SCOPE

This GI, "Ionizing Radiation Protection Requirements for Medical and Veterinary Radiation Producing Equipment", specifies the requirements additional to GI 150.003 "Ionizing Radiation Protection".

CONTENT

1. DEFINITIONS

Computed Tomography (CT): The production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Diagnostic X-ray, Fluoroscopic, and Dental X-ray Equipment: X-ray equipment designed for irradiation of part(s) of the human body for the purpose of diagnosis or visualization.

Leakage Radiation: Radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Medical Accelerator: A device used to accelerate charged particles and produce radiation for radiotherapy.

Medical Radiation Producing Equipment: Equipment producing ionizing radiation for diagnostic or therapeutic purposes in medical, dental or veterinary practices.

Radiotherapy: The treatment of tumors through the use of ionizing radiation. In therapeutic applications, the objective is to deliver a pre-determined dose to a particular organ while minimizing the dose to the rest of the patient body.

Primary Beam: The radiation emanating from the tube housing port of the x-ray equipment.

Source to Image receptor Distance (SID): The distance from the x-ray source to the center of the input surface of the image receptor.

Source to Skin Distance (SSD): The distance between the x-ray source and the skin entrance plane of the patient.

Veterinary X-ray: The use of X-rays to view a cross sectional area of an animal body.

Useful Beam: The radiation which passes through the opening in the beam-limiting device and which is used for imaging or treatment.

2. MEDICAL DIAGNOSTIC X-RAY

This section includes requirements for the use of x-ray machines for diagnostic purposes only.

2.1 FIXED RADIOGRAPHIC EQUIPMENT

2.1.1 All rooms/facilities housing fixed diagnostic x-ray machines shall satisfy all structural, radiation shielding, penetrations, radiation monitoring, safety interlock, warning signs and all other requirements as deemed necessary by the Radiation Protection Unit of Environmental Protection Department.

2.1.2 A radiation protection survey shall be performed annually on existing installations and on all new installations prior to use, or after any changes or alterations in equipment that may affect the radiation characteristics of the system.

2.1.3 Leakage radiation from the diagnostic source assembly shall not exceed 0.1 R/h at a distance of 1 meter when the tube is operated at the leakage technique factor. If leakage technique factors cannot be set on the control panel, then compliance shall be determined by measuring leakage at maximum kVp and appropriate electric current.

2.1.4 The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED".

2.1.5 The entrance to a room containing x-ray equipment shall be posted with a radiation warning sign that bear in Arabic and English, the following statement "CAUTION X-RAY, THE EQUIPMENT IN THIS ROOM PRODUCES X-RAY WHEN ENERGIZED".

2.1.6 Warning light and emergency button shall be regularly tested.

2.1.7 Personnel monitoring devices shall be provided to and worn by all persons routinely involved in x-ray work. Deliberate exposure to an individual's personnel monitoring device is prohibited.

2.1.8 Persons operating the x-ray equipment shall be instructed in their safe operating procedures and be competent in the safe use of the equipment.

2.1.9 The operator shall stand behind the barrier provided during exposure, except where procedures require his presence outside it.

2.1.10 Ionizing radiation producing equipment shall be operated only by authorized personnel.

2.1.11 Only persons whose presence is necessary shall be in the x-ray room during exposure. X-ray operator, other professional staff, and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

2.1.12 All workers shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent

2.1.13 Exposure of a person to the primary beam for training or demonstration purposes shall not be permitted.

2.1.14 Each diagnostic x-ray system shall have an available chart which specifies, for all examinations performed with that system, the following information:

a) Patient's body part and anatomical size or body part thickness or age (for pediatrics) versus technique factors to be utilized.
b) Type and size of the image receptor.
c) Type and focal distance of the grid to be used, if any.
d) Source image receptor distances (SID) to be used (except for dental intraoral radiographs).
e) Type and location of placement of patient shielding (e.g., gonad, etc.).

2.1.15 The useful x-ray beam shall always be limited to the smallest area practicable and be consistent with the objectives of the radiographic examination.

2.1.16 For patients who have not passed the reproductive age, gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

2.1.17 Protection of the embryo or fetus of a pregnant woman should be given special consideration during radiological examination.

2.1.18 When a patient must be held in position for radiography, mechanical support or restraining devices should be used when possible. If a patient must be held by another individual, the individual shall be protected with a leaded apron and leaded gloves and should be positioned so that no part of his body will be struck by the primary x-ray beam. Pregnant women or persons under 18 years of age shall not be permitted to hold patients during radiography procedures

2.1.19 Inspections of protective items such as leaded aprons and gloves should be made periodically and records shall be kept on file.

2.1.20 To eliminate retakes and minimize exposures, film processing materials and techniques should be those recommended by the manufacturer or those tested and shown to ensure maximum informational content of the developed x-ray film.

2.1.21 Following the guidelines of NCRP- 99, applicable standards and Saudi Arabia Competent authority regulation, Quality Assurance and Quality Control of all diagnostic x-ray equipment shall be performed periodically and documented.

2.2 MOBILE RADIOGRAPHIC EQUIPMENT

2.2.1 The use of mobile radiographic equipment shall meet the applicable requirements for fixed radiographic equipment (Section 2.1) and the additional paragraphs given in this section.
2.2.2 Mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a fixed radiographic room.
2.2.3 A leaded apron or mobile barrier shall be provided for the operator's protection.
2.2.4 Patient(s), other than the patient being examined, who cannot be removed from the room during the radiographic exposure, shall be protected from the direct scatter radiation by whole body protective barrier of not less than 0.25 millimeter lead equivalent material.
2.2.5 The exposure switch must allow the operator to stand at least 2 meters away from the useful x-ray beam during exposure.

2.3 FLUOROSCOPIC EQUIPMENT

2.3.1 The use of fluoroscopic equipment shall meet the applicable requirements for the use of fixed radiographic equipment (Section 2.1) and the additional paragraphs given in this section.
2.3.2 Fluoroscopy should not be used as a substitute for radiography, but should be reserved for the study of dynamics or spatial relationships or for guidance in spot-film recording of critical details.
2.3.3 The operator should use the maximum SSD consistent with medical requirements of the procedure. For fluoroscopic procedures, distances of less than 30 cm shall not be used.
2.3.4 X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure
2.3.5 Fluoroscopic table designs and operating procedures shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

2.4 COMPUTED TOMOGRAPHY EQUIPMENT

2.4.1 The use of computed tomography shall meet the applicable requirements for the use of fixed radiographic equipment (Section 2.1) and the additional paragraphs given in this section.
2.4.2 Provision shall be made for two-way aural communications between the patient and the operator at the control panel.
2.4.3 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel
2.4.4 When the primary viewing system is by electronic means, an alternate viewing system (which may also be electronic) shall be available for use in the event of failure of the primary viewing system.
2.4.5 Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include, but not limited to the following:

2.4.5.1 Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

2.4.5.2 Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.

2.4.5.3 The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized.

2.4.5.4 A current chart at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination.

2.4.6 The dose to the patient should be kept to a minimum consistent with clinical objectives.

2.4.7 The slice thickness and the number of slices per study should be as optimal as it is practically possible to reduce patient's radiation dose.

2.4.8 Contrast studies should be made only when necessary for obtaining critical diagnostic information.

2.5 DENTAL X-RAY EQUIPMENT

2.5.1 The use of dental x-ray equipment shall meet the applicable requirements for the use of fixed radiographic equipment (Section 2.1) and the additional paragraphs given in this section.

2.5.2 Source-to-image receptor distance for intraoral radiography shall not be less than 20 cm.

2.5.3 In the absence of a barrier in an existing facility, the operator shall remain at least 2 m from the tube head during exposure. If the 2 m distance cannot be maintained, then a barrier shall be provided.

2.5.4 Rectangular collimation of the x-ray beam shall be routinely used for intraoral radiography.

2.5.5 The operator's protected area shall provide means to view the patient during the x-ray procedure.

3. RADIOTHERAPY

3.1 MEDICAL ACCELERATORS

3.1.1 The entrance to the treatment room containing high-energy linear accelerator shall be restricted to authorized personnel and shall be posted with the appropriate warning signs.

3.1.2 Radiation protection surveys shall be performed annually on existing installations.

3.1.3 Radiation protection surveys shall be performed on all new installations prior to use, or after any changes or alterations in equipment that could affect the radiation characteristics of the beam.

3.1.4 Appropriate dosimetry measurements shall be performed after any maintenance or service is performed. The responsibility for release of the accelerator to clinical services after maintenance is that of the radiation oncology physicist.

3.1.5 Radiation survey instruments, used for occupational and public safety, shall be calibrated annually.

3.1.6 Radiation measuring instruments, used for patient-related treatment, shall be calibrated every two years by an Accredited Dosimetry Calibration Laboratory (ADCL).

3.1.7 The dosimetry system(s) used for periodic quality assurance (QA) checks shall be calibrated on a yearly basis by a radiation oncology physicist through inter-comparison with a dosimetry system calibrated by an ADCL.

3.1.8 Testing and full calibration of the medical accelerator shall be made by the radiation oncology physicist following the recommendations given in Technical Reports Series No. 398 of the International Atomic Energy Agency (IAEA).

3.1.9 Only persons or firms specifically authorized by the physicist in charge of the medical accelerator should perform any maintenance or repair of the unit.

3.1.10 Personnel monitoring devices (TLD Badges) shall be provided and worn by all persons routinely involved in the radiation therapy set-up and treatment. Records of personnel radiation dose shall be maintained

3.1.11 Only competent and authorized radiation therapists shall operate the treatment machines.

3.1.12 The operating radiation therapist shall stand in the control area, outside the treatment room, when the radiation beam is ON.

3.1.13 The treatment room shall be secured during nonworking hours and when left unattended.

3.1.14 The operator shall ensure that only the patient is present and in the prescribed position before energizing the accelerator. PATIENTS ARE NEVER HELD AND NO ONE ELSE IS PERMITTED IN THE TREATMENT ROOM DURING THE RADIATIN THERAPY.

3.1.15 Only authorized personnel shall be present in the treatment room during the set-up procedures.
3.1.16 No individual shall be exposed to radiation therapy unless prescribed by the radiation oncologist.
3.1.17 Protection of the embryo or fetus of a pregnant woman should be given special consideration before and during the treatment.
3.1.18 Exposure of normal tissue during radiotherapy shall be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate.
3.1.19 Radiation shields must be used whenever possible to protect critical organs and health tissues.
3.1.20 Quality assurance and calibration of the equipment shall be performed periodically and documented.
3.1.21 Interlocks, warning light and emergency buttons must be checked regularly.
3.1.22 Clearly post emergency procedures for all possible failures.

4. VETERINARY X-RAY EQUIPMENT

4.1 The use of veterinary x-ray equipment shall meet the applicable requirements for the use of fixed radiographic equipment (Section 2.1) except those referring specifically to human patients.
4.2 If an animal must be held during a radiographic procedure, the person holding the animal shall wear lead apron and protective leaded gloves and shall keep his body out of the primary x-ray beam.
4.3 Pregnant women or persons under 18 years of age shall not be permitted to hold animals during radiography.

5 REFERENCES:

5.1 General Instruction for Ionizing Radiation Protection in the Kingdom of Saudi Arabia, KACST (2007).
5.2 Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energy up to 50 MeV, Report No. 102, National Council on Radiation Protection and Measurements (NCRP), 1989.
5.3 Quality Assurance for Diagnostic Imaging. NCRP Report No. 99, 1988.
5.4 Absorbed Dose Determination in External Beam Radiography, Technical Reports Series no.398. International Atomic Energy Agency, 2000.
5.5 Medical Accelerator Safety Considerations, American Association of Physicists in Medicine, AAPM REPORT NO. 56. 1996.
5.6 Radiation Protection in Dentistry, NCRP Report No. 145, National Council on Radiation Protection and Measurements, 2003.
5.7 Diagnostic x-ray systems and their major components, 21 CFR 1020.30.
5.8 Basic Ionizing Radiation Symbol, SASO Draft No. 3331, Saudi Arabian Standards Organization, 2005.

RECOMMENDED: _____ DATE: _____
H. A. AL MUSAIID, MANAGER
ENVIRONMENTAL PROTECTION DEPARTMENT

CONCURRED: _____ DATE: _____
N. A. AL-JAMA', EXECUTIVE DIRECTOR
COMMUNITY SERVICES

CONCURRED: _____ DATE: _____
R.B. BIRRER, EXECUTIVE DIRECTOR
MEDICAL SERVICES