**Section 360.40 General Equipment and Operation Requirements for Diagnostic X-Ray Systems**

The requirements of this Section apply to all diagnostic x-ray systems. Additional requirements for specific equipment application classes are in Sections 360.41 through 360.100 of this Part.

a) Half-Value Layer

1) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Section 360. Table B of this Part.

2) For capacitor energy storage equipment, compliance with the requirements of this subsection (a) shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

b) Beam-On Indicators

1) The control panel shall include a device (usually a milliammeter or labeled indicator lamp) which will give positive indication of the production of x-rays whenever the x-ray tube is energized.

2) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

c) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system. The tube housing assembly supports shall not be hand-held unless the manufacturer has specifically designed the system to be operated while hand-held.

d) Diagnostic Source Assembly Leakage Radiation Limits. The leakage radiation measured at a distance of 1 meter from the source shall not exceed 25.8 microC/kg (100mR) in 1 hour when the tube is operated at its leakage technique factors.

e) Radiation From Capacitor Energy Storage X-ray Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 0.516 microC/kg (2mR) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f) Technique Indicators

1) The technique factors to be used during an exposure shall be indicated at the control panel before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated at the control panel.

2) The requirement of subsection (f)(1) of this Section may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films.

3) The indicated technique factors of exposure time and kilovolts peak (kVp) shall correspond to the actual exposure factors within ten percent of the indicated values.

g) Reproducibility of Exposures

1) For any specific combination of selected technique factors utilized, the coefficient of variation of radiation exposures shall not exceed 0.05 for any specific combination of selected technique factors.

AGENCY NOTE: It will not be necessary to calculate the coefficient of variation if for the first four measurements the value of the average exposure (Eavg) is greater than or equal to ten times the maximum exposure (Emax) minus the minimum exposure (Emin). This requirement is mathematically represented by the following:

Eavg = 10 (Emax - Emin)

2) For systems using automatic exposure control (AEC) (i.e., systems employing photo-multiplier tubes, or ionization chambers to terminate the x-ray exposure), compliance measurements shall be performed with the system operating in the AEC mode. Attenuating material shall be placed in the beam to provide exposure times in the range of those used clinically.

AGENCY NOTE: The intent of this subsection (g) is to require testing of the system in a manner that is clinically relevant. Reproducibility of exposures should be measured at technique factors that are commonly used and are subject to variation. For AEC systems, commonly used settings in combination with an appropriate thickness of attenuating material should be used to provide exposure times in the clinical range.

h) Patient or Film Support

1) When a patient or film must be provided with auxiliary support during a radiation exposure:

A) No person shall be used routinely to hold film or patients; and

B) Unless the procedure precludes their use, mechanical holding devices shall be used to restrain patients. For example, mechanical holding devices could not be used if the devices would preclude clear visualization of the tissue being examined.

2) When a patient or film must be held by an individual, written safety procedures, as required by Section 360.30(j) of this Part, shall indicate the criteria for selecting a holder and the procedure the holder shall follow.

AGENCY NOTE: The radiation dose received by radiation workers, patients and the general public can be reduced if mechanical patient and film support devices are used for radiographic and fluoroscopic procedures. In the event that an individual must be used in lieu of mechanical patient or film support devices to hold patients or films, every effort should be made to limit the individual's radiation dose. This can be accomplished by not assigning to a single individual the task of supporting patients and films during radiographic and fluoroscopic examinations. Rather, a number of individuals may be rotated through the assignment, thereby reducing the radiation dose to one individual.

i) Personnel Protection

1) Except for patients who cannot be moved out of the room, only the individuals required for the medical procedure or training shall be in the room during the radiographic/flouroscopic exposure.

2) Individuals who must be in the room with the patient being radiographed or fluoroscoped shall be protected by 0.25 millimeter lead equivalent apparel or device or shall be positioned at a distance such that the individual does not receive a radiation dose in excess of the limits specified in 32 Ill. Adm. Code 340.310.

j) Technique Guides

1) In the vicinity of each radiographic x-ray system's control panel, a technique guide shall be provided which specifies for routine examinations performed with that system, the following information:

A) Patient's anatomical size versus technique factors to be utilized;

B) Type of screen-film combination utilized, if more than one; and

C) SID to be used.

2) For automatic exposure control (AEC) systems with selectable exposure detectors and density settings, the technique guide shall also specify the appropriate exposure detectors and density setting to be utilized for each radiographic examination listed.

3) For AEC systems, if operated in a non-automatic mode, the technique guide shall specify the requirements of subsections (j)(1)(A) through (C) of this Section to be followed.

AGENCY NOTE: The Agency recognizes that alternate means may be available at the control panel to indicate technique factors for computerized imaging systems.

k) Patient Dose Criteria. Procedures and auxiliary equipment designed to minimize patient and occupational dose commensurate with needed diagnostic information shall be used.

AGENCY NOTE: It is the intent of this subsection (k) to provide for the optimum optical density, resolution and contrast on the film while minimizing patient dose. X-ray films, intensifying screens and other image recording devices should be as sensitive as is consistent with the requirements of the examination.

l) X-ray Film Processing Systems. The darkroom safe light illumination shall be adequate for the film speeds and the darkroom operating procedures used to prevent fogging of unprocessed film. The following additional requirements apply to film processing systems:

1) Manual film processing systems shall be monitored by the registrant to assure:

A) The use of a dedicated darkroom timer with an adjustable preset function. The timer shall be used to adjust film processing time according to solution temperature.

B) The use of a dedicated darkroom thermometer. The thermometer shall be used to adjust the film processing time according to solution temperature.

C) The use of a film processing guide. The guide shall contain, at a minimum, information regarding times and temperatures (as recommended by the film manufacturer) used by the registrant to develop radiographs.

D) The frequency at which film processing chemicals are changed is appropriate for the conditions of use.

2) Automated film processing shall be monitored by the registrant to assure:

A) The temperature of film processing chemicals and the film transport speed is appropriate for the type of films being utilized.

B) The film processing chemicals used and their replenishing rate (if applicable) are appropriate for the type of films and quantity processed.

m) Gonadal Shielding. Except for cases in which it would interfere with the diagnostic procedure, gonadal shielding of not less than 0.5 millimeter of lead equivalent shall be used for patients (who have not passed the reproductive age) during those radiographic procedures in which the gonads are in the useful beam.

AGENCY NOTE: Protection of the embryo or fetus from radiation dose during radiological examination or treatment of a woman of childbearing age (potentially pregnant) should be given special consideration.

(Source: Amended at 32 Ill. Reg. 3693, effective February 29, 2008)