both components must be worn. When not in use, XPPE should be stored using sturdy supporting frames and hangers or laid flat. XPPE should be stored away from sources of heat or ultraviolet light to avoid degradation of the vinyl covers.
3. Inspections by Wearers: Perform a visual inspection of your XPPE items for ripped seams, missing buckles, worn Velcro, evidence of compromise of the absorbing layer or other signs of wear or abuse prior to each use. Items of questionable quality should not be worn and should be reported to management.

4. Periodic Inspections by Management: Management must conduct a visual inspection of all their XPPE for damage at least once per year. Damaged articles may be removed from service or retained, depending upon the severity of the damage. Radiographic inspection may be used to evaluate visible evidence of damage. Damaged XPPE items containing lead are “hazardous waste” and may not be discarded in the normal trash. They must be returned to the supplier under existing contractual agreements or be evaluated for lead content and disposed by the Environmental Programs Division of OESO.
5. Documentation of Periodic Inspections: Management must document their XPPE inventory and the periodic inspection results. XPPE inventory software is available on the OESO web site and may be used to assist managers in tracking inventory, recording inspection results and generating reports required for Joint Commission or regulatory compliance purposes. Alternatively, managers may use software offered by their suppliers or other third-party products.

VII. PERSONNEL MONITORING

The documentation of the radiation dose received by radiation workers is critical to ensuring compliance with state and federal regulations and the Duke ALARA policy. The accepted approach to monitoring occupational radiation dose is through the use of the personal dosimeter. Individuals who may be expected to incur a cumulative annual radiation dose that exceeds 100 millirem (1 mSv) will be issued a dosimeter, or as directed by the Radiation Safety Officer (RSO).

Dosimeters are obtained through the Radiation Safety Division (RSD). The guidelines for personnel monitoring adopted by Duke University are summarized in the following sections.

A. DOSIMETERS AND ISSUANCE CRITERIA

The policies for obtaining a new dosimeter, exchanging badges, and obtaining an exposure history are outlined below.

1. Radiation workers shall wear an appropriate dosimeter if so directed by the RSO or designee. Radiation workers using the following types of radioactive material or radiation-producing equipment will be issued dosimeters with photon, electron and/or neutron capability, unless otherwise directed by the RSO:

    a. Radiographic, fluoroscopic or therapeutic x-ray machines, analytical X-ray machines, gamma emitting radioactive material (whole body and/or extremity, photons).

    b. Accelerators (whole body, photons and neutrons).

    c. Energetic (>250 keV) beta emitting radioactive material (extremity, electrons).

2. Dosimeters shall be exchanged and processed on a periodic basis, the frequency to be determined by the RSD. A contact person at each site, as assigned by the site managers, shall assist the RSD in the dosimeter distribution and exchange process.

3. For dosimeters that are lost, damaged, inadvertently subjected to significant non-occupational exposure or otherwise considered to be incapable of providing a true indication of occupational dose during a monitoring period, an estimate of the reported dose may be reconstructed as directed by the RSO.

4. Each individual to whom a badge is issued has the responsibility to ensure its proper use and exchange.

5. Small, portable ionization chambers or direct reading, digital, electronic dosimeters (so-called “pocket” dosimeters) may be used to monitor the dose received over brief intervals of time. These instruments give an immediate read-out of the dose to the individual. They may be worn at the discretion of the individual user. All unmonitored visitors to research accelerator facilities shall be given a pocket dosimeter prior to their entrance into laboratory areas. Records of the doses to visitors shall be maintained in each lab. Under certain circumstances, the use of both a routine monitoring dosimeter and pocket dosimeter may be required. If pocket dosimeters are utilized, they must be calibrated annually by the RSD.

6. Other dosimetry monitoring may be provided as deemed appropriate by the RSO.

B. MEDICAL X-RAY DOSIMETRY

1. Personnel operating portable x-ray machines and fluoroscopic units, including practitioners performing image-guided procedures, shall wear whole-body dosimeters at the collar level, as directed by the RSO. Dosimeters shall be worn outside any shielding aprons or other shielding personal protective equipment, unless specified otherwise. In these cases, assigned occupational dose will be determined by the dosimetry vendor or responsible RSD staff as directed by the RSO.

2. For radiation workers routinely working with fluoroscopic x-ray where the wearing of protective shielding garments is mandatory, under the specification of the RSO, one of the following dosimeter wearing schemes shall be followed:

a. Two dosimeters: The first dosimeter worn outside the shielding apron at collar level, and the second dosimeter worn underneath the shielding apron at waist level.

b. One dosimeter: the single dosimeter worn outside the shielding apron at collar level.

C. REVIEW, MAINTENANCE AND REPORTING OF OCCUPATIONAL DOSE RECORDS

Records of occupational doses shall be maintained by the RSD. Copies of the periodic occupational dose reports shall be made available to wearers through the departmental contacts. Wearers are responsible for reading their reports and directing inquiries to the RSD staff. Wearers will be notified of doses that exceed the applicable ALARA levels, as set forth by the RSCs, during a given monitoring period.

The RSD periodically reviews selected occupational dose reports and investigates occupational doses exceeding ALARA levels in accordance with the Duke University and Duke University Medical Center (DUMC) ALARA Program Policy. The ALARA levels are shown in Table 3.

Table 3. ALARA Investigation Levels

Area of the Body	ALARA Levels (millirem per Calendar Quarter)		
	Level I	Level II	Level III
Whole Body, Deep Dose Equivalent	125	375	1,250
Extremities, Hands and Feet	1,250	3,750	12,500
Eye Lens Dose Equivalent	375	1,125	3,750
Skin of the Whole Body, Shallow Dose Equivalent	1,250	3,750	12,500

In accordance with regulations, the RSD sends and receives requests pertaining to individual radiation workers' dose histories. Due to occupational dose records being considered to be confidential, the consent of the radiation worker is required for release of their dosimetry history records. Unless directed otherwise by the RSO, only the occupational dose accrued at Duke University during the current calendar year will be forwarded to other institutions for purposes of compliance with annual occupational dose limits.

Under North Carolina regulations, employees who receive a recorded occupational dose (deep dose equivalent or effective dose) of greater than 100 millirem (1 mSv) in a calendar year will be notified of that fact in writing by electronic mail. Notifications will be made in a timely manner, typically from February to April during the following year, as reports become available from the dosimetry vendor.

D. BIOASSAYS

1. Clinical Radiotherapeutic Procedures with Radioiodine

    a. Nuclear Medicine and Radiotheranostics (NMRT) staff conducting clinical therapeutic radioiodine procedures, or Radiopharmacy staff preparing therapeutic dosages, shall obtain a thyroid burden measurement not less than 24 hours and not to exceed seven (7) days following the procedure. The Director of NMRT, in consultation with the RSO, may alter the assay time window in the event that extenuating circumstances make strict adherence to the formal time window impractical. These conditions are not applicable to (a) procedures using sealed radioactive material (pills or capsules) or (b) individuals observing procedures and not directly handling the dosage.

    b. In emergent situations where the possibility of an intake is high, the bioassay may be performed prior to 24 hours. “Emergent situations” include personal contamination through spills of the administration dosage or leaking administration apparatus. Spills of radioactive urine or other body fluids may occur during hospitalization or “code” situations. In that case, the RSO may direct that thyroid bioassays be performed on nursing staff or the code team.

    c. Quantitative thyroid content measurements shall be performed using instruments that have been calibrated annually by the RSD or the Clinical Imaging Physics Group.

    d. Results of thyroid bioassays shall be expressed as intake, using the methods prescribed in *NUREG/CR-4884 (BNL-NUREG-52063): Interpretation of Bioassay Measurements (1988)*. ALARA action levels for intakes of ^{131}I are given in Table 4.

    e. Reports of thyroid bioassay results shall be presented to the Medical Center RSC at its regularly scheduled meetings.

2. Iodinations Performed in Authorized Research Laboratories

Each individual handling radioiodine under any of the conditions listed in Table 5 shall undergo thyroid monitoring if the quantities used exceed those for the conditions specified. “Radioiodine” means any of the following radionuclides: iodine-123 (^{123}I), iodine-124 (^{124}I), iodine-125 (^{125}I), iodine-129 (^{129}I), and iodine-131 (^{131}I), or a combination of these radionuclides.

Note that the quantities shown apply to both the quantity used at one time or integrated as the total amount of activity used over a 3-month period. Laboratories may use their own equipment for thyroid monitoring, if the equipment is suitable for performing the required measurements and has been calibrated annually by staff of the RSD. Scheduling of the monitoring may be done through the RSD in cases where the research laboratory does not have suitable equipment. Laboratory use of volatile or dispersible forms of radioiodine in high-personnel risk quantities in an open room or bench top is prohibited.

Operations using only ^{125}I in the form of radioimmunoassay kits are exempt from thyroid monitoring.

Table 4. ALARA Action Levels for Radioiodine 131

Level	Intake Threshold	Value for I-131	Actions
Evaluation	> 2% of ALI	600 nCi	Interview worker, counsel on appropriate measures to avoid future intakes
Investigation	> 10% of ALI	3 µCi	*Evaluation Level actions*, AND surveillance and evaluation of workplace, summing of internal and external recorded doses required
Reporting	Near or Above ALI	30 µCi	*Investigation Level actions*, AND enhanced bioassay (multiple time points) to confirm

Table 5. Radioactivity Levels Above Which Bioassay for Radioiodine is Necessary (Source: *USNRC Regulatory Guide 8.20, Revision 2: Applications of Bioassay for Radioiodine (2014))*

Types of Operations	Radioiodine Radioactivity Levels in Unsealed Form above Which Bioassay is Necessary	
	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1 mCi (37 MBq)*	10 mCi (370 MBq)
Processes with possible escape of iodine carried out within well-controlled and ventilated areas (i.e., fume hood of adequate design, face velocity, and performance reliability)	10 mCi (370 MBq)	100 mCi (3.7 GBq)
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100 mCi (3.7 GBq)	1 Ci (37 GBq)

* Laboratory use of volatile or dispersible forms of radioiodine in high-personnel risk quantities in an open room or bench top is prohibited. The monitoring threshold is listed for incidental scenarios (e.g. spill response).

3. Bioassays for Other Radionuclides

a. General

Federal regulations (10 CFR 20.1204 and 10 CFR 20.1502) require the measurement of the intake of radioactive material in workers who may exceed 10% of the annual limit on intake (ALI). Compliance requires the measurement of the content of body organs or the concentration of radioactivity in excreta (urine or feces). In the event that radiation workers or other members of the Duke University community encounter expected or unexpected exposures to radioactive material, immediate assessments of intake and radiation health risks may be necessary. The RSD shall maintain a bioassay program to meet this need.

(i) Determination of intake based upon organ content and excreta radioactivity shall be based upon the biokinetic models in *NUREG/CR-4884* or other suitable regulatory guidance as it becomes available.

(ii) Quantitative organ and excreta contents shall be measured using calibrated instruments (ionization chambers, scintillation detectors, liquid scintillation/gamma counters, etc.).

(iii) Responses to intakes shall be based upon the criteria shown in Table 6.

(iv) Records of bioassays shall be retained by the RSD in compliance with applicable regulations.

(v) Reports of routine clinical radioiodine intakes shall be presented to the DUMC RSC at its regularly scheduled meetings. Reports of other bioassays, both routine or in response to incidents, shall be reported to the applicable RSC.

b. Operational

(i) Individuals involved in operations that utilize more than 100 millicuries of hydrogen-3 (tritium) in a non-contained form (excluding than metallic foil), within a 30 day period, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

(ii) In the event of unexpected exposures of individuals to hydrogen-3 or other radionuclides, bioassays shall be performed in consideration of the likely routes of intake and modes of excretion. Data on the behavior of the elemental nuclides and tables of the biokinetics of many of the radionuclides used in unsealed form in research and clinical practice are included in Appendix B to *NUREG/CR-4884*. Table 7 shows the page numbers in Appendix B of NUREG/CR-4884 for intake retention functions and other data for selected radionuclides. For most biomedical research and clinical use radionuclides (with the exception of tritium gas or water vapor), the most likely route of intake is ingestion. Where applicable, inhalation data for Class D, W and Y compounds are also included.

Table 6. Internal Dosimetry Action Levels for Intake of Radioactive Materials

Intake Threshold	Actions
> 2% of ALI	• Repeat bioassay within 24 hours of the last measurement to confirm intake; • Interview worker; • Surveillance and evaluation of workplace; • Implementation of corrective actions.
> 10% of ALI	• *All of the above; and* • Summing of internal and external recorded doses, for further ALARA action level and regulatory dose limit implications.

Table 7. Page Number Index to Appendix B of NUREG 4884

Element	Data Sheet	Ingestion IRFs	Inhalation IRFs		
			Class D	Class W	Class Y
Hydrogen (tritiated water vapor or liquid)	B713	---	B711	---	---
Carbon (C-14 CO_2 or CO)	B715	---	B709	---	---
Phosphorus	B722	B481	B22	B174	
Sulphur	B723	B485	B26	B178	
Yttrium	B744	B555	---	B228	B391
Technetium	B748	B565	B82	B238	
Iodine	B758	B581	B97		
Lutetium	B775	B636	---	B295	B425
Astatine	B788	---	B153	B319	---
Radium	B791	B670	---	B321	---
Actinium	B792	B674	B156	B325	---

Classes D, Y and W: Compounds of radionuclides are classified by their degree of transferability from the point of intake until excretion, as indicated by their retention half-times in the body: Class D (< 10 d), Class W (10 d – 100 d), Class Y (> 100 d).

VIII. REPRODUCTIVE HEALTH

Employees, in consultation with the Radiation Safety Division (RSD), shall be given specific instructions about prenatal exposure risks to the developing embryo and fetus and, if applicable, the ability to formally declare their pregnancies as set forth in the Duke University Reproductive Health Policy (see Section I-7 of the *Duke University Safety Manual*, available on the Occupational and Environmental Safety Office website). State and federal regulations and the Duke ALARA policy prescribe that the total dose equivalent to the embryo or fetus of a declared pregnant worker shall not exceed 500 millirem (5 mSv) during the period of gestation. Fetal radiation dose is determined by appropriate monitoring of the declared pregnant worker. It is recommended that radiation workers who participate in the care of patients who are being treated with radioactive drugs, or who work in proximity to radiation-producing devices declare their pregnancy in order to obtain appropriate monitoring and counseling. Radiation workers who become pregnant and must work with radioactive material or radiation sources during their pregnancy should contact Duke Employee Occupational Health and Wellness (EOHW) and complete a confidential Declaration of Pregnancy form. After declaring their pregnancy and upon receipt of the Declaration of Pregnancy form by the RSD, the employee will receive:

- An evaluation of the radiation hazard from external and internal sources;
- Counseling regarding modifications of technique that will help minimize exposure to the fetus;
- A fetal dosimeter, if appropriate.

Employees who are not declared pregnant workers will not be issued a fetal dosimeter.

An employee who has declared their pregnancy shall inform EOHW and the RSD if their pregnancy has ended for any reason.

IX. TRAINING

The goal of providing radiation safety training to the employees of Duke University and Duke University Medical Center is to empower workers to take personal responsibility for minimizing their exposure to radiation. By providing employees with the applicable knowledge of radiation and its biological effects and the regulations governing its use, the University and Medical Center can help provide an environment that is safe for its patients, students, visitors and workers. The content of radiation safety training courses will be determined by the Radiation Safety Officer (RSO) and the appropriate Radiation Safety Committee (RSC) based on applicable regulatory guidance, industry consensus standards, and the specific needs of the target audience.

Authorized Users (AUs) are responsible for ensuring that their staff members have received instruction regarding the safe use of radioactive material and radiation sources in their specific laboratory settings, both through on-the-job training and through didactic training offered by the Radiation Safety Division (RSD). The AU is responsible for maintaining documentation of the completion of required training and will be required to supply such documentation to the RSO or designee as a condition for continued Authorization to use radioactive material or radiation sources.

A. INDIVIDUALS OR GROUPS REQUIRING TRAINING

Individuals employed by Duke University fall into three general categories with respect to their exposure to radiation:

1. *Radiation Workers*[1]*:* those workers whose major responsibilities involve working with sources of ionizing radiation or radioactive material.

2. *Ancillary Workers*[2]*:* all personnel who may come in contact with or enter an area that contains radioactive material or sources of ionizing radiation.

3. *Non-Radiation Workers*[3]*:* personnel who would not normally be expected to encounter radioactive material or radiation sources in the course of their employment at Duke.

[1]"Radiation Workers" would include radiologists; radiographers; nuclear medicine physicians and technologists; radiopharmacy technologists; radiation therapy technologists; cardiology technologists working with fluoroscopy equipment; research scientists who are AUs of radioactive material or radiation sources; faculty, technicians

and graduate students in certain campus laboratories; nurses on hospital divisions regularly caring for radionuclide therapy patients.

[2]"Ancillary Workers" include non-radiology physicians, phlebotomists, Environmental Services workers, waste processors and animal caretakers.

[3]"Non-Radiation Workers" would include administrators and administrative assistants, Food Service employees, clerical staff, Materials Management and so forth.

These groups will require different levels and frequencies of training. AUs are required to submit evidence of prior training during the application process for medical or research use of radioactive material and radiation sources. This prior education and training may be applied in lieu of certain initial and update training requirements.

B. SPECIFIC TRAINING REQUIREMENTS

Training occurs on an as-needed basis. However, the RSD subscribes to some basic guidelines for the frequency and intensity with which different groups receive their training. These include:

1. Radiation workers: initial training including instruction in the proper use and handling of radioactive material and other sources of ionizing radiation. The content of the initial training may be modified for the specific job responsibilities.

2. Radiation workers and certain ancillary workers: periodic job-specific refresher training or “as needed” in-service training. Ancillary personnel who may enter accelerator vaults or high dose rate brachytherapy facilities shall be trained to recognize when the beam is activated and to use the “scram” button to terminate the beam.

3. Training of workers whose job responsibilities change concerning their use of or exposure to ionizing radiation, or who request additional radiation safety training.

4. Special training in connection with incidents involving a spill, accident, medical event, change in regulations, or a documented overexposure.

5. Radiation medicine professionals like radiologists, radiographers, nuclear medicine technologists, radiation oncology technologists and radiation dosimetrists, by virtue of their professional education, certification, and continuing education requirements for maintenance of certification will be trained on an "as needed" basis. Training venues will include Grand Rounds, seminars and special in-service sessions.

C. SPECIFIC UPDATE TRAINING REQUIREMENTS FOR RESEARCH LABORATORIES

Periodic retraining of all staff in the biomedical research laboratories and in those University research laboratories which routinely employ unsealed radioactive material in research will be required at intervals determined by the RSCs. The following guidelines will apply:

1. AUs, radiation workers, students and other users of unsealed radioactive material will periodically complete a module that emphasizes safe laboratory practices, including measures to minimize external exposure and to avoid ingestion of unsealed radioactive material.

2. Both modules may be offered as lecture-style presentations and on-line self-study presentations. Verification of participation will be by certificates or an electronic record. Participants will be responsible for maintaining verification of their training and providing copies of verification of training to their AUs if required.

3. Proper maintenance of training records in each laboratory is subject to periodic audit by the RSD.

4. Laboratories employing only radiation-producing machines or sealed sources will undergo re-training on an "as-needed" basis, at frequencies to be determined by the RSCs in conjunction with the RSO.

5. Individuals working in accelerator facilities will undergo re-training on an "as-needed" basis, at frequencies to be determined by the Accelerator RSCs in conjunction with the RSO.

X. CLINICAL RADIATION SAFETY PROCEDURES FOR RADIOPHARMACEUTICALS

The purpose of this Chapter is to provide radiation protection information to nursing staff and other hospital personnel who may come in contact with patients who have received diagnostic or therapeutic quantities of radioactive drugs.

Specific information on radiological protection for employees of the Departments of Radiology and Radiation Oncology may be found in the Radiation Safety Procedures documents located in those departments.

Radiation hazards to nursing staff, ancillary personnel and visitors are due to (a) irradiation by emissions from radioactive isotopes in the patient, (b) accidental contamination of the skin by radioactive material, and (c) accidental ingestion of radioactive material. Procedures to minimize the hazard associated with the therapeutic use of radiopharmaceuticals are outlined in Appendix D: *Nursing Care for Radioactive Patients and Intraoperative X-ray Procedures*. Basic considerations are as follows:

- Patients who require inpatient treatment shall be provided with a private room and private toilet facilities. The room may be prepared by staff of the Radiation Safety Division (RSD) in order to mitigate radioactive contamination.
- All potentially contaminated items, including trash, shall remain in the room until removal by RSD staff.
- All radiation precautions, including door signage, visitation, patient release from radiation precautions and release of the hospital room for non-radiation use, shall be managed by RSD staff.
- Nursing staff shall be trained in, and adhere to, measures to minimize external radiation exposure and inadvertent ingestion of radioactive material. These measures include minimizing time spent near the patient and maximizing distance from the patient, to the extent practical while providing good patient care. All staff shall adhere to universal blood and body fluid precautions upon entering and leaving the patient room.

XI. RADIOLOGICAL EMERGENCY PROCEDURES

A. CONTACTING RADIATION SAFETY

In the event that Radiation Safety Division (RSD) personnel are needed to respond to an incident on the Duke University campus or in the Duke University Medical Center , contact may be established as follows:

- By calling 911 from a Duke telephone and informing Duke Police that a radiological emergency exists; or
- By calling (919)684-2444 from a mobile phone or Duke telephone and informing Duke Police that a radiological emergency exists.

B. ACCIDENTS OR INJURIES INVOLVING RADIOACTIVE MATERIAL

1. For serious injuries, contact Duke Police (see above) to arrange transport to the Emergency Department.

2. For minor injuries, wash the wound thoroughly under lukewarm water to flush out radioactive material. If an instrument contaminated with human blood or body fluids caused the wound, immediately call Duke's "Blood and Body Fluids Exposure Hotline" (115 from a Duke telephone, or (919)684-8115 from a mobile phone) to report the exposure. Seek appropriate medical care from Employee Occupational Health and Wellness (EOHW) or the Emergency Department.

3. For any ingestion, inhalation, or other absorption of any quantity of radioactive material, immediately arrange for appropriate medical evaluation and care.

4. For all intakes of radioactive material or injuries involving radioactive material, contact the RSD as soon as practical for consultation regarding treatment or further monitoring, including urine or thyroid bioassay, or whole-body counting.

C. MAJOR SPILLS OF RADIOACTIVE MATERIAL

Major spills of radioactive material include spills of relatively large quantities of material, spills of material with high radiotoxicity, spills involving large areas or permeable surfaces, or spills resulting in significant personnel contamination. For such spills:

1. Notify other persons in the area of the spill.

2. Evacuate area if spill is of a volatile material.

3. Immediately remove any contaminated shoes or clothing.

4. Mark the spill area and limit access to avoid the inadvertent spread of contamination.

5. Immediately flush contaminated skin thoroughly with lukewarm water, then wash thoroughly with soap and lukewarm water. Do not scrub contaminated skin with a brush.

6. Notify the RSD promptly for assistance with decontamination, post-spill monitoring via thyroid or urine bioassay or dose reconstruction.

D. LOSS OR THEFT OF RADIOACTIVE MATERIAL

1. Immediately report the loss or suspected theft of radioactive material to the RSD.

2. RSD staff will assist in locating the missing radioactive material. If theft is known or suspected, RSD staff will work with the applicable law enforcement authorities to recover the material.

3. If required under North Carolina or federal regulations, the Radiation Safety Officer (RSO) shall report the loss or theft to the appropriate regulatory authorities.

E. MEDICAL EVENTS AND OTHER PATIENT CARE RELATED INCIDENTS

1. Immediately contact the RSO or designee to report any instance of a significant deviation of a therapeutic dosage of radioactive material to a patient or research subject, or delivery of a radiation dose to a patient or research subject via brachytherapy or medical accelerator, that significantly differs from the prescribed dosage or dose. The RSO or designee shall determine if a reportable medical event has occurred, and will manage incident reporting according to the *Policy/Procedure for Reporting Radiation Treatment Deviations in Nuclear Medicine and Radiation Oncology* (see Appendix E for current version).

2. Immediately contact the RSO or designee if an unintended radiation exposure has occurred to a pregnant patient from radioactive material or x-rays, or to a breast-feeding infant from radioactivity administered to the mother.

F. FIRES INVOLVING RADIOACTIVE MATERIAL

1. Follow the Site-Specific Fire Plan for your area found on the Fire and Life Safety section of the Occupational and Environmental Safety Office website. If you discover a fire, follow the RACE procedures: *R*emove all persons in immediate danger to safety, activate the manual pull station *A*larm and call 911, *C*lose doors and fire shutters, and *E*xtinguish the fire if you are able to do so safely. When safe to do so, advise first responders that radioactive material may be stored in the affected locations.

2. Notify the RSD as soon as possible for consultation on the potential of radiation exposure associated with the radioactive material inventory in the facility for the first responders and impacted personnel. The RSD shall directly provide or support (if large-scale incident where a higher authority takes over the incident response command) the needed additional radiological hazard response such as personnel monitoring, environmental survey and the cleanup of any radioactive contamination.

G. X-RAY PRODUCING DEVICES

1. Operating conditions that may result in unintended and/or potentially harmful radiation exposure to patients or personnel must be identified and mitigated as soon as is feasible. For potentially harmful exposures to patients, follow the departmental procedures for reporting safety-related events.

2. Personnel who experience an unintended exposure may contact the RSD for a dose reconstruction and risk assessment, or EOHW for an evaluation.

H. PARTICLE ACCELERATORS AND HIGH DOSE RATE BRACHYTHERAPY

Operating conditions that may result in potentially harmful radiation exposure to patients or personnel shall be terminated immediately by means specified in the departmental standard operating procedures and equipment manufacturer's instructions. For particle accelerators, this includes but is not limited to beam termination at the operator's console, activating door interlocks or the use of in-vault "scram" buttons. For high dose rate brachytherapy, this includes, but is not limited to automatic or manual retraction of the source train. Incidents shall be reported according to departmental procedures.

XII. ACCESS TO RADIOACTIVE MATERIAL PRESENT IN QUANTITIES OF CONCERN

The purpose of this chapter is to ensure compliance with federal regulations regarding access to and security of specific types and quantities of radioactive material, as set forth in 10 CFR Part 37. This policy applies to entities at Duke University and the Duke University Health System (DUHS) that possess and use such quantities of radioactive material which have the potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety through loss of control of the material, whether it be inadvertent or through a deliberate act ("Quantities of Concern"). Specifically, this policy addresses (a) access to certain irradiators containing sealed radioactive material that are used to irradiate blood products, small animals, cell cultures or other biological samples for clinical or research purposes and (b) access to certain high-dose-rate brachytherapy sources.

A. UNESCORTED ACCESS TO MATERIAL

Unescorted access to irradiators or other quantities of concern shall be granted only to personnel whose job duties require unescorted access, and for whom the Radiation Safety Officer (RSO) has approved an Application for Unescorted Access. Criteria for granting unescorted access shall include, but not be limited to, obtaining the applicant's fingerprints for submission to the Federal Bureau of Investigation, and completion of the required irradiator safety training. All other personnel may access quantities of concern only when escorted by, and under the direct constant supervision of personnel who have been granted unescorted access. Personnel with escorted access must first complete the applicable safety training course.

B. OBTAINING POLICY INFORMATION ABOUT QUANTITIES OF CONCERN

Information about the policies and procedures required to obtain access to applicable Duke facilities may be obtained by contacting the Radiation Safety Division. All questions regarding the policy, or the application, vetting and training process, shall be addressed to the RSO.

XIII. DISTRIBUTION OF DUKE RADIOACTIVE MATERIAL LICENSES

The following notice appears at the bottom of radioactive material licenses issued by the North Carolina Radiation Protection Section: WITHHOLD FROM PUBLIC DISCLOSURE UNDER NCGS 104E-9(A)(4) EXCEPT TO INDIVIDUALS WITH A NEED TO KNOW. Because licenses contain information about licensees' holdings that could be considered to be sensitive, the intent of this notice is to limit dissemination of that information. Copies of Duke University's radioactive material licenses are subject to restricted distribution. Comprehensive information is included in Appendix F: *Policy for Issuance of Medical and Academic Radioactive Material Licenses.* Basic policy elements include the following:

- The determination of "need to know" and the method of documenting the possession and use of radioactive material is solely the responsibility of the Radiation Safety Officer (RSO).
- In general, full licenses will be issued to transferors of radioactive material to Duke. "Transferors" does not include organizations that manage clinical trials ("CROs"). Instead, CROs may obtain a letter of affirmation of Duke's authorization to possess and use a specific radionuclide under the applicable license.

APPENDICES TO THE RADIATION SAFETY MANUAL FOR DUKE UNIVERSITY AND DUKE UNIVERSITY MEDICAL CENTER

Appendix A. *Terms and Abbreviations*

Appendix B. *Faculty Positions Qualifying for Authorized User Status*

Appendix C. *Human-Use Authorized User, Authorized Medical Physicist and Authorized Nuclear Pharmacist: Qualifications and Process*

Appendix D. *Nursing Care for Radioactive Patients and Intraoperative X-ray Procedures*

Appendix E. *Policy & Procedure for Reporting and Management of Medical Events Occurring During the Administration of Radiopharmaceuticals, Brachytherapy or External Beam Radiation Therapy*

Appendix F. *Policy for Distribution of Medical and Academic Radioactive Material Licenses*

APPENDIX A. Terms and Abbreviations

Term or Abbreviation	Definition
Accelerator Radiation Safety Committee, Accelerator RSC	General term referring to (1) TUNL Radiation Safety Committee, (2) Cyclotron Facility Radiation Safety Committee or (3) or committees that may be appointed to future accelerator facilities
ALARA	As Low As is Reasonably Achievable
Ancillary worker	A person who may come in contact with or enter an area that contains radioactive material or sources of ionizing radiation but is not considered to be a radiation worker.
Authorized User	A person using licensed radioactive material for clinical use or non-human research who is approved to do so by the Radiation Safety Committee
AU	Authorized User
CFR	Code of Federal Regulations
CPM	counts per minute
DFELL, FELL	Duke Free Electron Laser Laboratory
Dosimeter, personnel dosimeter	Device, such as film badge, pocket dosimeter, thermoluminescence dosimeter or optically stimulated luminescence dosimeter, designed to be worn or carried by an individual for the purpose of estimating the dose of radiation received by the individual.
Dosimetry vendor (processor)	Individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.
DOT, USDOT	United States Department of Transportation
DPM	disintegrations per minute
DUH	Duke University Hospital
DUHS	Duke University Health System
DUMC	Duke University Medical Center
EOHW	Employee Occupational Health and Wellness
EPA, USEPA	United States Environmental Protection Agency

Term or Abbreviation	Definition
IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging, including specific MR functional modalities
NCAC	North Carolina Administrative Code
NCGS	North Carolina General Statutes
NCRPS	Radiation Protection Section of the North Carolina Department of Health and Human Services
NRC, USNRC	United States Nuclear Regulatory Commission
OESO	Occupational and Environmental Safety Office
Radiation producing machine or device	A device designed to produce or which produces radiation or nuclear particles when the associated control devices of the machine are operated.
Radiation Safety Committee for Medical License	A committee constituting an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service (for medical license), a representative of management who is not an authorized user and other members deemed appropriate [10 CFR 35.24(f)]
Radiation Safety Committee for Non-Medical License	A committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material
Radiation Safety Officer (RSO)	A person who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters.
Radiation worker	A person whose major job responsibilities involve working with sources of ionizing radiation or radioactive material.
RDRC	Radioactive Drug Research Committee
RSC	Radiation Safety Committee
RSD	Radiation Safety Division
RSOD	RSO or Designee

Term or Abbreviation	Definition
Sealed source	Any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.
TUNL	Triangle Universities Nuclear Laboratory
Unsealed radioactive material	Radioactive material that is not encapsulated as defined in “Sealed source”.
X-ray Authorized User (XAU)	An individual who has assumed the responsibility of the possession and use of one or more x-ray devices and meets the qualifications in VI.C.1
X-ray Device	A device that produces x-rays of energy greater than 5 keV, either purposely for: (a) clinical use, (b) non-human basic research use (c) veterinary use, or incidentally in normal operation. In general, devices requiring registration with the NCRPS under NCGS § 104E-7 are considered to be “x-ray devices” for the purposes of this manual.

APPENDIX B. Faculty Positions Qualifying For Authorized User Status

(1) “Full time member of the faculty” generally means a person holding a faculty rank that carries voting privileges on the Duke University Academic Council and permits a position on Departmental review panels for appointment, re-appointment and promotion of faculty. Such positions include, but are not necessarily limited to, the following:

- Professor (or as qualified by “Assistant” or “Associate”)
- Research Professor (or as qualified by “Assistant” or “Associate”)
- Associate and Assistant Professors Tracks IV/V
- Professor “of the Practice of” (or as qualified by “Assistant” or “Associate”)

(2) Individuals holding full-time positions such as “Research Scientist” or the equivalent may also be eligible for Authorized User Status, depending upon their qualifications and the nature of their use of ionizing radiation sources.

(3) Faculty ranks *not eligible* for Authorized User status include the following:

- Lecturer
- Instructor
- Associate
- Research Associate
- All ranks qualified by terms such as “Consulting”, “Visiting”, or “Emeritus”.

Source: *The Duke University Faculty Handbook*, Chapter 2, "Rank and Title", 2023.

APPENDIX C. Human-Use Authorized User, Authorized Medical Physicist and Authorized Nuclear Pharmacist: Qualifications and Process

The process for attaining Authorized User, Authorized Medical Physicist or Authorized Nuclear Pharmacist status, as defined in 10 CFR 35, are outlined below.

Authorized User (Physician) Applicant: The physician applicant for clinical use of radioactive material or accelerators must fulfill all the following conditions:

1. Hold an active, unrestricted license to practice medicine in the State of North Carolina, as issued by the North Carolina Medical Board.

2. Have training and experience commensurate with the types and amounts of radioactive material applied for, as set forth in 10A NCAC 15.0307. Applicants may demonstrate fulfillment of the requirements either by (a) a combination of specialty board certification, documentation of alternative training and experience and by preceptor attestation; or (b) by having previously been named as an Authorized User on an NRC or Agreement State license or registration for the clinical use of radioactive material or medical particle accelerators.

3. Have contacted the Secretary of the Radiation Safety Committees or the Radiation Safety Officer, through their Departmental Chair or other individual designated by the Department. The applicant should submit a curriculum vitae, a copy of the applicant's applicable specialty board certificate and evidence of full and unrestricted medical licensure in North Carolina. If Authorization is sought through preceptor attestation in lieu of board certification, a preceptor attestation form as provided by the North Carolina Radiation Protection Section or equivalent Agreement State or USNRC form (e.g. Form 313a series) should be submitted. For AU status for medical particle accelerators, a state form or letter providing written attestation may be acceptable; other conditions may apply. The Secretary may obtain verification of current "Maintenance of Certification" for the specialty board and medical licensure through the web sites of the American Board of Radiology, the American Board of Medical Specialties or the North Carolina Medical Board.

Authorized Medical Physicist Applicant: The medical physicist applicant must fulfill all the following conditions:

1. Have training and experience commensurate with the clinical activities applied for, as set forth in North Carolina and USNRC regulations.

2. Apply to the Secretary of the Radiation Safety Committees or the Radiation Safety Officer through their Departmental Chair or other individual designated by the Department. The

application must be accompanied by a curriculum vitae and a copy of the applicant's specialty board certificate. Other conditions may apply

Authorized Nuclear Pharmacist Applicant: The nuclear pharmacist applicant for clinical use of radioactive material must fulfill all the following conditions:

1. Hold an active license to practice pharmacy in the State of North Carolina, as issued by the North Carolina Board of Pharmacy.

2. Have training and experience commensurate with the types and amounts of radioactive material applied for, as set forth in North Carolina and USNRC regulations. Applicants may demonstrate fulfillment of the requirements either by specialty board certification, or by preceptor attestation.

3. Make application to the Secretary of the Radiation Safety Committees or the Radiation Safety Officer. The application must be accompanied by a copy of the licensee's registration certificate issued by the North Carolina Board of Pharmacy as documentation of current active licensure, a curriculum vitae and a copy of the applicant's specialty board certificate, or letter of intent to certify from the specialty board. If Authorization is sought through preceptor attestation, a complete, signed preceptor attestation form is required.

Once all the application materials are received by the Secretary, the applicant may be granted provisional approval by the Human Use Subcommittee of the Medical Center Committee. Formal approval will be granted by vote of the full Medical Center Committee at its next scheduled meeting.

Authorized User status terminates if either (a) the Authorized User terminates their employment with Duke University Medical Center, (b) the applicant does not maintain active licensure with the applicable North Carolina licensing board or (c) the Authorized User's clinical privileges at Duke University Medical center are suspended or revoked by action of Medical Center senior management. Authorized User status may also be revoked by action of the Radiation Safety Committee.

APPENDIX D. Nursing Care for Radioactive Patients and Intraoperative X-ray Procedures

Duke University Medical Center enjoys national prominence in the treatment of patients with cancer and other conditions. Radioactive drugs ("radiopharmaceuticals") and other radiation sources such as x-ray machines and CT scanners are commonly employed in the diagnosis and treatment of our patients. The purpose of this Appendix is to inform nurses and ancillary patient caregivers about the impact of radiation exposure on their interaction with patients. The practical considerations in working with diagnostic nuclear medicine patients, radiopharmaceutical patients, are presented, along with some of the health and regulatory considerations and how they impact radiation safety practices at Duke.

Nuclear Medicine Diagnostic Patients

Patients may undergo imaging procedures in Radiology's Division of Nuclear Medicine and Radiotheranostics while hospitalized. These procedures include bone scans, "MUGA" scans, PET/CT scans and so forth. They are performed with very small ("radiotracer") amounts of radioactive material. The radiation levels from these patients are negligible and present no hazard. Other than "Universal Blood and Body Fluid Precautions", there are no special radiation safety considerations for interacting with these patients.

Radiopharmaceutical Therapy Patients

Most radiopharmaceutical patients are treated as outpatients. However, medical or regulatory compliance considerations may require some of them to be hospitalized. These patients would fall into two groups as follows.

Patients treated with Iodine-131 Labeled Drugs

Radiation protection considerations for these patients are (a) the external radiation from the radioactive iodine in the patient's body and (b) radioactive iodine in blood and body fluids, including saliva and perspiration ("contamination"). The external radiation exposure levels may require the patients to be housed in special lead-lined rooms on Division 9300 or in the Duke Central Tower. Here are some ways to reduce external radiation exposure and avoid ingesting contamination while caring for these patients.

- X-ray shielding ("lead") aprons are minimally effective and their routine use during ordinary caregiving is not recommended.
- Put on shoe covers and protective gloves before entering the patient's room.
- Work quickly, but effectively and courteously. Minimize time in the room. No matter how long they are in the room, staff will not receive a radiation exposure large enough to cause adverse health effects.
- Maintain the greatest distance possible from the patient, consistent with effective care. Radiation exposure drops off drastically with increasing distance.
- Observe "Universal Precautions" while handling blood and other body fluids, especially urine.
- Leave all trash, linens and food trays in the room. Upon leaving the room, remove gloves and shoe covers and place them in the trash box inside the room.

- After leaving the room, practice good handwashing according to the National Health Safety Goals ("Universal Precautions").

In the event of a medical emergency (Code Blue) involving the patient, the patient's well-being is the primary consideration. All initial measures necessary to sustain the patient should be undertaken, regardless of radiation considerations.

Patients Treated with Other Radiopharmaceuticals

These treatments include radioablation of liver tumors with yttrium-90 microspheres, treatment for neuroendocrine tumors and metastatic prostate cancer with lutetium-177 labeled drugs (Lutathera™ and Pluvicto™). There is little or no external radiation from these patients, so they may be housed in regular hospital rooms. However, contamination is an issue and strict adherence to "Universal Precautions" is required.

Intraoperative X-rays and Mobile X-rays

- Imaging-guided surgical procedures using x-rays are commonly performed in Duke's many operative suites. Here are two simple ways to reduce radiation exposure.
    - If you are not needed directly at tableside during exposures, step back a few feet.
    - Wear x-ray shielding protective garments according to your local procedures.
- For radioactive "seed" localizations, be sure to label the container containing seed-containing specimens and/or dislodged seeds as "radioactive material" before sending them to Surgical Pathology.
- For mobile x-rays performed on the Divisions, simply leaving the room during exposures is adequate protection, and shielding garments are not needed. However, if needed to be in the room to assist, staff must wear shielding garments. Holding patients during exposures is not recommended and mechanical measures should be used instead. Do not hold the patient or the x-ray cassette without wearing a shielding mitt.

Medical, Reproductive and Fertility Considerations

The potential adverse health effects of very high doses of ionizing radiation are well known. Potential health issues include immediate medical effects, cancer induction and reproductive health effects. Through basic radiation biology research in animal models and epidemiologic studies in people, we have been able to establish with some certainty the levels of exposure that can be sustained without significantly increasing the risk of harm to an individual or their offspring.

Medical Considerations: Measurements of the radiation doses accrued by nurses who work with radiopharmaceutical patients at Duke show that staff can expect to receive less than 200 millirem per year consequential to their employment. This is in addition to the "natural background" exposure of about 300 millirem per year. That occupational dose of 200 millirem is about 4% of the federal annual occupational exposure limit. This level of radiation will not result in any noticeable symptoms and is not expected to have any long-term consequences.

Pregnancy Considerations: State and federal laws limit the radiation dose to the fetus of a declared pregnant worker to 500 millirem during the period of gestation. If they discover they are pregnant, staff

should declare your pregnancy as soon as possible. To declare pregnancy, contact Employee Occupational Health and Wellness at 684-3136 for an occupational health consult.

Fertility Considerations: Epidemiological studies on populations of both men and women who were exposed to radiation doses at or below the occupational limit (5,000 millirem per year) do not demonstrate a significant increase in the risk of birth defects or other genetic defects in the offspring of these individuals. In keeping with the “precautionary principle” for exposure to any occupational hazard, we encourage staff who are considering having children to employ the techniques we have outlined above to minimize their radiation exposure.

Regulatory and Occupational Dose Considerations

We stated above that contact with radionuclide patients would not be expected to result in adverse health effects. Why, then, do we have the lead-lined rooms, the requirement to save trash and urine and all the other precautions involved in the care of these patients? There are several reasons for this.

First, Duke is obligated to comply with North Carolina and federal regulations regarding the possession and use of radioactive materials. These regulations are intended to protect both the public and employees. Unlike a nuclear power plant, which can secure its perimeter, Duke is an open institution that is freely accessible to patients and their visitors, as well as students and staff who do not work with radioactivity. Therefore, we must adhere to some stringent requirements which are directed toward protection of the public. By law, operations at Duke must not result in a member of the general public receiving more than one hundred millirem in one year. "One hundred millirem" is about one third the annual natural background exposure. While some patient treatments can meet these criteria, others require extra shielding. Similarly, the special collection of urine and trash is dictated by environmental concerns.

Second, Duke's Radiation Safety Committees believe that "less is more" when it comes to radiation exposure. Duke subscribes to a policy called "ALARA" -- As Low as is Reasonably Achievable. By subscribing to ALARA, our Radiation Safety program strives to keep the annual radiation dose to employees below one-tenth the federal occupational limit. Epidemiological studies have not demonstrated adverse effects on medical or reproductive health effects at or below the occupational dose limit. However, we believe that it is in the best interest of our staff to maintain their radiation exposure to below 500 millirem per year wherever feasible. To meet this goal, we support several training modules on the OESO safety training web site or the Learning Management System.

If you wear a personal radiation dosimeter (also known as "film badge"), you can obtain your radiation dose history by contacting the Nurse Manager on your Division, or Radiation Safety.

APPENDIX E. Policy & Procedure for Reporting and Management of Medical Events Occurring During the Administration of Radiopharmaceuticals, Brachytherapy or External Beam Radiation Therapy

Policy & Procedure for Reporting and Management of Medical Events Occurring During the Administration of Radiopharmaceuticals, Brachytherapy or External Beam Radiation Therapy

Duke Radiation Safety Division

Last Update: 8/25/2025

Purpose: To ensure consistent, timely reporting of medical events to the North Carolina Radiation Protection Section (NCRPS) per requirements set forth in North Carolina Radiation Protection Regulations.

Applies To: All Duke University Medical Center (DUMC) clinical and research entities that administer radiation medicine to patients or human research subjects, such as the Department of Radiology (e.g. the Division of Nuclear Medicine & Radiotheranostics and the Division of Interventional Radiology) and the Department of Radiation Oncology.

Limited To: Internal reporting of treatment deviations as defined below. Nothing in this policy relieves individuals of their other reporting responsibilities (e.g. the Safety Reporting System) or restricts their right to report safety concerns to governmental agencies.

Regulatory Reference: North Carolina Administrative Code (10A NCAC 15 "Radiation Protection")

Definitions:

(1) *"RSOD"* means the Duke Radiation Safety Officer (RSO) or a duly designated staff within the Radiation Safety Division of the Occupational and Environmental Safety Office.

(2) *"Treatment Deviation"* is an unintended deviation of patient dose in (a) the therapeutic administration of radioactive material or radiation from an accelerator, therapeutic x-ray unit or brachytherapy source, or (b) in the administration of any form of radioiodine for diagnostic purposes.

(3) *"Medical Event"* means a treatment deviation that is reportable to the NCRPS as required in 10A NCAC 15.0307(l)(1), which incorporates 10 CFR 35.3045 by reference.

Introduction: Treatment deviations occasionally occur in the practice of nuclear medicine or radiation

oncology and reporting them to the NCRPS may be required. Reporting treatment deviations that occur within DUMC is the responsibility of the RSO. Due to the reporting requirements of other agencies, it is also important that members of the hospital administration be made aware of treatment deviations in a timely fashion.

Treatment deviations must meet specific radiation dose or dosage criteria, as defined in the applicable statutes, to qualify as reportable medical events. *Individuals other than the RSO should not attempt to interpret the regulations and make the decision as to whether a treatment deviation meets the criteria for a medical event.*

Procedure:

1. Any individual who discovers or is made aware of one of the following treatment deviations shall report it to the RSOD, *immediately upon discovery,* by calling the RSO directly at 919-812-4985 or the Duke University Police Department Dispatch (911 from a campus phone, or 919-684-2444 from other phones) and requesting immediate connection to Radiation Safety. Other individuals to be notified immediately include the Authorized User (AU) or those individuals as may be identified in departmental policies.

a. *For all therapeutic radiopharmaceuticals, and for iodine-131, 123 or I-124 in diagnostic amounts:*

i. administration to the wrong patient or research subject;

ii. administration of the wrong radiopharmaceutical;

iii. administration via the wrong route; or

iv. the administered dosage differs from the dosage as prescribed in the written directive by more than 20 percent or falls outside the prescribed dosage range.

b. *For radiation produced by accelerators:*

i. the total dose delivered differs from the prescribed dose by 20 percent or more;

ii. the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

iii. the wrong treatment mode is employed;

iii. the wrong anatomical site is treated; or

iv. the wrong patient or research subject is treated.

c. *For brachytherapy or yttrium-90 microspheres:*

i. the total dose delivered or activity differs from the prescribed dose by 20 percent or more;

ii. the wrong route or mode of administration is employed;

iii. the wrong anatomical site is treated (exception: permanently implanted seed migration);

iv. the wrong patient or research subject is treated;

v. a sealed source is discovered to be leaking; or

vi. for Y-90 microspheres: the administration of dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

2. The RSOD may require further consultation with the clinical staff as part of the investigation and shall determine whether a treatment deviation may be reportable to the NCRPS as a medical event, and if necessary, shall report the event within the time frame mandated in 10 CFR 35.3045, which is currently "no later than the next calendar day following the discovery of the *medical event*" (i.e. when the treatment deviation is determined to be a medical event). The decision to notify the NCRPS about a treatment deviation, regardless of whether it strictly meets the definition of a medical event, is solely the responsibility of the RSOD. Additional statutory requirements, including timely notifications of the referring physician and the patient may apply.

3. The RSOD shall prepare a written report to the NCRPS within the time frame mandated in 10 CFR 35.3045 (15 calendar days following the discovery of the medical event). The RSOD is solely responsible for ensuring compliance with all regulatory requirements.

Policy for Distribution of Medical and Academic Radioactive Material Licenses
Duke Radiation Safety Division

Revision Date: 8/6/2025

Purpose: to ensure that Duke radioactive material licenses are distributed (a) only to those entities with a "need to know", and (b) only by personnel of the Duke Radiation Safety Division.

Applies To: Radiation Safety Program of Duke University and Duke University Medical Center

Regulatory Authority: NCGS 104E-9(a)(4), 10 CFR 30.41(c), 10 CFR 30.41(d)(1-2), 10 CFR 37

Definitions:

(1) *"RSOD"* means the Duke Radiation Safety Officer, or any staff member within the Duke Radiation Safety Division who has been designated by the Radiation Safety Officer to assist in the implementation of this policy.

(2) *"Transferor"* means any entity permitted to possess and transfer radioactive material as defined in 10 CFR 30.41(b)(1-7). This includes, but is not limited to, duly licensed commercial or academic manufacturers of radioactive compounds for research or medical purposes, and duly licensed distributors.

(3) *"Quantities of Concern" (QOC)*: Quantities of those radionuclides listed in Table 1 of Appendix A to 10 CFR Part 37 that exceed the thresholds listed in that table.

Introduction: The following notice appears at the bottom of radioactive material licenses issued by the North Carolina Radiation Protection Section (NCRPS): *WITHHOLD FROM PUBLIC DISCLOSURE UNDER NCGS 104E-9(A)(4) EXCEPT TO INDIVIDUALS WITH A NEED TO KNOW*. Because licenses contain information about licensees' holdings that may be sensitive, the intent of this notice is to limit dissemination of that information.

Transferors of radioactive material have a "need to know" under 10 CFR 30.41(c). However, other entities and individuals, such as external clinical trial sponsors and Duke clinical trial study/regulatory coordinators may request copies of Duke licenses for purposes of documenting Duke University's permission to possess and use specific radionuclides. Such use may also constitute a "need to know".

Policy Provisions:

(1) *Need for License:* Copies of Duke University's radioactive material licenses shall be issued only to transferors of radioactive material that require the license for regulatory compliance purposes, or to other entities that require documentation of Duke University's authorization to possess specific radioactive materials. "Need to know" shall be determined solely by the RSOD.

(2) *Distribution by Duke Radiation Safety Division Staff Only:* Copies of licenses will be sent to individuals with a need to know only by the RSOD or designated Radiation Safety Division staff.

(3) *Redacting QOC Items:* Prior to license distribution, line items for which the value for "*Maximum amount that licensee may possess at any one time under this license"* exceeds the QOC for the radionuclide shall be redacted. Redaction shall be done using an irreversible method. The RSOD may waive this provision.

(4) *Preventing Re-distribution of Outdated Licenses:* Copies of licenses shall not be issued to any entities or individuals within Duke University or Duke University Health System unless expressly authorized by the Radiation Safety Officer.

Implementation:

1. Transferors of radioactive material who already have Duke licenses on file may be issued updated redacted licenses by Radiation Safety Division staff without consulting the RSOD. If the transferor must ship radioactive material that exceeds QOC, then a license without redaction shall be supplied. If a license has expired but is in "timely renewal" status, a copy of the letter from the North Carolina Radiation Protection Section documenting "timely renewal" shall accompany the license.

2. A redacted copy of the license may be issued to other entities or individuals upon request (per 10 CFR 30.41(d)(1)). "Other entities or individuals" include but are not limited to the following:

- External study sponsors
- External Clinical Research Organizations (CROs)
- Federal, State or private granting agencies