ILLINOIS EMERGENCY MANAGEMENT AGENCY

NOTICE OF PROPOSED AMENDMENT

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

Section

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

SOURCE: Filed April 20, 1974 by the Department of Public Health; old rules repealed, new rules adopted at 4 Ill. Reg. 25, p. 157, effective July 1, 1980; transferred to the Department of Nuclear Safety by P.A. 81-1516, effective December 3, 1980; codified at 7 Ill. Reg. 16406; amended at 10 Ill. Reg. 13271, effective July 28, 1986; amended at 13 Ill. Reg. 803, effective April 1, 1989; amended at 15 Ill. Reg. 6180, effective April 16, 1991; amended at 17 Ill. Reg. 17972, effective October 15, 1993; amended at 18 Ill. Reg. 11524, effective July 11, 1994; emergency amendment adopted at 19 Ill. Reg. 273, effective December 30, 1994, for a maximum of 150 days; emergency expired May 30, 1995; amended at 19 Ill. Reg. 8284, effective June 12, 1995; amended at 22 Ill. Reg. 5904, effective March 13, 1998; amended at 23 Ill. Reg. 14516, effective January 1, 2000; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 32 Ill. Reg. 3693, effective February 29, 2008; amended at 38 Ill. Reg. 12031, effective May 29, 2014; Chapter II recodified at 49 Ill. Reg. 2359; amended at 49 Ill. Reg. _____, effective _____.

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" or “DIS” 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").

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"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.

"Enhanced Radiation Protection Systems (ERPS) means non-wearable, externally mounted shielding systems designed to reduce occupational exposure to scattered ionizing radiation for operators and ancillary personnel involved in fluoroscopically guided interventional procedures.

"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.

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"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 milliampere-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").

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"Therapeutic radiological physicist" or “TRP” 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 49 Ill. Reg. _____, effective _____)

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 (l) 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 (l) 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.

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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 and other interventional 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).

3) In lieu of protective aprons required in subsection (k)(2), the use of ERPS can be utilized provided the following requirements have been met:

A) ERPS shall provide operator protection equivalent to or greater than 0.5 millimeters of lead-equivalent shielding under clinical use conditions.

B) Documentation pertaining to manufacturer test data, peer-reviewed shielding studies, institutional training protocols and quality assurance documentation for the specific device to be put in place are to be reviewed by an Agency approved DIS/TRP and be maintained at the facility for review by facility personnel and the Agency. Such documentation shall be maintained by the facility for three years following the date such a device is last used and shall include:

i) Manufacturer provided attenuation testing data demonstrating ≥ 0.5 mm lead-equivalent shielding performance across the relevant energy spectrum for diagnostic and interventional fluoroscopy.

ii) Independent third-party verification (i.e., DIS/TRP) of the system's protective capabilities.

iii) Peer-reviewed clinical studies demonstrating that operator radiation exposure using the ERPS is equivalent to or less than exposure achieved with conventional .05 mm lead-equivalent personal protective garments.

iv) Facility-specific operating protocols addressing proper ERPS system installation, positioning, use, and maintenance consistent with manufacture specifications.

v) Staff training protocols to ensure all operators and ancillary personnel are properly trained in the correct use and limitations of the ERPS.

vi) A quality assurance program for ongoing periodic testing, inspection and maintenance of the ERPS to ensure consistent performance over time.

C) An Agency approved DIS/TRP has reviewed the ERPS device to be implemented, associated documentation for the device, and conducted a comprehensive study of the device in clinical use at the facility with specific attention to the location and expected exposure to personnel required to be in the area during the performance of the procedure.

D) The Agency may suspend or revoke approval for ERPS use at any facility upon finding non-compliance with approved procedures, system performance deficiencies, or upon determination that personnel safety may be compromised.

E) Approval of ERPS under this Section does not exempt facilities from compliance with all other provisions of this Part or with other applicable State or federal radiation protection regulations.

F) All personnel required to be in the area where ERPS devices are used shall wear an individual monitoring device defined in 32 Ill. Adm. Code 310 or a real-time dosimetry.

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 49 Ill. Reg. _____, effective _____)