

TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION

PART 360
USE OF X-RAYS IN THE HEALING ARTS INCLUDING MEDICAL,
DENTAL, PODIATRY, AND VETERINARY MEDICINE

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AUTHORITY: Implementing and authorized by the Radiation Protection Act of 1990 [420 ILCS 40].

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Section 360.10 Scope

- a) This Part establishes requirements for use of x-ray producing devices in the healing arts by a practitioner licensed to practice a treatment of human ailments by virtue of the Medical Practice Act of 1987 [225 ILCS 60], the Illinois Dental Practice Act [225 ILCS 25], or the Podiatric Medical Practice Act of 1987 [225 ILCS 100], or by a medical radiographer or radiation therapist accredited in accordance with the provisions of 32 Ill. Adm. Code 401.100 or an individual exempt from the provisions of 32 Ill. Adm. Code 401, by Section 401.30 of that Part, acting under the supervision, prescription or direction of such licensed person or the non-human use of x-ray by veterinarians by virtue of the Veterinary Medicine and Surgery Practice Act of 1983 [225 ILCS 115]. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of 32 Ill. Adm. Code 310, 320, 340, 400 and 410.
- b) It is recognized that some installations and equipment designed before the adoption of this Part, coupled with conditions of use, may be adequate to achieve minimum doses. Request for exemption from some provisions of this Part will be considered in accordance with 32 Ill. Adm. Code 310.30(a).

(Source: Amended at 22 Ill. Reg. 5904, effective March 13, 1998)

Section 360.20 Definitions

As used in this Part, the following definitions apply:

"Accelerator" (also "particle accelerator") means any therapeutic machine capable of producing a useful beam of x-rays or charged particles with energies of 1 MeV or greater. Accelerators include cyclotrons, betatrons and linear accelerators.

"Accelerator facility" means the location at which one or more particle accelerators are installed and are operated under the same administrative control.

"Agency" means the Illinois Emergency Management Agency.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Applicator" means a structure which determines the extent of the treatment field at a given distance from the source of the beam.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of aluminum equivalent. Copper may be substituted for aluminum if an appropriate thickness is used for the kVp selected, as indicated below:

kVp	Millimeters of Copper Equivalent to 3.8 centimeters of aluminum
99 or less	2.0
100 to 125	2.5
greater than 125	3.0

"Automatic exposure control" means a device that automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation (see "Phototimer").

"Barrier" (see "Protective barrier").

"Beam" means a flow of electromagnetic or particulate radiation that passes through the opening in the beam limiting device and that is used for diagnosis or treatment.

"Beam axis" (see "Central axis of the beam").

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field (see "Collimator", "Diaphragm" and "Shutter").

"Beam monitoring system" means a system of devices that will monitor the useful beam during irradiation and will terminate irradiation when a preselected number of monitor units has been accumulated.

"Beam scattering filter" means a filter placed in an electron beam in order to scatter the beam and provide a more uniform distribution of electrons in the beam.

"Central axis of the beam" means the line passing through the source of the beam and the center of the plane formed by the edge of the first beam-limiting device.

"Charged particle beam" (see "Beam").

"Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.

"Collimator" means a device or mechanism by which the x-ray beam is restricted in size (see "Beam-limiting device").

"Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" or "CTDI" means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

"Contact hour" means the number of hours an individual is in contact with an instructor. One contact hour equals 50 minutes.

"Contact therapy system" means an x-ray system used for therapy that is designed for very short treatment distances (5 centimeters or less), usually employing peak tube potentials in the range of 20 to 50 kVp.

"Control panel" means that part or parts of the x-ray system upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for setting the technique factors prior to initiating an x-ray exposure.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors and the supporting structures and frames that hold these components.

"Dead-man switch" means a switch constructed so that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

"Diagnostic imaging specialist" means a person who possesses the knowledge, training and experience to apply the principles of radiological physics to diagnostic x-ray applications. The diagnostic imaging specialist shall be approved and registered by the Agency pursuant to 32 Ill. Adm. Code 410.

"Diagnostic source assembly" means an x-ray tube housing assembly, designed for use in diagnostic x-ray applications, with a beam-limiting device attached.

"Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size (see "Beam-limiting device").

"Direct supervision" means an individual is in the physical presence of a licensed practitioner who assists, evaluates and approves of the individual's performance of the various tasks involved in the application of ionizing radiation.

"Electronic brachytherapy" means a method of radiation therapy in which an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver a therapeutic radiation dosage.

"Electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation, including x-ray tube, the control mechanism, the cooling system and the power source.

"Electronic brachytherapy device operator" means a radiation therapist accredited in accordance with 32 Ill. Adm. Code 401 or a physician.

"Electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device.

"Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

"Filter" means material placed in the useful beam to absorb, preferentially, radiations based on energy level or to modify the spatial distribution of the beam.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"General purpose x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective device for the testes or ovaries that provides a minimum of 0.5 millimeter lead equivalent protection.

"Half-value layer" or "HVL" means the thickness of a specified material that attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value.

AGENCY NOTE: The contribution of all scattered radiation, other than any that might be present initially in the beam concerned, should be minimized.

"Healing arts screening" means the examination of human beings using x-ray machines for the detection or evaluation of potential diseases when the examinations are not specifically ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray examinations for the purpose of diagnosis or treatment. However, healing arts screening does not include mammography on self-referred patients.

"Image intensifier" means a device, installed in a housing, that converts an x-ray pattern into a corresponding light image, usually by electronic means.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

"Institutional review board" means a committee that has been formally designated by the registrant to approve, monitor and review biomedical and behavioral research involving humans.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the useful beam passes at any beam orientation.

"Kilovolts peak" or "kVp" means the crest value, in kilovolts, of the electric potential applied to the x-ray tube between the cathode and anode of a pulsating electric potential generator.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means all radiation emanating from the diagnostic source assembly except for:

The useful beam; and

The radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors used to measure leakage radiation from the diagnostic source assembly. They are defined as follows:

For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in 1 hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere-seconds, or the minimum obtainable from the unit, whichever is larger.

For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in 1 hour for operation at the maximum-rated peak tube potential.

For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and any one of the sets of planes parallel to and including the plane of the image receptor. The edge of the light field is defined as the locus of points at which the illumination is 25 percent of that at the center of the light field.

"Medical event" means an event that meets the criteria in Section 360.120(i)(3).

"Medical radiographer" means a person other than a licensed practitioner, accredited in accordance with the provisions of 32 Ill. Adm. Code 401, or an individual exempt from the provisions of 32 Ill. Adm. Code 401, who performs medical radiation procedures and applies x-radiation, to any part of the human body, for diagnostic purposes while under the supervision of a licensed practitioner.

"Mobile equipment" (see "X-ray equipment").

"Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Moving beam therapy" means radiation therapy in which there is displacement of the useful beam relative to the patient. Moving beam therapy includes arc therapy, skip therapy and rotational beam therapy.

"Operator" means an individual who applies ionizing radiation for diagnostic or therapeutic purposes.

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation monitoring devices. The radiation monitoring devices is part of an electronic circuit that controls the duration of time the tube is activated (see "Automatic exposure control").

"Portable equipment" (see "X-ray equipment").

"Portable x-ray service provider" means a registrant who, under a physician's authorization, provides x-ray procedures with hand-held or mobile radiographic equipment in a patient's place of residence.

"Position indicating device" means a device on intraoral dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance.

"Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

"Primary protective barrier" (see "Protective barrier").

"Protective apron" means an apron of radiation absorbing materials, at least 0.25 millimeter lead equivalent, used to reduce exposure from leakage and scatter radiation.

"Protective barrier" means a barrier of radiation absorbing materials used to reduce radiation dose. The types of protective barriers are as follows:

"Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation dose.

"Secondary protective barrier" means a barrier sufficient to attenuate the leakage and scatter radiation to the required degree.

"Protective glove" means a glove made of radiation absorbing materials, at least 0.25 millimeter lead equivalent, used to reduce dose from leakage and scatter radiation.

"Radiation beam" (see "Beam").

"Radiation therapy simulation system" means a radiographic/ fluoroscopic x-ray

system used exclusively for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiologist assistant" means a person, other than a licensed practitioner, who, as a medical radiographer with advanced-level training and certification, performs a variety of activities under the supervision of a radiologist certified by the American Board of Radiology or the American Osteopathic Board of Radiology, in the areas of patient care, patient management, clinical imaging and interventional procedures. The radiologist assistant may not interpret images, make diagnoses or prescribe medications or therapies.

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient support device with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scatter radiation" means radiation that, during passage through matter, has been deviated in direction.

"Secondary protective barrier" (see "Protective barrier").

"Shadow tray" means a device attached to the radiation head to support auxiliary beam-limiting material.

"Shutter" means an adjustable beam-limiting or attenuating device, usually made of lead, fixed to an x-ray tube housing to intercept or collimate the useful beam (see "Beam-limiting device").

"SID" means source-image receptor distance (see "Source-image receptor distance").

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Source to skin distance" or "SSD" means the distance measured along the central

ray from the center of the front surface of the x-ray focal spot to the surface of the irradiated object.

"Special purpose x-ray system" means any radiographic x-ray system that, by design, is limited to radiographic examination of a specific anatomical region or to the extremities collectively.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Stationary beam therapy" means radiation therapy in which there is no displacement of the useful beam relative to the patient during irradiation.

"Stationary equipment" (see "X-ray equipment").

"Supervision" means responsibility for and control of quality, radiation safety and protection, and technical aspects of the application of ionizing radiation to human beings for diagnostic and/or therapeutic purposes.

"Technique factors" means the electrical potential (kilovolts), current (milliamperes), exposure time parameters (seconds or pulses) or a combination thereof, selectable at the control panel of an x-ray system (see "Control panel").

"Therapeutic radiological physicist" means an individual who has the knowledge, training and experience to measure ionizing radiation, evaluate safety techniques, advise regarding radiation protection needs and apply the principles of radiological physics to clinical radiation therapy. The therapeutic radiological physicist shall be approved and registered by the Agency pursuant to 32 Ill. Adm. Code 410.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Useful beam" (see "Beam").

"X-ray equipment" means an x-ray system, sub-system or component thereof. Types of x-ray equipment are as follows:

"Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled. Mobile x-ray equipment includes x-ray equipment permanently mounted in vehicles.

"Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

"Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

"X-ray field" means, for diagnostic purposes, that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor. The edge of the x-ray field is defined as the locus of points at which the exposure is 25 percent of that at the center of the x-ray field.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control panel, an x-ray tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system. X-ray systems include diagnostic systems, therapeutic systems and accelerator systems.

(Source: Amended at 38 Ill. Reg. 12031, effective May 29, 2014)

Section 360.30 General Requirements and Administrative Controls

The requirements in this Section apply to all uses of x-rays in veterinary medicine and to all uses of x-rays in the healing arts including the use of x-rays for both diagnostic and therapeutic purposes. Additional requirements for all diagnostic x-ray systems are in Section 360.40 and specific equipment application classes are contained in Sections 360.41 through 360.100. For therapeutic x-ray systems also see Sections 360.110 and 360.120.

- a) Registrant. The registrant shall:
 - 1) Direct the operation of the x-ray systems;
 - 2) Register with the Agency, in accordance with the provisions of 32 Ill. Adm. Code 320, all x-ray equipment which is used at the facility and all portable or mobile x-ray equipment used by the registrant;
 - 3) Verify that each individual required to be accredited by 32 Ill. Adm. Code

401 to apply x-rays for either diagnostic or therapeutic purposes is properly accredited with the Agency prior to allowing the individual to apply medical radiation procedures on human beings;

- 4) Permit operation of the x-ray systems only by individuals who are licensed in accordance with State law (see Section 360.10(a)), or who are accredited by the Agency pursuant to 32 Ill. Adm. Code 401 or who are exempt from such requirements in accordance with the provisions of 32 Ill. Adm. Code 401.
- b) Shielding. Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with the provisions of 32 Ill. Adm. Code 340.210, 340.270, 340.280 and 340.310.
- c) An x-ray system which does not meet the provisions of this Part shall not be operated for diagnostic or therapeutic purposes.
- d) If an x-ray system is identified as not being in compliance with the provisions of this Part and if that system is accessible for use, it shall be rendered inoperable (i.e., dismantle the x-ray source from the source support assembly) if so ordered by the Director.
- e) Prohibitions
 - 1) Unauthorized Exposure. Individuals shall not be exposed to the useful beam except for healing arts purposes and only when the exposure has been authorized by a licensed practitioner of the healing arts. A physician assistant or an advanced practice nurse may give authorization as long as he or she is acting under the supervision or direction of a licensed physician. This provision specifically prohibits deliberate exposure for the following purposes:
 - A) Exposure of individuals for training, demonstration or other non-healing arts purposes.
 - B) Exposure of individuals for the purpose of "healing arts screening" (see Section 360.20).
 - 2) Fluoroscopy shall not be used as a substitute for radiography or in lieu of proper anatomical positioning/centering procedures prior to radiographic studies.
 - 3) Fluoroscopic equipment using phosphorescent screens shall not be used.

Image intensification shall be utilized on all fluoroscopic equipment.

- 4) The use of direct exposure x-ray film (without intensifying screens) for routine diagnostic radiological imaging procedures, other than intraoral dental radiography and therapeutic portal imaging, is prohibited.

AGENCY NOTE: Therapeutic portal imaging is a technique used in radiation therapy to verify correct alignment of therapy beams with the patient's anatomy.

- 5) The use of photofluorographic systems is prohibited.
- 6) The use of an individual accredited as a limited diagnostic radiographer by the Agency pursuant to 32 Ill. Adm. Code 401 by a portable x-ray service provider is prohibited.

AGENCY NOTE: Photofluorography is frequently called mass miniature radiography. In this technique the image of a fluorescent screen is recorded on film by means of a camera.

- f) Individual Monitoring and Reporting Requirements. All persons who are associated with the operation of an x-ray system are subject to the radiation dose standards, requirements for the determination of the doses, requirements for individual monitoring and requirements for reporting of radiation doses that are contained in 32 Ill. Adm. Code 340.
- g) The registrant shall comply with the requirements of the Agency's rules entitled Notices, Instructions and Reports to Workers; Inspections (32 Ill. Adm. Code 400).
- h) Records and Associated Information. The registrant shall maintain at the facility, for a period of at least one inspection cycle (see 32 Ill. Adm. Code 320.10(c)), records showing the receipt, transfer, storage and disposal of all sources of radiation in accordance with the provisions of 32 Ill. Adm. Code 310 and 320.
- i) Staff Qualifications. The registrant shall maintain at the facility, for review by the Agency, current certificates of accreditation (clear, legible copies are acceptable), issued by the Agency in accordance with the provisions of 32 Ill. Adm. Code 401, for all individuals who are required to be so accredited.
- j) Radiation Safety Procedures. The registrant shall provide to each individual who operates x-ray equipment at the facility written operating and safety procedures. These procedures shall include restrictions required for the safe operation of each

radiation machine and shall include the topics listed in the radiation safety program of subsection (k).

- k) Radiation Safety Program. The registrant shall provide for initial and annual in-service training in radiation safety for individuals (excluding licensed practitioners) that apply ionizing radiation at the facility, to ensure their awareness of the registrant's radiation safety practices and policies. The in-service training shall include the following topics:
 - 1) Operating and emergency procedures for the radiation machines;
 - 2) Use of personnel and patient protective devices;
 - 3) Procedures to minimize patient and occupational doses, including procedures for selecting personnel to support patients or film, as required by Section 360.40;
 - 4) Use of individual monitoring devices (if such devices are used at the facility);
 - 5) Film processing procedures; and
 - 6) Prohibited uses of x-ray machines, as described in subsection (e).
- l) Operator Training. Individuals who operate radiation machines shall be instructed in and able to demonstrate competence with the registrant's operating and safety procedures.

(Source: Amended at 38 Ill. Reg. 12031, effective May 29, 2014)

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 (E_{avg}) is greater than or equal to ten times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is mathematically represented by the following:

$$E_{avg} = 10 (E_{max} - E_{min})$$

- 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/fluoroscopic 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)

Section 360.41 Additional Requirements for Use of Diagnostic X-Ray Systems in the Healing Arts of Medicine, Podiatry and Chiropractic

- a) Viewing System. Windows, mirrors, closed circuit television or an equivalent system shall be provided to permit the operator to continuously observe the patient during irradiation.
- b) The operator shall be able to maintain aural contact with the patient.
- c) Each x-ray control shall be located in such a way as to meet the following requirements:
 - 1) Stationary x-ray systems and mobile or portable x-ray systems used as stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted behind a protective barrier.
 - 2) For mobile and portable single event exposures and configuration, the x-ray control shall be positioned so that the operator is at least 1.83 meters (6 feet) away from the tube housing and the patient during an exposure.
 - 3) Stationary podiatric x-ray systems are exempt from the requirements of subsection (c)(1) of this Section, provided that the x-ray control meets the

requirements of subsection (c)(2) of this Section.

- d) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

(Source: Amended at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.50 Fluoroscopic Systems

In addition to the provisions of Sections 360.10, 360.30, 360.40 and 360.41 of this Part, the requirements of this Section apply to x-ray equipment and associated facilities used for fluoroscopy.

- a) **Beam Limitation.** The x-ray field shall be limited by stepless adjustable shutters. In addition:
 - 1) The minimum field size at the greatest SID shall be no greater than 5 centimeters by 5 centimeters.
 - 2) The mechanisms (manual/automatic mode selectors) provided for activating and positioning the beam-limiting shutters shall function properly. This requirement applies to shutters used in fluoroscopic procedures or spot filming procedures or both fluoroscopic and spot filming procedures.
 - 3) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. This requirement applies to field sizes for fluoroscopic procedures or spot filming procedures or both fluoroscopic and spot filming procedures.
 - 4) For fluoroscopic equipment with only a manual mode of beam limitation, the x-ray field produced shall be limited to the area of the spot film cassette at 40.6 centimeters (16 inches) above the tabletop. Additionally, during fluoroscopy, the operator shall restrict the beam to the area of the input phosphor.
 - 5) Spot film devices shall meet the following additional requirements:
 - A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size which has been selected on the spot film selector. Such

adjustment shall be accomplished automatically except when the x-ray field size in the plane of the image receptor is smaller than that selected;

- B) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the film to within two percent of the SID; and
 - C) If the angle between the plane of the image receptor and beam axis is variable, a device shall be provided to visually indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- 6) The beam limitation requirements of this subsection shall not apply to fluoroscopic systems specifically designed for examination of extremities only and meeting the requirement of subsection (1) of this Section.
- b) Fluoroscopic Timer. A manual reset, cumulative timing device shall be used which will either indicate elapsed on-time by an audible signal or turn off the system when the total exposure time exceeds a predetermined limit not exceeding 5 minutes in one or a series of exposures.
 - c) Primary Barrier/Interlock. These devices shall be provided and shall function so that:
 - 1) The entire cross section of the useful beam is intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID; and
 - 2) The fluoroscopic tube is interlocked to prevent the unit from producing x-rays unless the primary barrier is in position to intercept the useful beam, as specified in subsection (1) of this Section, at all times.
 - d) Source-Skin Distance. The SSD shall not be less than:
 - 1) 38 centimeters (15 inches) on all stationary fluoroscopes;
 - 2) 20 centimeters (8 inches) on all mobile fluoroscopes; and
 - 3) 9 centimeters (3.5 inches) for fluoroscopes specifically designed for examination of extremities only and meeting the requirements of subsection (1) of this Section.
 - e) Indication of Potential and Current. During fluoroscopy and recording of

fluoroscopic images, the kVp and the mA shall be continuously indicated at the control panel and/or the operator's position.

- f) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.
- g) Entrance Exposure Requirements
 - 1) Maximum Exposure Rate. Fluoroscopic systems shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.58 mC/kg (10 R) per minute at the point where the center of the useful beam enters the patient, except:
 - A) During recording of fluoroscopic images; or
 - B) When an optional high level control is activated (see subsection (g)(2)).
 - 2) When a high level control is activated, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5.15 mC/kg (20 R) per minute at the point where the center of the useful beam enters the patient. In addition, the following requirements apply to high level controls:
 - A) Separate means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
 - B) A continuous signal audible to the operator shall indicate that the high level control is being employed.
 - 3) Compliance with the requirements of subsections (g)(1) and (2) of this Section shall be determined using technique factors that produce the maximum exposure rate. For systems employing automatic exposure rate control, material having an equivalency of at least 3 millimeters of lead shall be placed in the primary beam between the image receptor and the radiation measuring device. The lead or equivalent material shall be positioned to ensure that the entire primary beam is blocked.

AGENCY NOTE: Many fluoroscopic systems do not yield their maximum exposure rate at the maximum tube potential or tube current. The exposure rate should be checked at various kVp and mA settings to establish the maximum exposure rate for the system.

- 4) Fluoroscopic systems shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29 mC/kg (5 R) per minute at the point where the center of the useful beam enters the patient, when measured under the following conditions:
- A) Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - B) For systems without automatic exposure rate control, the measurement shall be performed using technique factors clinically used for a standard adult patient thickness of 23 centimeters.

AGENCY NOTE: An attenuation block or other suitable material should be placed in the beam to protect the imaging system.

- C) For systems with automatic exposure rate control, the measurement shall be performed with a 2.5 millimeter thick sheet of copper in the beam between the radiation measuring device and the image receptor.

AGENCY NOTE: Use of a 2.5 millimeter thick sheet of copper approximates the attenuation of a standard adult patient thickness of 23 centimeters, and assures consistency in the measurement of fluoroscopic exposure rate.

AGENCY NOTE: The Agency recommends additional measurements be made of the entrance exposure rate for fluoroscopic systems capable of recording fluoroscopic images, and the entrance exposure for spot film techniques for fluoroscopic systems with that modality. In either case, measurements should be made under the conditions specified in subsection (g)(4)(B) of this Section.

- D) The requirements of subsection (g)(4) of this Section shall not apply to fluoroscopes specifically designed for examination of extremities only and meeting the requirements of subsection (1) of this Section.

- 5) Measurements performed pursuant to the requirements of subsections (g)(1) through (4) of this Section shall meet the following additional requirements:
- A) If the source is below the table, the exposure rate shall be determined for the center of the useful beam 1 centimeter above the tabletop or cradle, with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (12 inches) above the tabletop.
 - B) If the source is above the table, the exposure rate shall be determined at 30 centimeters (12 inches) above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - C) For a fixed SID C-arm type of fluoroscope, the exposure rate shall be determined 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly.
 - D) For a variable SID C-arm type of fluoroscope, the exposure rate shall be determined 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.
 - E) For a lateral type fluoroscope, the exposure rate shall be determined on the central axis of the primary beam at a point 15 centimeters (6 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.
- AGENCY NOTE: A lateral type fluoroscope is a fluoroscope that cannot be rotated so that the source or the fluoroscopic imaging assembly can be positioned below the fluoroscopic table or cradle.
- F) For a fluoroscopic system specifically designed for examination of extremities only, the exposure rate shall be determined for the minimum source-skin distance.

- 6) The measurements required by this subsection (g) shall be performed when the system is inspected as specified in 32 Ill. Adm. Code 410 as well as after any maintenance of the system which might affect the exposure rate.
- 7) The results of the measurements required by subsections (g)(1), (2) and (4) of this Section shall be posted or available at the control panel. The measurement results shall be stated in millicoulombs per kilogram (roentgens) per minute or microcoulombs per kilogram (milliroentgens) per second and shall include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results.

AGENCY NOTE: The resolution and efficiency of the fluoroscopic imaging system should be evaluated periodically, whenever deterioration in the imaging system is suspected and when the measured exposure rate exceeds the standards of this Section.

h) Barrier Transmitted Radiation Rate Limits

- 1) The exposure rate due to transmission through the primary protective barrier shall not exceed 0.516 microC/kg (2mR) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor per 258 microC/kg (1R) per minute of entrance exposure rate.
- 2) Measuring Compliance of Barrier Transmission
 - A) The exposure rate due to transmission through the primary protective barrier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
 - B) If the source is below the tabletop, the exposure rate shall be determined with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
 - C) If the source is above the tabletop and the SID is variable, the exposure rate shall be determined with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

- D) Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - E) An attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- i) **Staff and Ancillary Personnel Protection.** The operator, assistants and observers allowed in the examining room shall be protected from scatter radiation by protective aprons of not less than 0.25 millimeter lead equivalent or whole body protective barriers or shall be positioned at a sufficient distance to ensure that the individual does not receive a radiation dose in excess of the limits specified in 32 Ill. Adm. Code 340.310.
- j) **Control of Scattered Radiation**
- 1) For fluoroscopic systems utilizing an x-ray tube that is mounted below the table, the table shall be provided with shielding (bucky slot cover) equivalent to 0.25 millimeter lead equivalent to attenuate scattered radiation emanating from below the table.
 - 2) A shield of at least 0.25 millimeter lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided and used to intercept scatter radiation which would otherwise reach the operator and others near the machine. This shielding shall not be a substitute for the wearing of a protective apron (0.25 millimeter lead equivalent) for protection against scattered radiation.
 - 3) Where sterile fields or special procedures prohibit the use of protective barriers or drapes, subsection (j)(2) of this Section shall not apply.
- k) **Additional Requirements for Stationary Fluoroscopic Systems Used for Cardiac Catheterization Procedures**
- 1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the x-ray tubes. If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.
 - 2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient).

AGENCY NOTE: Because modern equipment allows great flexibility in the direction of the beam, individuals in the room should step back from the x-ray system and behind protective barriers during activation of the x-ray tubes.

- l) Additional Requirements for Fluoroscopic Systems Specifically Designed for Examination of Extremities Only
 - 1) The radiation safety procedures required pursuant to Section 360.30(j) of this Part shall include the following:
 - A) A warning concerning the potential for, and the hazards of, increased patient radiation dose associated with x-ray systems employing short source-skin distances;
 - B) Procedures for obtaining imaging magnification with minimum patient dose, including imaging systems or screen-film combinations;
 - C) Technique factors for specific examinations for which the system is designed;
 - D) Radiation exposure data, including skin entrance exposure for each set of technique factors used.
 - 2) The x-ray system shall be clearly labeled as follows: "For Examination of Extremities Only."
 - 3) Fluoroscopic systems specifically designed for examination of extremities only shall be used solely for examination of extremities.
- m) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from the requirements of subsections (a), (b), (c), (g) and (h) of this Section provided that:
 - 1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
 - 2) Such systems that do not meet the requirements of subsection (b) of this Section are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require

in such cases that the timer be reset between examinations.

- n) Operator Restrictions. No person shall intentionally administer radiation to a human being with a fluoroscopic radiation machine unless such person is licensed to practice a treatment of human ailments under the Medical Practice Act of 1987, the Illinois Dental Practice Act or the Podiatric Medical Practice Act of 1987, except:
- 1) An accredited medical radiographer may operate a fluoroscope for static functions when diagnostic interpretation of the fluoroscopic image is not required by the radiographer and only under the supervision of a licensed practitioner; or
 - 2) An accredited medical radiographer may operate a fluoroscope as directed by, and under the direct supervision of, a licensed practitioner who is physically present and participating in the procedure; or
 - 3) An accredited medical radiographer or radiation therapist may operate a fluoroscope for radiation therapy simulation procedures under the supervision of a licensed practitioner; or
 - 4) An accredited radiologist assistant may operate a fluoroscope under the supervision of a licensed practitioner certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

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

Section 360.60 Radiographic Systems Other Than Fluoroscopic, Dental, Veterinary or Computed Tomography Systems

In addition to the provisions of Sections 360.10, 360.30, 360.40 and 360.41 of this Part, the requirements of this Section apply to x-ray equipment and associated facilities used in the healing arts of medicine, chiropractic and podiatry. It does not apply to fluoroscopic, dental, veterinary or computed tomography systems.

- a) Beam Limitation. The useful beam shall be limited to the area of clinical interest.
- 1) Stationary General Purpose and Mobile/Portable X-Ray Systems
 - A) Variable X-Ray Field Limitation. An adjustable collimator shall be provided with means for independent stepless adjustment of the size of the x-ray field.

- B) Visual Indication of Field Size. Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field, with respect to the edges of the x-ray field, along either the length or the width of the visually defined field, shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

AGENCY NOTE: When a light localizer is used to define the x-ray field, it should provide an average illumination of not less than 100 lux (9 footcandles) at 100 centimeters or at the maximum SID, whichever is less.

2) Special Purpose X-Ray Systems

- A) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- B) The requirements of subsection (a)(2)(A) of this Section may be met:
- i) With a system that meets the requirements specified in subsection (a)(1) of this Section; or
 - ii) With an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is used, with each such device having permanent, clearly legible markings, in centimeters and/or inches, to indicate the image receptor size and SID for which it is designed; or
 - iii) With a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is used. Permanent, clearly legible markings, in centimeters and/or inches, shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

- 3) Radiation therapy simulation systems shall be exempt from the beam limitation requirements of this Section.
- b) Radiation Exposure Control Devices
- 1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses or preset radiation exposure to the image receptor. Also, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
 - 2) X-Ray Control
 - A) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
 - i) Exposures of 0.5 second or less; or
 - ii) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
 - B) The exposure switch shall be a dead-man switch.
 - 3) Automatic Exposure Controls (AEC). Systems which are provided with automatic exposure control devices shall incorporate a back-up timer to terminate the radiation exposure in the event of AEC failure. In addition, they shall meet the following requirements:
 - A) Indication shall be made on the control panel when this mode of operation is selected; and
 - B) A visible signal shall indicate when an exposure has been terminated by the back-up timer, and manual resetting shall be required before further automatically timed exposures can be made.
- c) Source-Skin Distance (SSD). All mobile or portable radiographic systems shall be provided with means to limit the SSD to 30 centimeters or greater.
- d) Linearity. For equipment that is operated at more than one x-ray tube current or

current-time product setting, the average ratios of exposure (microcoulombs per kilogram or milliroentgens) to the indicated milliamperere-seconds (mAs) product obtained at any two tube current or current-time product settings utilized shall not differ by more than 0.10 times their sum. This requirement is mathematically represented by the following:

$$[\bar{X}_1 - \bar{X}_2] \leq [0.10(\bar{X}_1 + \bar{X}_2)]$$

where \bar{X}_1 and \bar{X}_2 are the average microC/kg/mAs or mR/mAs values obtained at any two tube current or current-time product settings utilized. Compliance shall be determined at any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated tube potential.

- e) Medical Radiographic Entrance Exposure Limits. The in-air exposure determined for the technique used for the specified average adult patient for routine medical radiography shall not exceed the entrance exposure limits shown below: (See Section 360. Appendix A of this Part for measurement protocol and calculation of exposure at skin entrance.)

Technique	Thickness (cm)	Exposure Limit (microC/kg)	(mR)
Chest (PA), Grid	23	9	35
Chest (PA), Non-Grid	23	8	30
Abdomen (KUB)	23	155	600
Lumbo-Sacral Spine (AP)	23	206	800
Cervical Spine (AP)	13	52	200
Skull (lateral)	15	65	250
Foot (D/P)	8	26	100

AGENCY NOTE: These exposures are maximums. With careful selection of technique factors, adjustment of film processing systems, and choice of film and screen-film combinations, patient exposures can be further reduced.

- f) SID Indication
- 1) Means shall be provided to indicate the SID.
 - 2) SIDs shall be indicated in centimeters and/or inches and the measured SID shall correspond to the indicated value to within two percent.
- g) X-Ray Field/Image Receptor Alignment. Means shall be provided to:

- 1) Indicate when the axis of the x-ray field is perpendicular to the plane of the image receptor; and
- 2) Align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID.

(Source: Amended at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.70 Mobile/Portable Radiographic Systems Other Than Systems Used Solely For Mammography (Repealed)

(Source: Repealed at 17 Ill. Reg. 17972, effective October 15, 1993)

Section 360.71 Additional Requirements for Facilities Performing Mammography (Repealed)

(Source: Repealed at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.75 Computed Tomography (CT) Systems

- a) Requirements for Equipment
 - 1) Termination of Exposure
 - A) In the event of equipment failure affecting data collection, means shall be provided to terminate the x-ray exposure automatically, either by de-energizing the x-ray source or by shuttering the x-ray beam, through the use of either a back-up timer or devices that monitor equipment function.
 - B) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by subsection (a)(1)(A).
 - C) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans, of greater than 0.5 second duration.
 - 2) Tomographic Plane Indication and Alignment
 - A) Means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

- B) If a device using a light source is used to satisfy subsection (a)(2)(A), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (45 footcandles).
 - C) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
 - D) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with a typical patient mass resting on the patient support device. The patient support device shall be moved incrementally from a typical starting position to the maximum incremental distance or 30 centimeters, whichever is less, and then returned to the starting position. If the CT system has the capability of variable gantry angles, the compliance measurements shall be performed with the CT gantry positioned at zero degrees.
- 3) Beam-On and Shutter Status Indicators. The CT x-ray control panel and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
 - 4) Technique Indicators. The CT x-ray control panel shall provide visual indication of the technique factors, tomographic section thickness and scan increment prior to the initiation of a scan or a series of scans.
- b) Facility Design Requirements
 - 1) The control panel shall be located behind a protective barrier.
 - 2) Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
 - 3) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.
 - c) Radiation dose measurements shall be performed by a diagnostic imaging specialist on each CT x-ray system. The measurements shall be specified in terms of the computed tomography dose index (CTDI), for the head and abdomen, using

a head or abdomen phantom, respectively, and the facility's technique factors most frequently used for a CT examination of the head or abdomen, respectively, and shall be performed:

- 1) At least annually by a diagnostic imaging specialist and after any change or replacement of components that could cause a change in the radiation output;
- 2) With a dosimetry system that has been calibrated within the preceding 12 months. The calibration of such system shall have no more than a three-step (tertiary) calibration, traceable to the National Institute of Standards and Technology; and
- 3) Using the computed tomography dose measurement protocol found in Report 111 of the American Association of Physicists in Medicine (AAPM), entitled "Comprehensive Methodology for the Evaluation of Radiation Dose in X-Ray Computed Tomography" published by AAPM, February 2010, exclusive of subsequent amendments or editions. A copy of this report is available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois or may also be obtained directly from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

AGENCY NOTE: The Agency recognizes that other phantoms and protocols are available to provide accurate dose measurements as specified in this Section. The Agency will consider use of such phantoms and protocols as satisfying this Section if the intent of the regulation is met.

- d) Diagnostic Imaging Specialists who perform radiation dose measurements and develop quality assurance procedures for CT systems shall have CT training as follows:
 - 1) Individuals certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology or the American Board of Medical Physics shall have 20 contact hours of documented specialized training in conducting surveys of CT equipment;
 - 2) Individuals not certified as specified in subsection (d)(1) shall have 40 contact hours of documented specialized training in conducting surveys of CT equipment.
- e) Documentation of the training required by subsection (d) shall be available for review at the facility by January 1, 2015. Documentation shall include the name

of the individual performing the CT training.

- f) Quality assurance procedures shall be conducted on each CT system and shall meet the following requirements:
 - 1) The quality assurance procedures shall be in writing and shall have been developed by a diagnostic imaging specialist. The procedures shall include, but need not be limited to, the following:
 - A) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and
 - B) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.
 - 2) Quality assurance procedures shall include acquisition of images using a CT phantom that has the capability of providing an indication of the resolution capability of the system. Quality assurance procedures shall include, at a minimum:
 - A) Image quality evaluation, including CT number uniformity, noise, and low and high contrast resolution;
 - B) Quantitative accuracy including CT number calibration and constancy;
 - C) Image display evaluation, including visual and hard copy output.
- g) Operating Procedures. Information shall be available at the control panel regarding the operation of the system. The information shall include written quality assurance procedures, as required in subsection (f)(1).

(Source: Amended at 38 Ill. Reg. 12031, effective May 29, 2014)

Section 360.80 Photofluorographic Systems (Repealed)

(Source: Repealed at 17 Ill. Reg. 17972, effective October 15, 1993)

Section 360.90 Dental Radiographic Systems

In addition to the provisions of Sections 360.10, 360.30 and 360.40 of this Part, the requirements

of this Section apply to x-ray equipment and associated facilities used for dental radiography. Refer to Section 360.50 of this Part for requirements for dental fluoroscopic systems.

a) General Requirements

- 1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses or preset radiation exposure to the image receptor. Also, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
- 2) X-Ray Control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for exposures of 0.5 second or less.
- 3) Exposure Switch Arrangement. The exposure switch shall be a dead-man switch and shall be arranged so that the operator can be behind a protective barrier or at least 1.83 meters (6 feet) from the patient and the tube housing during an exposure.

b) Additional Requirements for Dental Intraoral Systems

- 1) Source-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the SSD to not less than:
 - A) 18 centimeters if operable above 50 kVp; or
 - B) 10 centimeters if operable at 50 kVp and below.
- 2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters.
- 3) Dental Radiographic Exposure Limits (Single Film). The entrance exposure to an adult patient for a routine intraoral bitewing exam shall not exceed the limit specified for the kVp used in the table below. Exposures are specified as free-in-air exposures without backscatter.

Tube Potential (KVP)	"D" Speed Film (microC/kg) (mR)	"E" Speed Film (microC/kg) (mR)
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50	142	550	72	280
55	134	520	65	250
60	121	470	57	220
65	107	415	49	190
70	93	360	43	165
75	80	310	36	140
80	67	260	30	115
85	61	235	27	105
90	54	210	25	95
95	50	195	22	85
100	46	180	18	70

Linear extrapolation or interpolation shall be used for an x-ray tube potential (kVp) not listed in the table.

AGENCY NOTE: The exposures specified in the above table were empirically determined by a panel of dentists in a U.S. FDA study.

- 4) The kVp shall be measured at the time the entrance exposure is determined pursuant to subsection (b)(3) of this Section to determine the correct exposure limit to be applied.
- c) Beam Limitation Requirements for Dental Extraoral Systems
- 1) Dental rotational panoramic systems shall be provided with means to limit the x-ray beam to the imaging slit in the transverse axis and shall not exceed a total of 13 millimeters (0.5 inch) larger than the imaging slit in the vertical axis.
 - 2) All other dental extraoral radiographic systems (e.g., cephalometric) shall be provided with means to both size and align the x-ray field so that it does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- d) Additional Requirements for Dental Radiography
- 1) Patient and film holding devices shall be used when the techniques permit;
 - 2) The tube housing and the position indicating device shall not be hand-held during an exposure;
 - 3) The x-ray system shall be operated in such a manner that the useful beam

at the patient's skin does not exceed the criteria specified in subsection (b)(2) of this Section;

- 4) **Personnel Protection.** The operator shall be behind a protective barrier or be provided with a protective apron of not less than 0.25 millimeter lead equivalent, or at least 1.83 meters (6 feet) from the patient and the tube housing during an exposure. Individuals whose presence is required in the room during an x-ray examination shall be protected from leakage and scatter radiation by protective aprons of not less than 0.25 millimeter lead equivalent or a protective barrier or shall be positioned at a sufficient distance to ensure that the individual does not receive a radiation dose in excess of the limits specified in 32 Ill. Adm. Code 340.310.

AGENCY NOTE: Strict adherence to radiation protection practices should minimize occupational dose and may eliminate the need for individual monitoring. The requirements for individual monitoring are specified in 32 Ill. Adm. Code 340.520.

(Source: Amended at 22 Ill. Reg. 5904, effective March 13, 1998)

Section 360.100 Veterinary Radiographic Systems

In addition to the provisions of Sections 360.10, 360.30 and 360.40 (except Section 360.40(a)) of this Part, the requirements of this Section apply to x-ray equipment and associated facilities used for radiography with veterinary systems.

- a) **Beam Limitation.** The useful beam shall be limited to the area of clinical interest. The size of the image receptor used for each radiographic projection shall be consistent with the objectives of the examination.
 - 1) **Limitation Criteria.** Means shall be provided to limit the x-ray field in the plane of the image receptor so that the field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - 2) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
 - 3) The requirements of subsection (a)(1) of this Section may be met with:
 - A) An adjustable collimator with a field defining light; or

- B) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is used, with each such device having permanent, clearly legible markings in centimeters and/or inches, to indicate the image receptor size and SID for which it is designed; or
 - C) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is used. Permanent, clearly legible markings, in centimeters and/or inches, shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.
- 4) SID Indication
- A) Means shall be provided to indicate the SID.
 - B) SIDs shall be indicated in centimeters and/or inches and the measured SID shall correspond to the indicated value to within two percent.
- b) Exposure Switch Arrangement. The exposure control switch shall be arranged so the operator can be at least 1.83 meters (6 feet) from the animal, the x-ray tube and the useful beam.
- c) Radiation Exposure Control Devices
- 1) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses or preset radiation exposure to the image receptor. Also, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
 - 2) The exposure switch shall be a dead-man switch.
- d) Veterinary fluoroscopic, computed tomography and therapy systems shall meet the requirements specified in Sections 360.50, 360.75, 360.110 and 360.120 of this Part, except that the requirements pertaining to aural communication specified in Sections 360.75(b)(2), 360.110(a)(8) and (e)(5) and 360.120(a)(6) and (g)(1)(H) of this Part, need not be satisfied unless a human is used to hold the animal.

- e) Additional Requirements for Veterinary X-Ray Systems
- 1) All individuals whose presence is required during an x-ray examination shall be protected from scatter radiation by protective aprons or gowns of not less than 0.25 millimeter lead equivalent or whole body protective barriers.
 - 2) All exams and retakes shall be ordered by the veterinarian.
 - 3) Unless required to restrain an animal, the operator shall stand at least 1.83 meters (6 feet) away from the useful beam and the animal during radiographic exposures.
 - 4) No individual, other than the operator, shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.
 - 5) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used when technique permits.
 - 6) When a person is required to hold an animal during a radiographic procedure, the individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and the person shall be so positioned that no part of his/her body except hands and arms will be struck by the useful beam.

AGENCY NOTE: Veterinarians should review 32 Ill. Adm. Code 340.520 to determine if individuals who hold animals will need to use individual monitoring devices.

(Source: Amended at 22 Ill. Reg. 5904, effective March 13, 1998)

Section 360.110 Therapy Systems Operating Below 1 MeV

In addition to the provisions of Sections 360.10 through 360.30 of this Part, the requirements of this Section apply to x-ray therapy systems and associated facilities operating at energies less than 1 MeV.

- a) Facility Design
- 1) A therapeutic radiological physicist shall be consulted in the design of an x-ray therapy installation.

- 2) Shielding requirements
 - A) Each x-ray therapy installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.
 - B) For all x-ray therapy systems capable of operating above 150 kVp installed after October 15, 1993, facility design information shall be submitted to the Agency for review prior to installation of the x-ray therapy system. Information submitted to the Agency shall include, but need not be limited to, the following:
 - i) Name and address of the planned installation.
 - ii) Name, address and telephone number of the therapeutic radiological physicist who was consulted in the design of the installation.
 - iii) A scale drawing that includes the location of the therapy system, control panel and doors to the room.
 - iv) The structural composition and thickness of all walls, doors, partitions, floor and ceiling of the installation.
 - v) The occupancy of areas adjacent to the installation.
 - vi) Calculations that demonstrate the adequacy of the amount of shielding specified for each primary and secondary protective barrier.
 - vii) Projected weekly dose rates in areas adjacent to the installation.
- 3) Interlock. X-ray therapy systems operating at greater than 150 kVp shall have an interlock installed on each door of the therapy room. The interlock shall be wired into the electrical circuit in such a manner that when the door is opened, for any reason, the generation of x-rays will automatically be terminated and irradiation can be resumed only by manually resetting the controls on the control panel after the door is closed.
- 4) Doors. The doors to the therapy room shall be designed and installed to allow opening from the inside at all times and shall be capable of being opened manually.

- 5) Warning Lights. X-ray therapy systems operating above 150 kVp, and all therapy rooms to which access is possible through more than one entrance shall be provided with warning lights in a readily observable position near the outside of all access doors. The warning lights shall indicate when the useful beam is on.
- 6) Operator and control position
 - A) X-ray Therapy Systems Operating at 150 kVp and Below. The control panel and operator shall be located either outside the therapy room or behind a protective barrier within the room.
 - B) X-ray Therapy Systems Operating Above 150 kVp. The control panel and operator shall be located outside the therapy room.
- 7) Viewing System. Windows, mirrors, closed-circuit television or an equivalent system shall be provided to permit continuous visual observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

AGENCY NOTE: When the primary viewing system is electronic, a back-up system should be available for use in the event of failure of the primary system in order to ensure compliance with the requirements of subsection (e)(5) of this Section.

- 8) Communication. The facility design shall permit two-way aural communications between the patient and the operator at the control panel.
 - 9) Signs required by 32 Ill. Adm. Code 340.920 shall be posted in the facility.
- b) Equipment Requirements
- 1) Leakage Radiation. When the tube is operated at its maximum rated continuous current for the maximum rated tube potential, the leakage radiation shall not exceed the value specified in the table below at the distance specified in the table for the classification of that x-ray system. Radiation measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters.

X-Ray System	Leakage Limit	Measurement Location
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Contact Therapy	25.8 microC/kg (0.1 R) per hour	5 centimeters from the tube housing
0 - 499 kVp	258 microC/kg (1 R) per hour	1 meter from the source
500 kVp - 999 kVp	0.1 percent of useful beam or 258 microC/kg (1 R) per hour, whichever is greater	1 meter from the source

2) Beam-Limiting Devices

- A) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.
- B) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
- C) Adjustable beam-limiting devices installed after October 15, 1993 shall meet the requirements of subsection (b)(2)(B) of this Section.
- D) Adjustable beam-limiting devices installed on or before October 15, 1993 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

3) Filter System. The filter system shall be designed so that:

- A) The filters are securely positioned and will not become dislodged when the machine is positioned at any possible orientation;
- B) The radiation dose at one meter from the filter insertion slot opening does not exceed 258 mC/kg (1 R) per hour when the machine is operated at its maximum current and maximum tube potential;

- C) Each filter is labeled with its composition and thickness (for wedge filters, the wedge angle and maximum design field size shall appear on the wedge or wedge tray);
 - D) If the x-ray therapy system uses changeable filters, there is a filter indication system which permits recognition of any added filter in place and indicates from the control panel the presence of a particular filter or absence of any filter; and
 - E) For x-ray therapy systems installed after October 15, 1993, an interlock prevents irradiation if the selected filter is not installed.
- 4) Tube/Aperture Alignment. The x-ray tube shall be mounted so that it cannot turn or slide with respect to the housing aperture.
- 5) Tube Housing Stability. The tube housing shall remain stable during treatment unless tube housing movement is a designed function of the system.
- 6) Source-Skin Distance (SSD) Indication
- A) Means shall be provided to indicate the SSD.
 - B) The SSD shall be indicated in centimeters and/or inches and the measured SSD shall correspond to the indicated value to within 0.5 percent.
- 7) Timer. A timer, which has a display at the control panel, shall be provided and shall meet the following requirements:
- A) The timer shall be activated with the production of radiation;
 - B) For systems equipped with a shutter mechanism to control irradiation, the timer shall be activated when the shutter is opened;
 - C) The timer shall terminate irradiation when a preselected time has elapsed;
 - D) The timer shall permit presetting and determination of exposure times at least as short as 1 second; and
 - E) The timer shall not permit an exposure if the operator has not selected a time for the exposure.

AGENCY NOTE: The control panel should be equipped with a count-up timer to serve as a back-up to the control timer.

- 8) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this Section, shall have:
 - A) An indication of whether x-rays are being produced;
 - B) A means for indicating x-ray tube potential and current; and
 - C) A means for terminating an exposure at any time.
 - 9) Shutters. Equipment that is provided with shutters shall meet the following requirements:
 - A) The shutters shall have a lead equivalency not less than that of the tube housing assembly;
 - B) The shutter shall be controlled electrically by the operator at the control panel; and
 - C) An indication of shutter position shall appear at the control panel.
 - 10) Multiple Tubes. Control panels capable of energizing more than one x-ray tube shall meet the following requirements:
 - A) It shall be possible to energize only one x-ray tube at any time;
 - B) There shall be an indication at the control panel identifying which x-ray tube is energized; and
 - C) There shall be an indication at the tube housing assembly when that tube is energized.
 - 11) Low-Filtration X-Ray Tubes. Each x-ray therapy system equipped with a beryllium window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
- c) Radiation Protection Survey. A radiation protection survey shall be performed by a therapeutic radiological physicist on each x-ray therapy system. The registrant shall maintain at the facility a copy of the most recent radiation protection survey report for review by the Agency. Radiation protection surveys shall meet the

following additional requirements:

- 1) X-ray therapy systems installed after October 15, 1993 shall have a radiation protection survey performed by a physicist before the therapy system is first used for irradiation of a patient.
- 2) For all x-ray therapy systems, a radiation protection survey shall be performed by a physicist after any change in the x-ray therapy system or facility that might produce a radiation hazard. The survey shall be performed before the therapy system is used to treat patients.
- 3) Survey reports shall include, but need not be limited to, the following:
 - A) A diagram of the facility that details building structures and the position of the control panel, x-ray therapy system and associated equipment;
 - B) A description of the x-ray therapy system, including the manufacturer, model number and range of kilovolt potential;
 - C) A description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;
 - D) Conditions under which radiation measurements were taken; and
 - E) Survey data including:
 - i) Projected weekly dose equivalent in areas adjacent to the therapy room; and
 - ii) A description of workload, use and occupancy factors employed in determining the projected weekly dose equivalent.
- 4) The registrant shall retain a copy of the radiation protection survey report and a copy of the report shall be provided to the Agency within 30 days after completion of the survey.
- 5) Any deficiencies detected during the radiation protection survey that would constitute or result in a violation of 32 Ill. Adm. Code 340 shall be corrected prior to using the machine for treatment of patients.

- 6) The facility shall be operated in compliance with any limitations indicated by the therapeutic radiological physicist as a result of the radiation protection survey required by the Agency.
- d) Calibrations and Quality Assurance Checks.
- 1) Each x-ray therapy system installed after October 15, 1993 shall be calibrated by a therapeutic radiological physicist before the therapy system is first used for irradiation of a patient. The calibration of the x-ray therapy system shall include, but need not be limited to, determination of the following:
 - A) The radiation output, expressed as exposure rate in air or dose rate in tissue, as a function of distance, field size, x-ray tube potential and current, filters and treatment applicators used;
 - B) The half-value layer for each kilovoltage setting and filter combination used;
 - C) The degree of congruence between the radiation field and the field indicated by each beam-limiting device; and
 - D) An evaluation of the uniformity of the radiation field.
 - 2) Quality assurance checks shall be made by a therapeutic radiological physicist at intervals not to exceed 1 year. Quality assurance checks shall include, but need not be limited to, determination of the following:
 - A) The radiation output for a set of operating conditions specified by the therapeutic radiological physicist;
 - B) The coincidence of the radiation field and the field indicated by the beam-limiting device, except for systems equipped with fixed diaphragms or cones; and
 - C) The therapeutic radiological physicist shall establish criteria for quality assurance check measurements and shall determine corrective actions to be implemented if the criteria are exceeded.

AGENCY NOTE: Quality assurance checks should be performed at a frequency which is appropriate for the particular therapy system, as determined by the therapeutic radiological physicist and based on the history of stability of the radiation output of the

machine. A suggested frequency is one that would result in a quality assurance check being performed at least once during a typical patient's course of treatment.

- 3) Whenever service or maintenance is performed on the therapy system, a therapeutic radiological physicist shall be notified and shall determine whether a calibration or quality assurance check is necessary to verify the characteristics of the beam.
- 4) Measurements of the radiation output of the x-ray therapy system shall be performed using a dosimetry system that has been calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). Calibration of the dosimetry system shall have been performed using a radiation beam of comparable half-value layer to the x-ray system to be calibrated. The dosimetry system shall meet one of the two conditions below:
 - A) The calibration of the dosimetry system shall have been performed within the previous 2 years and after any servicing that may have affected the calibration of the dosimetry system; or
 - B) The dosimetry system shall have been calibrated within the previous 4 years and shall have been subjected to a protocol which provides for checks of dosimetry constancy and provides for corrective action when results deviate by more than two percent from the expected values.
- 5) The registrant shall maintain at the facility records of machine calibrations, quality assurance checks and instrument calibrations for inspection by the Agency for a period of 5 years. Records to be maintained by the registrant shall include, but need not be limited to, the following:
 - A) Records of machine calibrations and quality assurance checks shall include identification of the x-ray therapy system, radiation measurements, the date the measurements were performed and the signature of the therapeutic radiological physicist who performed the measurements.
 - B) Instrument calibration records shall include the date of the last calibration and identity of the calibration laboratory. If a dosimetry system has been subjected to a protocol as described in subsection (d)(4)(B) of this Section, records shall be maintained

that show the date and results of each constancy check performed on the system.

e) Operating Procedures

- 1) No x-ray therapy system shall be left unattended unless the system is secured against unauthorized use.
- 2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
- 3) Other than the patient, no individual shall be in the therapy room unless such individual is protected by a barrier sufficient to meet the requirements of 32 Ill. Adm. Code 340.
- 4) Other than the patient, no individual shall be in the therapy room during exposures from x-ray therapy systems operating above 150 kVp.
- 5) The x-ray therapy system shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.
- 6) On contact therapy systems, a shield of at least 0.5 millimeter lead equivalency at 100 kVp shall be positioned over the entire useful beam exit port during periods when the tube is energized and the beam is not being used.
- 7) The tube housing assembly shall not be held by hand during operating unless the x-ray therapy system is designed to require such holding and the peak tube potential of the system does not exceed 50 kilovolts. In such cases, the person holding the tube shall wear protective gloves and apron of not less than 0.5 millimeter lead equivalency at 100 kVp.

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

Section 360.120 Therapy Systems Operating at 1 MeV or Greater

In addition to the provisions of Sections 360.10 through 360.30, the requirements of this Section apply to particle accelerator systems operating at energies of 1 MeV or greater. Accelerator systems capable of producing radioactive materials in excess of the exempt quantities specified in 32 Ill. Adm. Code 330.Appendix B shall also be licensed pursuant to the provisions of 32 Ill. Adm. Code 330.

- a) Facility Design
 - 1) The registrant shall consult a therapeutic radiological physicist in the design of a particle accelerator installation.
 - 2) Shielding Requirements
 - A) Each accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.
 - B) Facility design information for all accelerators installed after October 15, 1993 shall be submitted to the Agency for review prior to installation. Information submitted to the Agency shall include, but need not be limited to, the following:
 - i) Name and address of the planned installation;
 - ii) Name, address and telephone number of the therapeutic radiological physicist who was consulted in the design of the installation;
 - iii) A scale drawing that includes the location of the accelerator, control panel and doors to the room;
 - iv) The structural composition and thickness of all walls, doors, partitions, floor and ceiling of the installation;
 - v) The occupancy of areas adjacent to the installation;
 - vi) Calculations that demonstrate the adequacy of the amount of shielding specified for each primary and secondary protective barrier; and
 - vii) Projected weekly dose rates in areas adjacent to the installation.
 - 3) Interlock. An interlock shall be installed on each door of the therapy room. The interlock shall be wired into the electrical circuit in such a manner that when the door is opened for any reason, the generation of radiation beams will automatically be terminated and irradiation can be resumed only by manually resetting the controls on the control panel after the door is closed.

- 4) Warning lights that indicate when the beam is on shall be provided in a readily observable position near the outside of all access doors to the therapy room.
- 5) Viewing System. Windows, mirrors, closed-circuit television or an equivalent system shall be provided to permit continuous visual observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

AGENCY NOTE: When the primary viewing system is electronic, a back-up system should be available for use in the event of failure of the primary system in order to ensure compliance with the requirements of subsection (g)(1)(H).

- 6) The facility design shall permit two-way aural communications between the patient and the operator at the control panel.
- 7) Signs required by 32 Ill. Adm. Code 340.920 shall be posted in the facility.
- 8) The control panel shall be outside the therapy room.
- 9) The facility design shall include emergency off buttons, at locations that allow shutting off the machine from inside the therapy room and at the control panel.
- 10) The doors to the therapy room shall be designed to allow opening from the inside at all times and shall be capable of being opened manually.

b) Equipment Requirements

- 1) Leakage radiation to the patient area shall be measured for each accelerator. Measurements shall be repeated following maintenance or service performed on the accelerator, as determined by a therapeutic radiological physicist.
 - A) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, excluding neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose of

the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Radiation measurements shall be averaged over an area up to but not exceeding 100 square centimeters.

- B) Records of the most recent radiation leakage measurements and the machine parameters used during the survey shall be maintained at the facility for inspection by the Agency.
- 2) Beam-Limiting Devices. Adjustable or interchangeable beam-limiting devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam that is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be subject to this requirement. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
- 3) Source-Skin Distance (SSD) Indication
- A) Means shall be provided to indicate the SSD.
 - B) The SSD shall be indicated in centimeters and/or inches and the measured SSD shall correspond to the indicated value to within 0.5 percent.
- 4) Filters
- A) Each filter that is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle and maximum design field size shall appear on the wedge or wedge tray.
 - B) If the machine calibration measurements required by subsection (d) relate exclusively to operation with an x-ray field flattening filter or electron beam scattering filter in place, such filters shall be removable from the machine only by the use of tools.
 - C) Equipment utilizing a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters shall meet the following requirements:
 - i) The equipment shall have an interlock that prevents

- irradiation if any filter selection operation carried out in the therapy room is not consistent with the selection of filter, beam type or beam energy at the control panel; and
- ii) The equipment shall have an interlock system that prevents irradiation if any selected filter is not in the correct position.
- 5) **Beam Monitoring System.** All accelerator systems shall be provided with a beam monitoring system in the radiation head capable of monitoring and terminating irradiation.
- A) Each beam monitoring system shall have a display at the treatment control panel which shall register accumulated monitor units.
 - B) The beam monitoring system shall terminate irradiation when the preselected number of monitor units has been detected by the system.
 - C) Accelerator systems manufactured after October 15, 1993 shall be equipped with a primary and a secondary beam monitoring system. Each beam monitoring system shall be independently capable of monitoring and terminating irradiation.
 - D) For units with a secondary beam monitoring system, the primary beam monitoring system shall terminate irradiation when the preselected number of monitor units has been detected. The secondary beam monitoring system shall terminate irradiation if the primary system fails.
 - E) An interlock device shall prevent irradiation if any beam monitoring system is inoperable.
 - F) In the event of power failure, the display information required in subsection (b)(5)(A), shall be retrievable in at least one system for 20 minutes.
- 6) **Beam Symmetry.** For equipment equipped with beam bending magnets, the symmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. The equipment shall provide means of terminating irradiation automatically if the difference in dose rate between one region and another region exceeds criteria specified by the manufacturer.

- 7) Control Panel
 - A) Selection and Display of Monitor Units
 - i) Irradiation shall not be possible until a selection of a number of monitor units has been made at the control panel.
 - ii) The selected number of monitor units shall be displayed at the control panel until reset.
 - iii) After completion of irradiation, it shall be necessary to reset the accumulated beam monitor units before treatment can be restarted.
 - B) Termination of Irradiation. It shall be possible to terminate irradiation and equipment movements at any time from the operator's position at the control panel.
 - C) Selection of Radiation Type. Equipment capable of both photon and electron therapy shall meet the following requirements:
 - i) Irradiation shall not be possible until the radiation type has been selected and displayed at the control panel.
 - ii) An interlock shall be provided to ensure that the machine will emit only the radiation type that has been selected.
 - iii) An interlock shall be provided to prevent irradiation with x-rays, except to obtain port films, when electron applicators are installed.
 - iv) An interlock shall be provided to prevent irradiation with electrons if accessories specific for x-ray therapy are installed.
 - D) Selection of Radiation Energy. Equipment capable of producing radiation beams of different energies shall meet the following requirements:
 - i) Irradiation shall not be possible until a selection of energy has been made at the control panel.

- ii) An interlock shall be provided to ensure that the machine will emit only the nominal energy of radiation that has been selected.
 - iii) The nominal value of the energy selected shall be displayed at the treatment control panel.
- E) Selection of Stationary or Moving Beam Therapy. Equipment capable of both stationary and moving beam therapy shall meet the following requirements:
- i) Irradiation shall not be possible unless either stationary therapy or moving beam therapy has been selected at the control panel. The selection of stationary therapy may be performed as a default selection if moving beam therapy is not selected.
 - ii) An interlock shall be provided to ensure that the machine will operate only in the mode that has been selected.
 - iii) An interlock shall be provided to terminate irradiation if the gantry fails to move properly during moving beam therapy.
 - iv) Means shall be provided to prevent movement of the gantry during stationary therapy.
 - v) The mode of operation shall be displayed at the control panel.
- F) Timers. A timer shall be provided with a display at the treatment control panel, as a back-up device to the beam monitoring system.
- i) The timer shall permit presetting and determination of exposure times.
 - ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated.
 - iii) The timer shall terminate irradiation when a preselected time has elapsed if the beam monitoring system has not previously terminated irradiation. If set at zero, the timer

shall not permit irradiation.

- G) Security. The control panel shall be capable of being locked to prevent unauthorized use.
- c) Radiation Protection Survey. A radiation protection survey shall be performed by a therapeutic radiological physicist on each accelerator. The registrant shall maintain at the facility a copy of the most recent radiation protection survey report for review by the Agency. Radiation protection surveys shall meet the following additional requirements:
- 1) For each accelerator installed after October 15, 1993, a radiation protection survey shall be performed by a physicist before the system is first used for irradiation of a patient. The physicist who performs the radiation protection survey shall be a person who did not consult in the design of the accelerator installation (see subsection (a)) and is not employed by or within any corporation or partnership with the person who consulted in the design of the installation.
 - 2) A radiation protection survey shall be performed by a physicist after any change in the accelerator or facility that might produce a radiation hazard. Such survey shall be performed before the system is used to treat patients.
 - 3) The survey report shall include, but need not be limited to, the following:
 - A) A diagram of the facility which details building structures and the position of the control panel, accelerator and associated equipment;
 - B) A description of the accelerator system including the manufacturer, model number, beam type and beam energy range;
 - C) A description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;
 - D) Conditions under which radiation measurements were taken;
 - E) Survey data including:
 - i) Projected weekly dose equivalent in areas adjacent to the therapy room; and
 - ii) A description of workload, use and occupancy factors

employed in determining the projected weekly dose equivalent.

- 4) The registrant shall retain a copy of the radiation protection survey report and a copy of the report shall be provided to the Agency within 30 days after completion of the survey.
 - 5) Any deficiencies detected during the radiation protection survey that would constitute or result in a violation of 32 Ill. Adm. Code 340 shall be corrected prior to using the machine for treatment of patients.
 - 6) The facility shall be operated in compliance with any limitations indicated by the therapeutic radiological physicist as a result of the radiation protection survey.
- d) Machine Calibration. Calibration measurements shall be performed on each accelerator system by a therapeutic radiological physicist before the therapy system is first used for irradiation of a patient. Subsequent calibrations shall be performed at intervals not exceeding 1 year.
- 1) Calibration measurements shall include, but need not be limited to, the following determinations:
 - A) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, variation in the axes of rotation for the table, gantry and jaw system and the beam flatness and symmetry at the specified depth;
 - B) The absorbed dose rate at various depths in water for the range of field sizes used, for each beam type and energy;
 - C) The uniformity of the radiation field and any dependency upon the direction of the beam;
 - D) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions; and
 - E) Verification of transmission factors for all accessories such as wedges, shadow trays and compensators, as applicable.
 - 2) Calibration radiation measurements shall be performed using a dosimetry system that has been calibrated by a calibration laboratory accredited by

the American Association of Physicists in Medicine (AAPM), and meets the requirements of either subsection (d)(2)(A) or (B):

- A) The calibration shall have been performed within the previous 2 years and after any servicing that may have affected calibration of the dosimetry system; or
- B) The dosimetry system shall have been calibrated within the previous 4 years and shall have been:
 - i) Compared at annual intervals following the calibration to a dosimetry system with calibration obtained within the previous 2 years from a calibration laboratory accredited by the AAPM, and the results of the comparison indicate the calibration factor has not changed by more than two percent; or
 - ii) Subjected to a testing protocol that has been established by a therapeutic radiological physicist and that provides for checks of dosimetry constancy and provides for corrective action when results deviate more than two percent from the expected values.

AGENCY NOTE: Redundancy is a basic tenet of radiation dosimetry, therefore the therapeutic radiological physicist should establish a program of inter-comparison and constancy testing of calibrated dosimetry instruments to assure, as much as possible, the accuracy, reliability and reproducibility of the measurements performed with those instruments.

- 3) Calibration of the radiation output of the accelerator shall be performed in accordance with:
 - A) The protocol of Task Group 21, Radiation Therapy Committee, American Association of Physicists in Medicine (AAPM), entitled "A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams" published in Medical Physics, Volume 10, pages 741-771 (1983), exclusive of subsequent amendments or editions; or
 - B) The protocol of the Scientific Committee on Radiation Dosimetry of the AAPM, entitled "Protocol for the Dosimetry of X and

Gamma Ray Beams with Maximum Energies Between 0.6 and 50 MeV", published in Physics, Medicine, and Biology, Volume 16, pages 379-396 (1971), exclusive of subsequent amendments or editions; or

- C) Other machine calibration protocols provided that the registrant has submitted the protocols to the Agency and the protocols cover the same topics as those contained in subsections (d)(3)(A) and (B).

AGENCY NOTE: Copies of the two protocols referenced in subsections (d)(3)(A) and (B) are available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois. The protocols may also be obtained directly from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

- 4) The radiation output of each therapy system shall be independently verified at intervals not to exceed 2 years. Independent verification shall consist of:
 - A) Verification of the machine output by a therapeutic radiological physicist who is not employed at the facility and does not perform the annual calibration; or
 - B) Alternate methods of verification of machine output, such as the use of mailed dosimetry devices, that use devices and procedures approved by the AAPM.
- 5) Machine calibration records shall include identification of the accelerator calibrated, the results of the tests specified in subsection (d)(1) and shall be signed and dated by the therapeutic radiological physicist who performed the calibration.
- 6) The registrant shall maintain at the facility, for a period of 5 years, records of machine calibrations, instrument calibrations and independent verifications of machine output for inspection by the Agency.
- e) Quality Assurance Checks. A quality assurance (QA) check shall be performed by a therapeutic radiological physicist on each therapy system each calendar month. The interval between QA checks shall not exceed 45 days. QA checks shall also be performed after any change which could affect the radiation output, spatial distribution or other characteristics of the therapy beam, as determined by

the physicist. Quality assurance checks shall also meet the following requirements:

- 1) Quality assurance checks shall include determination of:
 - A) The radiation output for a set of operating conditions specified by a therapeutic radiological physicist; and
 - B) The coincidence of the radiation field and the field indicated by the localizing device.
 - 2) Radiation measurements shall be obtained using a dosimetry system that:
 - A) Meets the requirements of subsection (d)(2); or
 - B) Has been directly compared by a therapeutic radiological physicist within the previous year with a dosimetry system which meets the requirements of subsection (d)(2).
 - 3) The therapeutic radiological physicist shall establish criteria for quality assurance check measurements and shall determine corrective actions to be implemented if the criteria are exceeded.
 - 4) The registrant shall retain a record of quality assurance check measurements for inspection by the Agency for a period of 5 years. The record shall include the date of the quality assurance check, identification of the accelerator, results of the quality assurance check measurements and the signature of the individual who performed the quality assurance check.
- f) Quality Control. A comprehensive quality control program shall be implemented as specified by a therapeutic radiological physicist and shall meet the following requirements:
- 1) The program shall be designed to test the operation and performance of the accelerator in order to maintain radiation safety and clinical reliability. The program shall include as a minimum the items listed in Section 360.Appendix E.
 - 2) The physicist shall specify the tolerance and frequency of performance for each item of the quality control program.
 - 3) The physicist shall specify what actions are to be taken for any item

exceeding the specified tolerance.

- 4) The physicist shall review, sign and date the results of the quality control program each calendar month.

AGENCY NOTE: The elements of a comprehensive quality control program are described in Report No. 13 published by the AAPM, entitled "Physical Aspects of Quality Assurance in Radiation Therapy" (1984). A copy of this report is available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois. Report No. 13 may also be obtained directly from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

- g) Operating Procedures. The registrant shall have a therapeutic radiological physicist establish written operating and emergency procedures and shall ensure that the procedures are implemented before the accelerator is used for treatment of patients. Operators of accelerators shall receive training in the application of the procedures before using the accelerator to irradiate patients. A copy of the current operating and emergency procedures shall be maintained at the treatment control panel for use and review.
 - 1) Operating procedures to be implemented shall include instructions that:
 - A) The accelerator is used in such a manner that patients, workers and the general public are protected from radiation hazards and the provisions of 32 Ill. Adm. Code 340 are met;
 - B) No accelerator shall be left unattended unless it is secured against unauthorized use;
 - C) The safety interlock system shall not be used to turn off the beam except in an emergency;
 - D) The safety interlocks and warning systems required in subsections (a)(3), (a)(4) and (a)(9) shall be tested for proper operation at monthly intervals;
 - E) Mechanical supporting or restraining devices shall be used when a patient must be held in position for radiation therapy;
 - F) No individual other than the patient shall be in the therapy room during irradiation;
 - G) Start-up procedures for the accelerator, specified by the therapeutic

radiological physicist, shall be performed daily prior to treatment of patients; and

H) The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.

2) Emergency procedures shall include instructions for alternate methods for termination of irradiation and machine movements.

AGENCY NOTE: The operating and emergency procedures should contain as a minimum the machine manufacturer's operations manual for the accelerator.

3) Operating and emergency procedures shall include instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

h) Machine Maintenance. The therapeutic radiological physicist shall establish accelerator maintenance procedures that meet the following requirements:

- 1) Whenever service or maintenance is performed on the accelerator, a therapeutic radiological physicist shall be notified of such service or maintenance.
- 2) Following completion of service or maintenance involving radiation beam generation, beam steering or monitoring of the beam, but before the accelerator is again used for treatment of patients, the therapeutic radiological physicist shall review the service or maintenance report and shall determine whether a calibration or quality assurance check is necessary to verify the characteristics of the beams. If the therapeutic radiological physicist determines that a calibration or quality assurance check is necessary, the calibration or quality assurance check shall be performed before the accelerator is again used for treatment of patients.
- 3) The therapeutic radiological physicist shall establish the frequency of routine maintenance and ensure that records of all service and maintenance performed on the machine are maintained at the facility.
- 4) The therapeutic radiological physicist shall sign and date records of all service and maintenance performed on the machine.

- 5) The therapeutic radiological physicist shall specify the qualifications of maintenance personnel and prohibit non-qualified personnel from repairing the machine or adjusting parameters on the machine.
 - 6) Circuit diagrams of the accelerator and interlock systems shall be maintained at the facility and kept current.
- i) Quality Management Program. Each registrant shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the physician. The quality management program shall address, as a minimum, the following specific objectives:
- 1) Written Directives. A written directive must be dated and signed by a physician prior to the administration of radiation.
 - A) A written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.
 - B) A written revision to an existing written directive may be made provided that the revision is dated and signed by a physician prior to the administration of the external beam dose, or the next fractional dose.
 - C) An oral revision to an existing written directive is acceptable provided that:
 - i) a delay in providing a written revision would jeopardize the patient's health; and
 - ii) the oral revision is documented as soon as possible in writing in the patient's record; and
 - iii) a revised written directive is signed by a physician within 48 hours after the oral revision.
 - D) The registrant shall retain a copy of each written directive for 3 years.
 - 2) Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

- A) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
 - B) Each administration is in accordance with the written directive;
 - C) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;
 - D) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and
 - E) The registrant retains a copy of the procedures for administrations for three years.
- 3) Reports and Notifications of Medical Events
- A) A registrant shall report any event in which the administration of therapeutic radiation machine radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
 - B) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which:
 - i) The administration of a therapeutic radiation machine therapy dose involves the wrong patient, wrong treatment modality, or wrong treatment site; or
 - ii) The calculated weekly administered dose differs from the weekly prescribed dose by more than (30%); or
 - iii) The calculated total administered dose differs from the total prescribed dose by more than (20%) of the total prescribed dose;
 - C) The registrant shall notify the Agency by telephone no later than the next calendar day after the discovery of a medical event.

- D) The registrant shall submit a written report to the Agency within 15 days after the discovery of a medical event. The written report must include:
- i) The registrant's name;
 - ii) The name of the prescribing physician;
 - iii) A brief description of the event;
 - iv) Why the event occurred;
 - v) The effect, if any, on the individuals who received the administration;
 - vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;
 - vii) Certification that the registrant notified the individual (or the individual's responsible relative or guardian) and if not, why not.
- E) The report shall not contain the individual's name or any other information that could lead to the identification of the individual.
- F) The registrant shall provide notification of the event to the referring physician and shall notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care required as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection (i)(3)(F), the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or

guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide the written description if requested.

- G) Aside from the notification requirement, nothing in this Section affects any rights or duties of registrants and physicians in relation to each other, to an individual affected by the medical event, or to that individual's responsible relatives or guardians.
 - H) The registrant shall retain a record of a medical event in accordance with subsection (i)(4). A copy of the record required shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the medical event.
 - I) The registrant shall annotate a copy of the report provided to the Agency with:
 - i) The name of the individual who is the subject of the event;
 - ii) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
 - iii) A copy of the annotated report to the referring physician, if other than the registrant, no later than 15 days after the discovery of the event.
- 4) Records of Medical Events. A registrant shall retain a record of medical events for 3 years. The record must contain the following:
- A) The registrant's name and the names of the individuals involved;
 - B) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the medical event;
 - C) A brief description of the event; why it occurred; the effect, if any, on the individual;
 - D) The actions, if any, taken or planned to prevent recurrence; and

- E) Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(Source: Amended at 38 Ill. Reg. 12031, effective May 29, 2014)

Section 360.130 Electronic Brachytherapy

- a) **Applicability.** Electronic brachytherapy devices shall be subject to the requirements of this Section and shall be exempt from the requirements of Section 360.110, unless otherwise noted in this Section.
 - 1) An electronic brachytherapy device that does not meet the requirements of this Section shall not be used for irradiation of patients; and
 - 2) An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board.
- b) **Possession of Survey Instruments.** Each registrant using an electronic brachytherapy device in accordance with this Section shall possess appropriately calibrated portable monitoring equipment. At a minimum, the monitoring equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated within the prior 12 months for the applicable electronic brachytherapy source energy.
- c) **Facility Design Requirements for Electronic Brachytherapy Devices.** Each electronic brachytherapy installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.
 - 1) If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
 - 2) Access to the treatment room shall be controlled by a door at each entrance.
 - 3) Each treatment room shall have provisions to permit continuous aural communication and visual observation of the patient from the treatment

control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

- d) Control Panel Functions. The control panel, in addition to the displays required by other provisions in this Section, shall:
 - 1) Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
 - 2) Provide an indication of whether x-rays are being produced;
 - 3) Provide a means for indicating electronic brachytherapy source potential and current;
 - 4) Provide a means for terminating an exposure at any time; and
 - 5) Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.
- e) Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor. The timer shall operate according to the manufacturer's design specifications.
- f) Therapeutic Radiological Physicist Support. The services of a therapeutic radiological physicist shall be required in facilities having electronic brachytherapy devices. The therapeutic radiological physicist shall be responsible for:
 - 1) Evaluation of the output from the electronic brachytherapy source;
 - 2) Generation of the necessary dosimetric information;
 - 3) Supervision and review of treatment calculations prior to initial treatment of any treatment site;
 - 4) Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection (j);
 - 5) Consultation with the physician in treatment planning, as needed;

- 6) Performing calculations/assessments regarding patient treatments that may constitute a misadministration.
 - 7) Determination of the need for shielding or safe distances for individuals in the room during electronic brachytherapy treatments, in accordance with the radiation dose limits of 32 Ill. Adm. Code Part 340;
 - 8) Implementation of the use of shielding or safe distances as determined in subsection (f)(7).
- g) Operating Procedures
- 1) Only individuals approved by the physician or therapeutic radiological physicist shall be present in the treatment room during treatment.
 - 2) Electronic brachytherapy devices shall not be made available for medical use unless the requirements of this Section have been met.
 - 3) The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel.
 - 4) During operation, the therapeutic radiologic physicist shall ensure that all persons in the treatment room, and all persons entering the treatment room, are prevented from exceeding the radiation dose limits of 32 Ill. Adm. Code Part 340.
 - 5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
 - 6) Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
 - A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
 - B) The names and telephone numbers of the physician and the therapeutic radiological physicist to be contacted if the device or console operates abnormally.
 - 7) A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console.

- 8) Instructions shall be posted at the electronic brachytherapy device control console to inform the electronic brachytherapy device operator of the names and telephone numbers of the physician and the therapeutic radiological physicist to be contacted if the device or console operates abnormally.
- h) Safety Precautions for Electronic Brachytherapy Devices
- 1) A therapeutic radiological physicist shall determine which persons in the treatment room require radiation monitoring when the beam is energized.
 - 2) A physician and a therapeutic radiological physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device.
 - 3) A therapeutic radiological physicist and either a physician or an electronic brachytherapy device operator, under the supervision of a physician, who has been trained in the operation of, and emergency response for, the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device.
 - 4) A therapeutic radiological physicist shall designate shield locations or safe distances sufficient to meet the requirements of 32 Ill. Adm. Code 340 for any individual, other than the patient, in the treatment room;
 - 5) All personnel in the treatment room are required to remain behind shielding or at a safe distance specified by the therapeutic radiological physicist during treatment. A therapeutic radiological physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.
- i) Electronic Brachytherapy Source Calibration Measurements
- 1) Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of, a therapeutic radiological physicist.
 - 2) Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the

- x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks.
- 3) Calibration of the electronic brachytherapy source output shall utilize a dosimetry system that meets the requirements of subsection 360.110(d)(4).
 - 4) Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
 - A) The output within 2% of the expected value, if applicable, or determination of the output if there is no expected value;
 - B) Timer accuracy and linearity over the typical range of use;
 - C) Proper operation of back-up exposure control devices;
 - D) Evaluation that the relative dose distribution about the source is within 5% of that expected; and
 - E) Source positioning accuracy to within one millimeter within the applicator.
 - 5) Calibration of the x-ray source output shall be in accordance with the manufacturer's calibration protocol.
 - 6) The registrant shall maintain a record of each calibration in an auditable form for 5 years. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the model numbers and serial numbers of the instruments used to calibrate the electronic brachytherapy device; and the name and signature of the therapeutic radiological physicist responsible for performing the calibration.
- j) Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices
- 1) Quality assurance checks shall be performed on each electronic brachytherapy device:
 - A) At the beginning of each day of use;
 - B) Each time the device is moved to a new room or site; and

- C) After each x-ray tube installation.
- 2) The registrant shall perform periodic quality assurance checks required by subsection (j)(1) in accordance with procedures established by the therapeutic radiological physicist;
- 3) Quality assurance checks shall include, at a minimum:
 - A) Verification that output of the electronic brachytherapy source falls within 3% of expected values, as appropriate for the device, as determined by:
 - i) Output as a function of time; or
 - ii) Output as a function of setting on a monitor chamber.
 - B) Verification of the consistency of the dose distribution to within 3% of that found during calibration required by subsection (i); and
 - C) Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within 1 mm.
- 4) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in subsection (i)(3) to make the quality assurance checks required in this subsection (j).
- 5) The registrant shall review the results of each radiation output quality assurance check according to the following procedures:
 - A) A physician and therapeutic radiological physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the therapeutic radiological physicist has determined that all parameters are within their acceptable tolerances; and
 - B) The therapeutic radiological physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
- 6) Quality assurance checks shall, at a minimum, assure:

- A) Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
 - B) Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
 - C) Proper operation of radiation monitors, if applicable;
 - D) The integrity of all cables, catheters or parts of the device that carry high voltages; and
 - E) Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
- 7) If the results of the safety device quality assurance checks indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
- 8) The registrant shall maintain a record of each quality assurance check in an auditable form for 3 years.
- A) The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check; and the name and signature of the therapeutic radiological physicist who reviewed the quality assurance check; and
 - B) The record shall also include the unique identifier for the electronic brachytherapy source; the manufacturer's name; and the model number and serial number for the instruments used to measure the radiation output of the electronic brachytherapy device.
- k) Therapy-Related Computer Systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with the manufacturer's acceptance testing protocol.

- 1) Acceptance testing shall be performed by, or under the direct supervision of, a therapeutic radiological physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:
 - A) The source-specific input parameters required by the dose calculation algorithm;
 - B) The accuracy of dose, dwell time, and treatment time calculations at representative points;
 - C) The accuracy of isodose plots and graphic displays;
 - D) The accuracy of the software used to determine radiation source positions from radiographic images; and
 - E) If the treatment planning system is different from the treatment delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
 - 2) The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
 - 3) Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the physician and the therapeutic radiological physicist for correctness through means independent of that used for the determination of the parameters.
- 1) Training
- 1) A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subsection (g). If the interval between patients exceeds one year, retraining of the individuals shall be provided.
 - 2) Physicians, therapeutic radiological physicists, and electronic brachytherapy device operators shall receive device specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by the manufacturer's training protocol. The training shall include, but not be limited to:

- A) Device-specific radiation safety requirements;
 - B) Device operation;
 - C) Clinical use for the types of use approved by the FDA;
 - D) Emergency procedures, including an emergency drill; and
 - E) The registrant's quality assurance program.
- 3) A registrant shall retain a record of individuals receiving instruction required by this subsection (l) for 3 years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.
- m) Mobile Electronic Brachytherapy Service. A registrant providing mobile electronic brachytherapy service shall, as a minimum:
- 1) Check all radiation survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive.
 - 2) Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address.
 - 3) Perform, at each location on each day of use, all of the required quality assurance checks specified in subsection (j) to assure proper operation of the device.

(Source: Added at 38 Ill. Reg. 12031, effective May 29, 2014)

Section 360.APPENDIX A Medical Radiographic Entrance Exposure Measurement Protocol

The following protocol shall be used for measuring and calculating entrance skin exposures (ESE) for routine diagnostic examinations. Radiation measurements shall be performed with a calibrated radiation measuring device that is sufficiently sensitive to determine compliance with the criteria specified in Section 360.60(e) of this Part. The instrument shall have been calibrated within the previous 12 months with devices which have no more than a three-step (tertiary) calibration, traceable to the National Institute of Standards and Technology. Patients are not involved in the measurement protocol.

- a) Position the x-ray tube at the source-image receptor distance (SID) routinely used and adjust the collimation to the active portion of a radiation measuring device.
- b) Measure the distance from the x-ray source to the source against which the patient rests. Subtract the thickness of the patient to obtain the source-skin distance (SSD). The standard patient thickness for each projection to be measured shall be the following:

<u>Projection</u>	<u>Thickness (cm)</u>
Chest (PA), Grid	23
Chest (PA), Non-Grid	23
Abdomen (KUB)	23
Lumbo-Sacral Spine (AP)	23
Cervical Spine (AP)	13
Skull (lateral)	15
Foot (D/P)	8

- c) Place a radiation measuring device in the center of the useful beam, measure and record the distance from the source to the device (SDD). Use of a test stand to position the device away from the table will reduce backscatter contribution. Placing the radiation measuring device at the actual source-skin distance (SSD) will accomplish this and allow direct reading of the ESE.
- d) Set the exposure technique as follows:
 - 1) For non-phototimed x-ray systems, set the controls to the exposure technique used by the x-ray operator for the standard patient thickness specified in subsection (b) of this Section.
 - 2) For phototimed x-ray systems, set the controls to the exposure technique used by the x-ray operator for the standard patient thickness specified in

subsection (b) of this Section, and use one of the two methods below:

- A) Place an appropriate phantom (simulating body attenuation) in the useful beam between the radiation measuring device and the radiographic tabletop; or
- B) Set an appropriate exposure technique in the manual mode (without activation of the phototimer).

AGENCY NOTE: Specifications for appropriate phantoms are included in the American Association of Physicists in Medicine (AAPM) Report No. 31, entitled "Standardized Methods for Measuring Diagnostic X-Ray Exposures" (July 1990). A copy of this report is available for public inspection at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, IL. Copies of this report may also be obtained from the AAPM, One Physics Ellipse, College Park MD 20740-3846.

- e) Make a radiographic exposure (without patient) and record the reading obtained from the radiation measuring device
- f) Calculate the entrance skin exposure for the specific examination, using the radiation exposure reading from subsection (e) of this Section and the equation in this subsection (f) below (if a direct result was not obtained with the dosimeter at the SSD). The entrance skin exposure equals the product of the radiation exposure reading from subsection (e) of this Section multiplied by the square of the ratio of the SDD, to the SSD. This expression is mathematically represented by the equation below (if a direct result was not obtained with the dosimeter at the SSD):

$$\text{ESE} = (\text{Dosimeter Reading}) \times \left[\frac{\text{SDD}}{\text{SSD}} \right]^2$$

where:

SDD = source-radiation measuring device distance

SSD = source to skin distance

- g) Compare the results of the calculation from subsection (f) of this Section with the criteria specified in Section 360.60(e) of this Part to determine compliance.

AGENCY NOTE: There are many different techniques for measuring ESE that may result in significant differences in measured values. Factors that can cause variations include instrument calibration, backscatter, collimation, estimation of

focal spot location, choice of phantom, location of dosimeter in the primary beam, etc. Because of these variations, the procedure for determining the ESE should be performed with strict attention to each detail noted above.

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

Section 360.APPENDIX B Mammography Dose Measurement Protocol (Repealed)

(Source: Repealed at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.APPENDIX C Mammography Phantom Image Evaluation (Repealed)

(Source: Repealed at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.APPENDIX D Computed Tomography Dose Measurement Protocol (Repealed)

(Source: Repealed at 38 Ill. Reg. 12031, effective May 29, 2014)

Section 360.APPENDIX E Minimum Quality Control Program for Medical Accelerators

- a) Mechanical tests
 - 1) Patient support assembly motions
 - 2) Gantry angle indicators
 - 3) Optical distance indicator
 - 4) Alignment lights
 - 5) Congruence of radiation beam and light field
 - 6) Accuracy of field size indicators
 - 7) Mechanical isocenter - gantry and collimator
 - 8) Mechanical interlocks
- b) Radiation beam tests
 - 1) Machine operating parameters
 - 2) Dose per monitor unit for x-ray and electron beams
 - 3) Dose per degree for moving beam therapy
 - 4) Radiation isocenter
 - 5) Flatness and symmetry
 - 6) Wedge transmission factors
 - 7) Shadow tray transmission factors
 - 8) Energy check on central axis
 - 9) Radiation output versus field size
- c) Control panel checks
 - 1) Radiation "ON" condition

- 2) Indicator lamp check
- 3) Computer control of accelerator
- d) Facility checks
 - 1) Patient audio-visual communication
 - 2) Entrance door interlock
 - 3) Warning lights
 - 4) Emergency off buttons
- e) Control Panel
 - 1) Digital displays
 - 2) Analog displays
 - 3) Status displays
 - 4) Interlock displays
 - 5) Reset display
- f) Patient Dosimetry Calculations
 - 1) Calculation of patient treatment times
 - 2) Computer calculations of patient treatment times

(Source: Added at 17 Ill. Reg. 17972, effective October 15, 1993)

Section 360.ILLUSTRATION A Thimble and Pancake Chamber-Radiation Measuring Devices (Repealed)

(Source: Repealed at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.ILLUSTRATION B Mammography Dose Evaluation Graph (Repealed)

(Source: Repealed at 17 Ill. Reg. 17972, effective October 15, 1993)

Section 360.TABLE A Mammography Dose Evaluation Table (Repealed)

(Source: Repealed at 23 Ill. Reg. 14516, effective January 1, 2000)

Section 360.TABLE B Half-Value Layer as a Function of Tube Potential

Designed operating range	X-ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of Al) ¹	
	Measured Operating Potential	Specified Dental Systems ²	Other X-Ray Systems ³	
Below 50	30	1.5	0.3	
	40	1.5	0.4	
	49	1.5	0.5	
50 to 70	50	1.5	1.2	
	60	1.5	1.3	
	70	1.5	1.5	
Above 71	71	2.1	2.1	
	80	2.3	2.3	
	90	2.5	2.5	
	100	2.7	2.7	
	110	3.0	3.0	
	120	3.2	3.2	
	130	3.5	3.5	
	140	3.8	3.8	
	150	4.1	4.1	

¹ Linear extrapolation or interpolation may be made for an x-ray tube potential (kVp) not listed in the table above (e.g., in the column entitled "Other X-ray Systems" operated at 20 kVp and 95 kVp, the minimum HVL required would be 0.2 and 2.6 millimeters of aluminum respectively).

² "Specified Dental Systems" means any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980.

³ "Other X-Ray Systems" means all x-ray systems required to meet the provisions of Sections 360.50, 360.60, 360.75, 360.90 (except "Specified Dental Systems") and 360.100 of this Part. Half-value layer requirements for mammography systems are specified in Section 360.71(e) of this Part.

(Source: Amended at 22 Ill. Reg. 5904, effective March 13, 1998)

Section 360.TABLE C Entrance Exposure Limits Per Intraoral Bitewing Film (Repealed)

(Source: Repealed at 17 Ill. Reg. 17972, effective October 15, 1993)