10A NCAC 15 .0603 GENERAL REQUIREMENTS

(a) Administrative controls

(1) The registrant shall be responsible for directing the operation of the x-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the x-ray machine(s):

(A) An x-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.

(B) Individuals who will be operating the x-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.

(C) In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source to image receptor distance. The chart shall also provide:

(i) type and size of the film or film-screen combination to be used,

(ii) type and ratio of grid to be used, if any, and focal spot to film distance,

(iii) type and placement of gonad shielding to be used.

(D) Written safety procedures and rules shall be established and made available to each individual operating x-ray equipment under his control. The operator shall be familiar with these rules.

(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:

(i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the useful beam.

(ii) 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 mm lead equivalent.

(iii) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least six feet from both the tube head and the nearest edge of the image receptor.

(iv) When a portion of the body of a non- occupationally exposed professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in Rule .1604 of this Chapter, additional protective measures shall be employed.

(v) Upon written application to the agency, the agency may waive the requirements in Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that such waiver is necessary for best management of patients and will not result in violation of the public and occupational dose limits established in the rules in this Chapter.

(F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct, or useful beam, except for cases in which this would interfere with the diagnostic procedures.

(G) Individuals shall not be exposed to the useful beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts purposes.

(H) When a patient or film must be provided with auxiliary support during a radiographic exposure:

(i) Mechanical holding devices shall be used whenever medical circumstances permit. Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the requirements for selecting a holder;

(ii) If a human holder is required, written safety procedures as required in Part (a)(1)(D) of this Rule, shall indicate the instructions provided to the holder;
(iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;
(iv) No individual shall be used routinely to hold patients or film.

(I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This includes, but is not limited to, the following requirements:
(i) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
(ii) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
(iii) Portable or mobile equipment shall be used only for examinations where it is impractical for medical reasons to transfer the patient to a stationary radiographic installation.

(J) All persons who are associated with the operation of an x-ray system are subject to the occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective clothing or equipment is worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
(i) When an apron is worn the monitoring device shall be worn at the collar outside the apron.
(ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.

(2) The registrant shall maintain at least the following information for each x-ray machine:
(A) current registration information and other correspondence with the agency regarding that machine;
(B) records of surveys and calibrations;
(C) records of maintenance or modifications which affect the useful beam after the effective date of these Rules, along with the names of persons who performed the service.

(b) Plans Review. Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing x-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.

(c) Radiation Survey

(1) For installations of x-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:
(A) a drawing of the room in which a stationary x-ray system is located and radiation levels in adjacent areas; and
(B) the name of the person approved by the agency performing the survey and the date the survey was performed.

(2) Any modification to the x-ray room or adjacent areas which could increase the radiation dosage to any individual shall require a new survey.

(3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.

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