NOTICE OF INTENT

Department of Environmental Quality
Office of the Secretary
Legal Affairs and Criminal Investigations Division

Chapter 6 X-Rays in the Healing Arts Update
(LAC 33:XV.602, 603, 604, 605, 606, 607, 610, 611, and 699) (RP068)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.602, 603, 604, 605, 606, 607, 610, 611, and 699 (RP068).

The proposed Rule updates the radiation regulations pertaining to X-rays in the healing arts. This will more closely align the Louisiana regulations with current national standards. The changes in the state regulations are necessary to align with current manufacturer requirements and new X-ray technology and industry standards that have evolved over the last decade. The basis and rationale for this Rule are to enable the state to mirror other states' regulations and regulate the use of new X-ray technologies. This Rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 6. X-Rays in the Healing Arts

§602. Definitions

A. As used in this Chapter, the following definitions apply. Other definitions applicable to this Chapter may be found in LAC 33:XV.Chapters 1 and 2.

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Air Kerma (K)—the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Air Kerma Rate (AKR)—air kerma per unit time.

Alert Value—a dose rate index (e.g. of $CTDI_{vol}$(mGy)or DLP(mGy-cm)) that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

Aluminum Equivalent—the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

Articulated Joint—a joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

* * *

Attenuation Block—a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters, that is large enough to intercept the entire X-ray beam.

Automatic Exposure Control (AEC)—a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also *Phototimer*).

Automatic Exposure Rate Control (AERC)—a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

* * *

Bone Densitometer—a device intended for medical purposes to measure bone density and mineral content by X-ray or gamma ray transmission measurements through the bone and

adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Bone Densitometry—a noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

* * *

Cantilevered Tabletop—a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette Holder—a device, other than a spot-film device, that supports and/or fixes the position of the image receptor during a radiographic exposure.

* * *

Certified Components—components of X-ray systems that are certified by the U.S. Food and Drug Administration (FDA).

* * *

Coefficient of Variation or "C"— Repealed.

Coefficient of Variation (C)—the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\Sigma_{i=1}^{n}(x_i - \bar{x})^2}{n-1}\right]^{1/2}$$

where:

s = estimated standard deviation of the population;

x = mean value of observations in sample;

x_i = i_{th} observation in sample; and

n = number of observations sampled.

Computed Radiography (CR; also see DR)—a digital X-ray imaging method in which a photostimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

* * *

Computed Tomography Dose Index (CTDI)—the average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one axial CT scan (one rotation of the X-ray tube), and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (16 and 32 cm in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders. The equation is:

$$\mathrm{CTDI} = \frac{1}{NT} \int_{-\infty}^{\infty} D(z)dz$$

where:

D(z) = the radiation dose profile along the z-axis;

N = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of N may be less than or equal to the maximum number of data channels available on the system; and

T = the width of the tomographic section along the z-axis imaged by one data channel. In multiple-detector-row (multislice) CT scanners, several detector elements may be grouped together to form one data channel. In single-detector-row (single-slice) CT, the z-axis collimation (T) is the nominal scan width.

$CTDI_{100}$—the accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The $CTDI_{100}$, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available "pencil" ionization chamber. $CTDI_{100}$ is acquired using a 100-mm long, 3-cc active volume CT "pencil" ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table. The equation is:

$$\mathrm{CTDI}_{100} = \frac{1}{NT}\int_{-50mm}^{50mm} D(z)\,dz$$

$CTDI_{vol}$—(See *Volume Computed Tomography Dose Index ($CTDI_{vol}$)*)

$CTDI_{w}$—(See *Weighted Computed Tomography Dose Index ($CTDI_{w}$)*)

Cone Beam Computed Tomography (CBCT)—a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a cone-shaped (instead of fan-shaped) X-ray beam that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

* * *

Contrast Scale—the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_X - (CTN)_w}$$

where:

μ_x = linear attenuation coefficient of the material of interest;

μ_w = linear attenuation coefficient of water;

$(CTN)_x$ = CTN of the material of interest; and

$(CTN)_w$ = CTN of water.

Control Panel—that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware necessary for manually setting the technique factors.

* * *

Cradle—a removable device which supports and may restrain a patient above an X-ray table; or a device:

a. where patient support structure is interposed between the patient and the image receptor during normal use;

b. which is equipped with means for patient restraint; and

c. which is capable of rotation about its long (longitudinal) axis.

CS—(See *Contrast Scale*)

CT—(See *Computed Tomography)*

CT Conditions of Operation—all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the *technique factors* as defined in LAC 33:XV.602.

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

CTN—(See *CT Number*)

CT Number—the number used to represent the X-ray attenuation associated with each elemental area of the CT image. The equation is:

$$\overline{C\ T\ N} = \frac{k\,(\mu_x - \mu_{w)}}{\mu_w}$$

where:

k = a constant. The constant has a normal value of 1,000 when the Hounsfield unit of CTN is used;

μ_x = linear attenuation coefficient of the material of interest; and

μ_w = linear attenuation coefficient of water.

Cumulative Air Kerma—the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

* * *

Diagnostic Reference Level (DRL)—an investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

* * *

Digital Radiography (DR)—an X-ray imaging method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

Direct Digital Radiography (DDR; also see *CR* and *DR)*—an X-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an X-ray image. Some DDR systems use a scintillator to convert X-rays to light and a photodiode array to convert

light to charge, while others use a photoconductor to convert X-rays directly to charge, which is stored on the thin-film transistor.

Direct Scattered Radiation—that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See *Scattered Radiation*)

Direct Supervision—general supervision by a qualified practitioner present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the licensed practitioner shall be present in the room when the procedure is being performed.

Dose—the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

Dose Area Product (DAP) (aka *Kerma-Area Product (KAP)*)—the product of the air kerma and the area of the irradiated field and is typically expressed in Gy-cm^2, so it does not change with distance from the X-ray tube.

Dose Length Product (DLP)—the indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the formula:

DLP (mGy-cm) = $CTDI_{vol}$ (mGy) x scan length (cm)

Dose Profile—the dose as a function of position along a line.

Effective Dose (E)—the sum of the tissue-weighted equivalent doses for the radiosensitive tissues and organs of the body. It is given by the expression $E = \Sigma_T (w_T H_T)$, in which H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor for tissue or organ T. The unit of E and H_T is joule per kilogram (J/kg), with the special name sievert (Sv).

Elemental Area—the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted. (See also *Picture Element*)

* * *

Exposure (X)—the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass "dm" are completely stopped in air; thus X=dQ/dm, in units of C/kg. Exposure is also the process or condition during which the X-ray tube produces X-ray radiation.

* * *

Fluoroscopic Imaging Assembly—a subsystem in which X-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic Irradiation Time—the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling X-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopically-Guided Interventional (FGI) Procedures—an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

Fluoroscopy—a technique for generating X-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term “radioscopy” in the standards of the International Electrotechnical Commission.

Focal Spot (actual)—the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

* * *

General Supervision—supervision of a procedure under the overall direction and control of the qualified practitioner but who is not required to be physically present during the performance of the procedure.

Gonad Shield— Repealed.

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Hand-Held X-Ray Equipment—X-ray equipment that is designed to be hand-held during operation.

* * *

Heat Unit—a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

* * *

Image Intensifier—a device, installed in its housing, that instantaneously converts an X-ray pattern into a corresponding light image of higher intensity.

Image Receptor—any device, such as a fluorescent screen, radiographic film, X-ray image intensifier tube, solid-state detector, or gaseous detector, 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. In those cases where means are provided to preselect a portion of the image receptor, the term *image receptor* shall mean the preselected portion of the device.

* * *

Isocenter—the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma—a measurement defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Kerma-Area Product (KAP)—(See *Dose Area Product*)

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kVp—(See *Peak Tube Potential*)

* * *

Last-Image Hold (LIH) Radiograph—an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lead Equivalent—the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

* * *

Licensed Practitioner—a person licensed or otherwise authorized by law to practice medicine, dentistry, chiropractic, osteopathy or podiatry, or a licensed nurse practitioner, or physician assistant.

* * *

Medical Event—one or more of the criteria that are listed in LAC 33:XV.613 have occurred.

* * *

Mode of Operation—for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, AKR, or image quality, such as image magnification, X-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Multiple Tomogram System—a computed tomography X-ray system that obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \text{ x C S x s}}{\mu_w}$$

where:

CS = contrast scale;

μ_w = linear attenuation coefficient of water; and

s = estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

Nominal Tomographic Section Thickness—the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

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PBL—(See *Positive Beam Limitation*)

* * *

Personal Supervision—general supervision by a qualified practitioner present in the room or adjacent control area during the performance of the procedure.

* * *

Photostimulable Storage Phosphor (PSP)—a material used to capture and store radiographic images in computed radiography systems.

* * *

PID—(See *Position Indicating Device*)

Picture Element—an elemental area of a tomogram.

Pitch—the table incrementation, in CT, per X-ray tube rotation, divided by the nominal X-ray beam width at isocenter.

* * *

Protected Area—an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:

a. 2 milliroentgens (20 micro Gray) in any one hour;

b. 100 milliroentgens (1 milli Gray) in any seven consecutive days; or

c. 500 milliroentgens (5 milli Gray) in any one year.

Protective Apron—an apron made of radiation absorbing or lead equivalent materials used to reduce radiation exposure.

* * *

Protocol—a collection of settings and parameters that fully describe an examination.

Pulsed Mode—operation of the X-ray system such that the X-ray tube current is pulsed by the X-ray control to produce one or more exposure intervals of duration less than one-half second.

Qualified Expert—an individual who meets one of the following criteria:

a. a qualified medical physicist;

b. not board certified in the required subspecialty but with a graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, and formal coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or similar topics related to the practice of medical physics and three years of documented experience in a clinical CT environment;

c. grandfathered by having conducted surveys of at least three CT units between January 1, 2007, and January 1, 2010; or

d. an individual approved by the department.

Qualified Medical Physicist (QMP)—an individual who meets each of the following credentials:

a. has earned a master's and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and

b. has been granted certification in the specific subfield(s) of medical physics with its associated medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education.

Qualified Practitioner—an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

Quality Assurance (QA)—a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

Quality Control (QC)—the routine measurement of image quality and the performance of the diagnostic X-ray imaging system, from X-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

* * *

Radiation Protocol Committee (RPC)—the representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

* * *

Radiography—a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

* * *

Recording—producing a permanent or retrievable form of an image resulting from X-ray photons.

Reference Plane—a plane that is displaced from and parallel to the tomographic plane.

* * *

Scan—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—the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

Scan Sequence—a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan Time—the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

* * *

Sensitivity Profile—the relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

* * *

SID—(See *Source-Image Receptor Distance*)

Single Tomogram System—a CT X-ray system that obtains X-ray transmission data during a scan to produce a single tomogram.

Size-Specific Dose Estimate (SSDE)—a patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.

Source—the focal spot of the X-ray tube or the region and/or material from which the radiation emanates.

* * *

Source-Skin Distance (SSD)—the distance from the source to the center of the entrant X-ray field in the plane tangent to the patient skin surface.

* * *

Spot Film Device—a device intended to transport and/or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. The term includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

* * *

Substantial Radiation Dose Level (SRDL)—an appropriately-selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

* * *

Tomographic Plane—that geometric plane identified as corresponding to the output tomogram.

Tomographic Section—the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

* * *

Unintended—a radiation dose received by a patient in diagnostic or interventional X-ray resulting from human error or equipment malfunction during a procedure.

* * *

Useful Beam—the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

* * *

Volume Computed Tomography Dose Index ($CTDI_{vol}$)—a radiation dose parameter derived from the $CTDI_w$ (weighted or average CTDI given across the field of view). The equation is:

$CTDI_{vol} = (N)(T)(CTDI_w)/I,$

where

N = number of simultaneous axial scans per X-ray source rotation;

T = thickness of one axial scan (mm); and

I = table increment per axial scan (mm).

Or, for helical scans,

$CTDI_{vol} = CTDI_w$ / pitch

Wedge Filter—an added filter effecting continuous progressive attenuation on all or part of the useful beam.

Weighted Computed Tomography Dose Index ($CTDI_w$)—the estimated average $CTDI_{100}$ across the field of view (FOV). The equation is:

$CTDI_w = 1/3CTDI_{100,\ center} + 2/3CTDI_{100,\ edge}$.

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom. CTDIw uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

* * *

X-Ray Equipment—an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. *Mobile X-Ray Equipment*—X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

b. *Portable X-Ray Equipment*—X-ray equipment designed to be hand-carried.

c. *Stationary X-Ray Equipment*—X-ray equipment that is installed in a fixed location.

d. *Transportable X-Ray Equipment*—X-ray equipment installed in a vehicle or trailer.

e. *Hand-Held X-Ray Equipment*—X-ray equipment that is designed to be hand-held during operation.

X-Ray Exposure Control—a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and back-up timers.

X-Ray Field—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, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

* * *

X-Ray Table—a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-Ray Tube—any electron tube which is designed for the conversion of electrical energy into X-ray energy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 23:1139 (September 1997), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2585 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 33:2362 (November 2007), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§603. General and Administrative Requirements

A. Radiation Safety Requirements. The registrant shall be responsible for directing the operation of the X-ray system(s) under his or her administrative control. The registrant or his or her agent shall assure that the requirements of LAC 33:XV are met in the operation of the X-ray system(s).

1. An X-ray system that does not meet the provisions of LAC 33:XV shall not be operated for diagnostic or therapeutic purposes unless approved by the department.

2. …

3. The qualified expert, if required in this Section, shall complete initial and routine compliance evaluations following nationally recognized procedures. These evaluations shall include a review of the required quality control tests.

4. All X-ray equipment shall be installed and used in accordance with the equipment manufacturer’s specifications.

5. For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:

a. patient’s (adult and pediatric, if appropriate) body part and anatomical size;

b. technique factors;

c. type of image receptor used;

d. source to image receptor distance used (except for dental intraoral radiography); and

e. type of grid, if any.

6. At the request of the department, the registrant shall create and make available written safety procedures to each individual operating X-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

7. Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel, including parents or guardians, required for the medical procedure or training shall be in the room during the radiographic exposure. The following conditions shall be met for those other than the patient being examined:

a. all individuals shall be protected by not less than 0.5 millimeter lead equivalent;

b. the X-ray operator, other professional staff, and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

c. human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

8. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. Any diagnostic information obtained from each exposure shall be reviewed by a licensed practitioner

of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

a. exposure of an individual for training, demonstration, or other non-healing arts purposes; and

b. exposure of an individual for the purpose of healing arts screening without prior written approval of the department.

9. In cases where a patient or image receptor must be provided with auxiliary support, mechanical support devices shall be used whenever possible. If a patient or image receptor must be provided with auxiliary support during a radiation exposure:

a. written safety procedures, as required by LAC 33:XV.603.A.19, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

b. the human holder shall be instructed in personal radiation safety and protected as required by LAC 33:XV.603.A.6;

c. no individual shall be used routinely to hold the image receptor or patients;

d. in those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;

e. when an animal must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices, such as lead equivalent aprons and gloves, and shall be positioned such that no part of his or her body shall be struck by the useful beam.

10. Each facility shall have lead equivalent aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in X-ray operations and who are otherwise not shielded.

11. All protective apparel and auxiliary shields shall be evaluated at intervals of no less than 12 months, and no more than 14 months, for integrity and clearly labeled with their lead equivalence.

12. Each registrant shall have a mechanism in place for the referring physician to access information on selecting the most appropriate diagnostic procedure to answer the clinical question.

13. Nationally recognized diagnostic reference levels (DRLs) shall be utilized when applicable.

14. The registrant shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.

15. 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.

16. Neither the X-ray tube housing nor the collimating device shall be held during an exposure. Exceptions are allowed for department approved devices specifically designed to be hand-held.

17. The useful X-ray beam shall be limited to the area of clinical interest.

18. Consideration shall be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.

19. A registrant shall have a documented procedure in place for verification of patient identity and exam performed, including identification of the appropriate body part.

20. Each registrant, except for veterinarians, covered under this Chapter shall establish written standards for the proper performance of each diagnostic X-ray imaging system under the

control of the registrant, and shall document by routine test record that the system is performing in accordance with these standards (quality control). Copies of this documentation shall be retained for at least six months and be available for inspection by the department. If a test interval is greater than six months, then a copy of the most recent test record shall be retained.

21. All individuals who are associated with the operation of an X-ray system are subject to the requirements of LAC 33:XV.410 and 411. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device or devices are required in accordance with LAC 33:XV.431, monitoring devices shall be used as follows:

a. when a protective apron is worn, at least one such monitoring device shall be worn at the collar outside of the protective apron;

b. the dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by LAC 33:XV.476. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body; and

c. deliberate exposure to an individual's personnel monitoring device is prohibited.

22. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the department. When requesting such approval, that person shall submit the information outlined in LAC 33:XV.699.Appendix C to the Office of Environmental Compliance. If any information submitted to the department becomes invalid or outdated, the Office of Environmental Compliance shall be immediately notified. See the definition of *healing arts screening* in LAC 33:XV.602.

23. Any person proposing to conduct a diagnostic or screening mammography program shall not initiate such a program without having a complete mammography facility survey performed

by a mammography physicist initially and at intervals of no less than 12 months, and no more than 14 months thereafter.

B. X-Ray Film Processing Facilities and Practices. See Appendix D.

C. Facilities Using Computed Radiography (CR) or Direct Digital Radiography (DDR).

1. When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

2. Facilities shall establish and follow an image quality control program in accordance with the recommendations of a qualified expert, the system manufacturer, or a nationally recognized organization.

D. Exemptions

1. Dental Facilities. Dental facilities performing only intraoral, panoramic, or cephalometric imaging are exempt from following the provisions of LAC 33:XV.603.A.12.

2. Podiatry Facilities. Podiatry facilities are exempt from following the provisions of LAC 33:XV.603.A.12.

3. Veterinary Facilities. Veterinary facilities are exempt from following the provisions of LAC 33:XV.603.A.12-14, LAC 33:XV.603.A.19-20, and LAC 33:XV.603.A.22.

E. Plans Review

1. Except for dedicated mammography radiographic systems, podiatric radiographic systems, panoramic dental radiographic systems, intraoral dental radiographic systems, and bone density radiographic systems prior to construction, the floor plans and equipment arrangement of

all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes shall be submitted to the Office of Environmental Compliance for review and approval. The required information is specified in LAC 33:XV.699.Appendices A and B.

2. The floor plans and equipment arrangement for all new, or modifications of existing, installations for veterinary and dental CBCT X-ray systems shall be reviewed for adequacy by the department on a case-by-case basis.

3. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plans review and approval.

4. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in LAC 33:XV.410, 416, and 421.

F. Quality Assurance

1. The registrant shall establish and maintain a quality assurance (QA) program. In addition to the standards in the modality specific sections, the registrant shall:

a. maintain documentation of minimum qualifications for practitioners, medical physicists, and X-ray equipment operators;

b. designate an individual to manage the QA program;

c. establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances;

d. complete preventative maintenance on the X-ray systems in accordance with manufacturer specifications. In lieu of manufacturer’s specifications, maintenance shall be completed at intervals of no less than 12 months, and no more than 14 months;

e. complete and document an annual review of the QA program; and

f. retain QA/QC records of evaluations and reviews for three years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:976 (October 1996), LR 23:1139 (September 1997), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2585 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2532 (October 2005), LR 33:2184 (October 2007), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§604. General Requirements for All Diagnostic X-Ray Systems

A. …

1. Warning Label

a. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: “WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.”

2. — 8.b. …

c. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within +/- 10 percent.

9. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§605. Fluoroscopic X-Ray Systems

A. Only image-intensified or direct digital receptor fluoroscopic equipment shall be used for fluoroscopy.

1. Primary Protective Barrier

a. The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

b. The X-ray tube used for fluoroscopy shall not produce X-rays unless the primary protective barrier is in position to intercept the entire useful beam.

2. Field Limitation

a. 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 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition, the following requirements apply:

i. a means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

ii. all equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless

adjustment shall provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less;

iii. for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and

iv. compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field that pass through the center of the visible area of the image receptor.

b. Spot-film devices shall meet the following additional requirements:

i. 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 of that portion of the image receptor that has been selected on the spot film selector. Such adjustment shall be automatically accomplished when the X-ray field size in the plane of the image receptor is greater than that of the selected portion of the image receptor. If the X-ray field size is less than that of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation;

ii. it shall be possible to adjust the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

iii. 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 image receptor to within 2 percent of the SID; and

iv. means shall be provided to reduce the X-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(a). for spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the X-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

(b). for spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

c. A capability may be provided for overriding the automatic X-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic X-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

d. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

e. Fluoroscopy and Radiography Using the Fluoroscopic Imaging Assembly with Inherently Circular Image Receptors

i. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(a). neither the length nor 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 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID; and

(b). for rectangular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

ii. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the X-ray field in the plane of the image receptor shall conform with one of the following requirements:

(a). when any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the X-ray field overlaps the visible area of the image receptor; or

(b). when any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the X-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

f. Fluoroscopy and Radiography Using Fluoroscopic Imaging Assembly with Inherently Rectangular Image Receptors

i. For X-ray systems manufactured on or after June 10, 2006, the following applies:

(a). neither the length nor 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 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID; and

(b). the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

g. Override Capability. If the fluoroscopic X-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.

3. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device that 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 exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

4. Air Kerma Rates (AKR)

a. Fluoroscopic Equipment Manufactured Before May 19, 1995

i. Fluoroscopic equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in LAC 33:XV.605.A.4.d, except as specified in LAC 33:XV.605.A.4.a.v.

ii. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in LAC 33:XV.605.A.4.d, except as specified in LAC 33:XV.605.A.4.a.v.

iii. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in LAC 33:XV.605.A.4.d, except as specified in LAC 33:XV.605.A.4.a.v.

iv. Equipment may be modified in accordance with this Section to comply with LAC 33:XV.605.A.4.b. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH LAC 33:XV.605.

v. Exceptions: during recording of fluoroscopic images.

b. Fluoroscopic Equipment Manufactured On or After May 19, 1995

i. Equipment shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in LAC 33:XV.605.A.4.d. Provision for manual selection of technique factors may be provided.

ii. Equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in LAC 33:XV.605.A.4.d, except as specified in LAC 33:XV.605.A.4.b.iii.

iii. Exceptions:

(a). for equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the X-ray source is operated in a pulsed mode; or

(b). for equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

c. When optional high level control is selected and the control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in LAC 33:XV.605.A.4.d. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the operator shall indicate that the high level control is being employed.

d. Compliance with the requirements of LAC 33:XV.605.A.4 shall be determined as follows:

i. if the source is below the X-ray table, the AKR shall be measured 1 centimeter above the tabletop or cradle;

ii. if the source is above the X-ray table, the AKR shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

iii. in a C-arm or L-U arm type of fluoroscope, the AKR shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

iv. in a C-arm type fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD; and

v. in a lateral type fluoroscope, the AKR shall be measured at a point 15 centimeters 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 center line of the X-ray table.

5. Barrier Transmitted Radiation Rate Limits

a. The AKR due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed $3.34X10^{-3}$ percent of the entrance AKR at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

b. Measuring Compliance of Barrier Transmission

i. The AKR due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

ii. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

iii. If the source is above the tabletop and the SID is variable, the measurement shall be made 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.

iv. Movable grids and compression devices shall be removed from the useful beam during the measurement.

v. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

6. Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

7. Source-to-Skin Distance. The SSD shall not be less than:

a. 38 centimeters on stationary fluoroscopic systems;

b. 30 centimeters on all mobile fluoroscopes; and

c. 20 centimeters for fluoroscopes intended for specific surgical or interventional applications that would be prohibited at the source-to-skin distances specified in this Paragraph. Provisions shall be made for operating at shorter source-to-skin distances.

d. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-to-image receptor distance of less than 45 cm, means shall be provided to limit the source-to-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical applications that would be prohibited at the source-to-skin distance specified in this Paragraph, provisions shall be made for operation at shorter source-to-skin distances, but not less than 10 cm.

8. Fluoroscopic Irradiation Time, Display, and Signal

a. Fluoroscopic equipment manufactured before June 10, 2006:

i. shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. Fluoroscopic equipment shall be modified in accordance with LAC 33:XV.605 to comply with the requirements of this Paragraph. When the equipment is modified, it shall bear a label indicating the statement:

MODIFIED TO COMPLY WITH LAC 33:XV.605; or

ii. as an alternative to the requirements of this Paragraph, radiation therapy simulation systems shall be provided with a means to indicate the total cumulative exposure time during which X-rays were produced, and which is capable of being reset between X-ray examinations.

b. For X-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

i. a display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this Subparagraph. The following requirements apply:

(a). when the X-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds;

(b). the fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset; and

(c). means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure;

ii. a signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds.

9. Display of Last-Image-Hold (LIH). Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

a. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to the initiation of the fluoroscopic exposure.

b. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

c. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

10. Displays of Values of AKR and Cumulative Air Kerma. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist’s working position the AKR and cumulative air kerma. The following requirements apply for each X-ray tube used during an examination or procedure.

a. When the X-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

b. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

c. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

d. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

i. For fluoroscopes with X-ray source below the X-ray table, X-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in LAC 33:XV.605.A.4.d.i, ii, or v for measuring compliance with AKR limits.

ii. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the X-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the X-ray beam with the patient's skin.

e. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

f. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than +/- 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication

of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.

11. Protection from Scattered Radiation

a. For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

b. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.

i. Shielding required under LAC 33:XV.605.A.11.a shall be maintained to the degree possible under the clinical conditions.

ii. All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm.

iii. The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest).

iv. Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or nonuse of the protective drapes.

12. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of LAC 33:XV.605.A.1, 4, 5, and 8, provided that:

a. 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 when the system is producing X-rays; and

b. systems that do not meet the requirements of LAC 33:XV.605.A.8 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.

B. Operator Qualifications

1. In addition to the applicable sections of these regulations, the operation of a fluoroscopic X-ray system for clinical purposes shall be limited to:

a. a licensed practitioner or medical resident working within his or her scope of practice;

b. an individual who has passed the American Registry of Radiologic Technologists (ARRT) Fluoroscopy Exam (or equivalent) and holds a valid certification, and only under the general supervision of the licensed practitioner meeting the conditions in LAC 33:XV.605.B.1.a; or

c. a radiologic technologist not meeting LAC 33:XV.605.B.1.b, or a radiologic technology student, in training, and only under the personal supervision of the licensed practitioner meeting the conditions of LAC 33:XV.605.B.1.a.

2. All persons operating, or supervising the operation of, fluoroscopy systems shall have completed a minimum of two hours of training that includes but is not limited to the following:

a. basic properties of radiation;

b. biological effects of X-ray;

c. radiation protection methods for patients and staff;

d. units of measurement and dose, including dose-area product (DAP) values and air kerma;

e. factors affecting fluoroscopic outputs;

f. high level control options;

g. dose management including dose reduction techniques, monitoring, and recording;

h. principles and operation of the specific fluoroscopic X-ray system(s) to be used;

i. fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and

j. applicable requirements of these regulations.

3. Documentation pertaining to the requirements of LAC 33:XV.605 shall be maintained for review by the department for three years.

C. Equipment Operation

1. All fluoroscopic images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

3. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.

4. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize dose to the conceptus.

5. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

6. The registrant shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

7. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures.

D. Qualified Expert (QE) Evaluations

1. Fluoroscopic equipment shall be evaluated by a QE within 30 days of installation and of any maintenance of the system that may affect the exposure rate. Thereafter, the measurements shall be made at intervals of no less than 12 months, and no more than 14 months, from the date of the prior measurement by or under the direction of a QE. At a minimum, these evaluations shall include:

a. a measurement of entrance exposure rates that covers the full range of patient thicknesses including those that are expected to drive the system to maximum output in normal mode. In addition, a single representative measurement of maximum output in all other available modes clinically used must be performed. These measurements shall:

i. for systems without automatic exposure control, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

ii. for systems with automatic exposure control, be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

b. a measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with LAC 33:XV.605.A.4.d;

c. an evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes;

d. an evaluation of the operation of the five-minute timer, warning lights, interlocks, and collision sensors;

e. an evaluation of the beam quality;

f. an evaluation of collimation in the fluoroscopy and spot-film modes;

g. an evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays; and

h. an evaluation of any changes that may impact patient and personnel protection devices.

2. Measurements required in LAC 33:XV.605.D.1 shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed two years and records maintained for five years for inspection by the department.

E. Additional requirements for facilities performing fluoroscopically-guided interventional (FGI) procedures are as follows:

1. provide an annual report to the radiation safety committee or the person responsible for radiation safety, in the absence of a radiation safety committee;

2. establish and implement FGI procedure protocols as follows:

a. the registrant shall establish and implement written protocols, or protocols documented in an electronic report system, that include but are not limited to the following:

i. identification of individuals who are authorized to use fluoroscopic systems for interventional purposes;

ii. a method to be used to monitor patient radiation dose during FGI;

iii. dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety; and

iv. a review of the established protocols at intervals of no less than 12 months, and no more than 14 months, from the previous review;

b. a record of each protocol shall be maintained for inspection by the department. If the registrant revises a protocol, documentation shall be maintained that includes the justification for the revision and the previous protocol for inspection by the department;

3. develop procedures for maintaining records as follows:

a. a record of radiation output information shall be maintained in an area where any fluoroscopist shall have ready access to such results while using the fluoroscope so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

i. patient identification;

ii. type and date of examination;

iii. identification of the fluoroscopic system used;

iv. peak skin dose, cumulative air kerma, or dose area product used if the information is available on the fluoroscopic system; and

v. if the peak skin dose, cumulative air kerma, or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following, as necessary:

(a). fluoroscopic mode, such as, high-level or pulsed mode of operation;

(b). cumulative fluoroscopic exposure time; and

(c). number of films or recorded exposures;

b. the registrant shall maintain records required by this Paragraph for inspection by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2270 (October 2000), LR 26:2586 (November 2000), LR 28:1952 (September 2002) , amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§606. Radiographic Systems Other Than Fluoroscopic, Dental, or Computed Tomography X-Ray Systems

A. — A.1. …

a. there shall be provided a means of stepless adjustment of the size of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

b. a method 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 the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 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;

c. when a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement;

d. the edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I1/I2, where I1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm; and

e. the department may grant an exemption on X-ray systems to LAC 33:XV.606.A.1.a-d provided the registrant makes a written application for such exemption and in that application:

i. demonstrates that it is impractical to comply with LAC 33:XV.606.A.1.a-d; and

ii. the purposes of LAC 33:XV.606.A.1.a-d will be met by other methods.

2. Additional Requirements for Stationary General Purpose X-Ray Systems, Including Veterinary Systems Installed after February 21, 1991. In addition to the requirements of LAC 33:XV.606.A.1, stationary general purpose X-ray systems shall meet the following requirements:

a. …

b. the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted;

c. indication of the field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

d. compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use or at any other specific dimensions at which the beam-limiting device or its associated diagnostic X-ray system is uniquely designed to operate.

3. …

4. Beam Limitation and Alignment on Stationary General Purpose X-Ray Systems. For stationary, general purpose X-ray systems that contain a tube housing assembly, an X-ray control, and for those systems so equipped, with a table, all certified in accordance with the USFDA regulations, the following requirements apply.

a. Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:

i. the image receptor is inserted into a permanently mounted cassette holder;

ii. the image receptor length and width are each less than 50 centimeters;

iii. the X-ray beam axis is within +3 degrees of vertical, and the SID is 90 centimeters to 130 centimeters inclusive, or the X-ray beam axis is within +3 degrees of horizontal, and the SID is 90 centimeters to 205 centimeters inclusive;

iv. the X-ray beam axis is perpendicular to the plane of the image receptor to within +3 degrees;

v. neither tomographic nor stereoscopic radiography is being performed; and

vi. the PBL system has not been intentionally overridden. This override provision is subject to LAC 33:XV.606.A.4.c.

b. Positive beam limitation (PBL) shall prevent the production of X-rays when:

i. either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by LAC 33:XV.606.A.4.e., from the corresponding image receptor dimensions by more than 3 percent of the SID;

ii. the sum of the length and width differences as stated in LAC 33:XV.606. A.4.b.i. without regard to sign exceeds 4 percent of the SID; or

iii. the beam-limiting device is at an SID for which PBL is not designed for sizing.

c. If a means of overriding the positive beam limitation (PBL) system exists, that means shall meet the following criteria:

i. the means of overriding the PBL system shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

ii. if in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator, the means for overriding the PBL system shall require that:

(a). a key be utilized to defeat the PBL;

(b). the key remain in place during the entire time the PBL system is overridden; and

(c). the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION

SYSTEM FAILURE

d. Compliance with LAC 33:XV.606. A.4.b. shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of LAC 33:XV.606. A.4.a. are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

e. The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

f. The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in LAC 33:XV.606.A.5.b, then any change of image receptor size or SID shall cause the automatic return.

5. X-Ray Systems Other Than Those Described in LAC 33:XV.606.A.1, 2, 3, and 4, including Veterinary Systems Prior to February 21, 1991. These systems shall meet the following requirements:

A.5.a. — B.2.b.iv. …

v. a visible signal shall indicate when an exposure has been terminated at the limits specified in LAC 33:XV.606.B.2.b.iv, and manual resetting shall be required before further automatically timed exposures can be made.

3. — 6. …

a. stationary X-ray systems shall be required to have the X-ray control, including the exposure switch, permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

b. — b.ii. …

7. Operator Protection for Veterinary Systems and Panoramic Dental Systems. All stationary, mobile, or portable X-ray systems used for veterinary work or panoramic dental systems shall be provided with either a 6.5 feet (2 meters) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 12 feet (3.7 meters) from the tube housing assembly during exposures. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam.

8. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the X-ray control and at or near the tube housing assembly which has been selected.

C. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to be equal to or greater than 30 centimeters, except veterinary equipment.

D. Exposure Reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control (phototiming) systems, the coefficient of variation of exposure for both manual and phototimed systems shall not exceed 0.05. This requirement shall be deemed to have been met if, when 10 exposures are made at identical technique factors, the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) shall be less than or equal to 10 percent of the average exposure (E):

$$(E_{max} - E_{min}) \leq 0.1E$$

E. Radiation from Capacitor Energy Storage 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 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm.

F. …

G. Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

1. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs or mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$$(X_1 - X_2) \leq 0.10\,(X_1 + X_2)$$

where:

X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two consecutive mAs selector settings.

2. Equipment Having a Combined X-Ray Tube Current Exposure Time Product (mAs) Selector. The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs or mR/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$(X_1 - X_2) \leq 0.10\,(X_1 + X_2)$$

where:

X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two consecutive mAs selector settings.

3. Measuring Compliance. Determination of compliance shall be based on 10 exposures, of no less than 0.05 seconds each, taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

H. Portable Radiographic X-Ray Systems. A tube stand or other mechanical support shall be used for portable X-ray systems except during veterinary field operations where it is impractical to do so.

I. Systems Designed for Mammography. Systems designed for mammography use shall meet all applicable sections of the most current Mammography Quality Standards Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2586 (November 2000), LR 27:1237 (August 2001), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§607. Dental Radiographic Systems

A. In addition to the provisions of LAC 33:XV.603 and 604, the requirements of this Section apply to dental radiographic facilities using intraoral, panoramic, and cephalometric systems. Dental facilities using cone beam computed tomography (CBCT) technology shall follow applicable provisions of LAC 33:XV.610.G.

1. Warning Label.

a. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, or the warning statement in LAC 33:XV.607.A.1.b, legible and accessible to view: “WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.”

b. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: “WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.”

2. — 2.c. …

3. Radiation Exposure Control for Certified Systems. The following requirements shall be met.

a. — b. …

i. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor;

ii. — iii. …

c. Exposure Indication. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

d. Exposure Duration (Timer) Reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to 10 percent of the average time (T), when 10 timing tests are performed:

$$(T_{\max} - T_{\min}) \leq 0.10T$$

e. Exposure Control Location and Operator Protection. Each X-ray control shall be located in such a way as to meet the following requirements. Except for units designed to be hand-held, the exposure control shall allow the operator to be:

i. behind a protective barrier at least 6.5 feet (2.0 m) high; or

ii. at least 12 feet (3.7 m) from the tube housing assembly while making exposures; and

iii. the operator’s protected area shall provide means to view the patient during the X-ray procedure.

f. Administrative controls include the following.

i. For human use:

(a). patient and film holding devices shall be used when the techniques permit;

(b). except for units designed to be hand-held, the tube housing and the PID shall not be hand-held during an exposure;

(c). the X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of LAC 33:XV.607.A.2.a; and

(d). dental fluoroscopy without image intensification shall not be used.

ii. For nonhuman use:

(a). Except for units designed to be hand-held, the tube housing and the PID shall not be hand-held during the exposure.

(b). The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of LAC 33:XV.607.A.2.a.

(c). Dental fluoroscopy without image intensification shall not be used.

(d). An operator shall wear a 0.25 lead equivalent apron during an exposure or a personal dosimetry badge.

(e). Unless required to restrain an animal, the operator shall stand at least six feet away from the useful beam and the animal during radiographic exposures.

(f). 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.

(g). When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be used when technique permits.

4. Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 10 exposures are made within a period of one hour at identical technique factors, the difference

between the maximum exposure value (E_{max}) and the minimum exposure value (E_{min}) shall be less than or equal to 10 percent of the average exposure (E):

$$(E_{\max} - E_{\min}) \leq 0.10E$$

5. — 7. …

8. Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than 18 centimeters.

9. Hand-Held Intraoral Equipment. In addition to the standards in this Chapter, the following applies specifically to hand-held devices.

a. The hand-held X-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.

b. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer.

c. The facility shall adopt and follow protocols provided by the manufacturer regarding the safe operation of the device.

d. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

e. The registrant shall secure the hand-held device from unauthorized removal or use.

10. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

11. 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.

12. Battery Charge Indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

13. Locks. All position locking, holding, and centering devices on the X-ray system components and systems shall function as intended.

B. Additional Requirements for Extraoral, Panoramic, and Cephalometric Units.

1. X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means 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 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and alignment of the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

a. 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 designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

b. a beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of the Secretary, Legal Affairs Division, LR 33:449 (March 2007), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§610. Computed Tomography X-Ray Systems

Contrast Scale—Repealed.

CS—Repealed.

CT Conditions of Operation—Repealed.

CT Gantry—Repealed.

CTN—Repealed.

CT Number—Repealed.

Dose Profile—Repealed.

Elemental Area—Repealed.

Multiple Tomogram System—Repealed.

Noise—Repealed.

Nominal Tomographic Section Thickness—Repealed.

Picture Element—Repealed.

Reference Plane—Repealed.

Scan—Repealed.

Scan Increment—Repealed.

Scan Sequence—Repealed.

Scan Time—Repealed.

Single Tomogram System—Repealed.

Tomographic Plane—Repealed.

A. Requirements for CT Equipment

1. Technical and Safety Information. The technical and safety information relating to the conditions of operation, dose information, and imaging performance provided by the CT manufacturer shall be maintained by the facility.

2. Termination of Exposure.

a. Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup 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 LAC 33:XV.610.A.2.a.

c. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than 0.5 second duration.

3. Tomographic Plane Indication and Alignment

a. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, 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.

c. If a mechanism using a light source is used to satisfy LAC 33:XV.610.A.3.a or b, the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

4. Beam On and Shutter Status Indicators and Control Switches.

a. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced.

b. Each emergency button or switch shall be clearly labeled as to its function.

5. Indication of CT Conditions of Operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

6. Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985

a. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

b. If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be discernible from

any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

c. The deviation of indicated scan increment versus actual increment shall not exceed +1 millimeter with any mass from zero to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

d. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

B. Facility Design Requirements

1. Aural Communication. Provision shall be made for two way aural communication between the patient and the operator at the control panel.

2. Viewing Systems. Provisions shall be made as follows:

a. windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel; and

b. when the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

C. CT Surveys, Performance Evaluations, Routine Quality Control, and Operating Procedures

1. Radiation Protection Surveys

a. All CT X-ray systems installed after February 20, 1991, shall have a radiation protection survey completed by, or under the general supervision of, a qualified expert within 30 days of installation. Existing systems not previously surveyed shall have a survey completed by, or under the general supervision of, a qualified expert. The survey shall be completed in no less than 12 months, and no more than 14 months, from [promulgation date], the effective date of these regulations. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

b. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the department upon request.

2. System Performance Evaluations

a. The testing of the CT X-ray system shall be at intervals of no less than 12 months, and no more than 14 months, performed by, or under the general supervision of, a qualified expert who assumes the responsibility and signs the final performance evaluation report.

b. Evaluation standards and tolerances shall be established by the qualified expert and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT X-ray system.

c. The evaluation of a CT X-ray system shall be performed within 30 days after initial installation and at intervals of no less than 12 months, and no more than 14 months thereafter. In addition, the qualified expert shall complete an evaluation of the CT system within 30 days or after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output or image quality.

d. The evaluation shall include but not be limited to:

i. geometric factors and alignment including:

(a). alignment light accuracy; and

(b). table increment accuracy;

ii. image localization from scanned projection radiograph (localization image);

iii. radiation beam width;

iv. image quality including:

(a). high-contrast (spatial) resolution;

(b). low-contrast resolution;

(c). image uniformity;

(d). noise; and

(e). artifact evaluation;

v. CT number accuracy;

vi. image quality for acquisition workstation display devices;

vii. a review of the results of the routine QC required under LAC 33:XV.610.C.3;

viii. a safety evaluation of audible and visual signals, posting requirements; and

ix. dosimetry.

e. The measurement of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall be calibrated per manufacturer recommendations not to exceed two years.

3. Routine Quality Control. A routine QC program on the CT system shall:

a. be developed by a qualified expert and include acceptable tolerances for points evaluated;

b. incorporate the use of a water equivalent phantom. At a minimum, noise, CT number, and artifacts shall be evaluated;

c. be completed at time intervals and under system conditions specified by the qualified expert. The interval shall not exceed one week; and

d. be documented and maintained for inspection by the department.

4. Operating Procedures

a. The operator of the CT X-ray system shall meet the minimum operator requirements of these regulations and be specifically trained on the operational features of the unit by a manufacturer's applications specialist or a qualified expert.

b. The following information shall be readily available to the CT operator:

i. instructions on performing routine QC, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the qualified expert for the indicated parameters, and the results of at least the most recent routine QC completed on the system; and

ii. if the qualified expert evaluation or routine QC of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

D. CT Radiation Protocol Committee (RPC). The registrant shall develop and maintain an RPC in accordance with the following.

1. Members of the RPC.

a. Members of the RPC shall include but not be limited to the:

i. lead CT radiologist;

ii. lead CT technologist;

iii. qualified expert; and

iv. other individuals as deemed necessary by the registrant (e.g., radiation safety officer, chief medical or administrative officer, radiology department administrator/manager).

b. If the registrant has more than one site with CT, they may establish a system-wide RPC.

c. Two or more registrants may form a cooperative RPC as long as each facility has a representative on the committee.

d. If the registrant has already established a radiation safety committee, the requirements of this Subsection may be delegated to that committee if the members meet the requirements of LAC 33:XV.610.D.1.

2. Responsibilities of the RPC. The RPC shall:

a. review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol;

b. review the capabilities of the individual CT scanner to ensure maximum performance is achieved;

c. determine and review the protocols used frequently or that could result in significant doses. This review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at 12 month intervals:

i. pediatric head;

ii. pediatric abdomen;

iii. adult head;

iv. adult abdomen;

v. adult chest; and

vi. brain perfusion;

d. establish and implement written protocols, or protocols documented in an electronic reporting system that include, but are not limited to, the following:

i. a method to be used to monitor the CT radiation output;

ii. a standardized protocol naming policy;

iii. a DRL and alert value for CT procedures reviewed in LAC 33:XV.610.D.2.c. Alert values may be applied by using trigger values in conformance with NEMA XR-29 or facility-established values and procedures as defined by the qualified expert;

iv. actions to be taken for cases when the dose alert value was exceeded which may include patient follow-up; and

v. a process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol;

e. if CT fluoroscopy is performed, the RPC shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure;

f. provide a report to the radiation safety committee, or in the absence of a radiation safety committee, the person responsible for radiation safety. Report shall be provided at intervals of no less than 12 months, and no more than 14 months; and

g. at a minimum, the RPC members in LAC 33:XV.610.D.1.a.i-iii shall meet as often as necessary to conduct business, but at 12 month intervals.

3. Records

a. A record of each RPC meeting shall be maintained. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any action taken.

b. The registrant shall maintain a record of the RPC policies and procedures.

c. The registrant shall maintain a record of radiation output information so the radiation dose may be estimated in accordance with established protocols (e.g., SSDE). The record shall include:

i. patient identification;

ii. type and date of examination;

iii. identification of the CT system used; and

iv. the dose values the CT system provides (e.g., $CTDI_{vol}$, DLP, SSDE).

E. Reserved.

F. PET CT and SPECT CT Systems. CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in Subsections A – D of this Section, unless otherwise exempted below.

1. In lieu of LAC 33:XV.610.C.2, a qualified expert shall complete a performance evaluation of the CT system following manufacturer's protocol. The evaluation shall be completed at intervals of no less than 12 months, and no more than 14 months.

2. In lieu of LAC 33:XV.610.C.3, routine QC checks shall be completed at intervals not to exceed one week. These checks shall be established and documented by a qualified expert following manufacturer's protocol.

3. Accreditation. Unless otherwise authorized by the department, all diagnostic CT x-ray systems for human use shall be accredited by a department-recognized accredited organization.

G. Cone Beam Computed Tomography (CBCT) Systems

1. CBCT facilities shall meet LAC 33:XV.604, 606.B and C, and 610.A.2-6, as applicable.

2. Beam Alignment. The X-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition , the center of the X-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.

3. A performance evaluation shall be performed by, or under the general supervision of, a qualified expert. The evaluation shall follow nationally recognized standards and tolerances. The evaluation shall be performed within 30 days of the initial installation, at intervals of no less than 12 months, and no more than 14 months, and within 30 days after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output or image quality. The facility shall maintain documentation of the established standards and tolerances and testing results.

4. The registrant shall follow the quality control recommendations provided by the CBCT manufacturer. In the absence of manufacturer provided quality control recommendations, the registrant shall implement and document quality control guidelines established by the qualified expert in accordance with nationally recognized guidelines.

5. The registrant or radiation protocol committee, if established, shall implement and document a policy addressing deviations from established protocols.

6. The CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.

7. The following information shall be readily available to the CBCT operator:

a. instructions on performing routine quality control, including the use of the CBCT phantom(s), a schedule of routine quality control appropriate for the system, allowable variations

set by the qualified expert, if required, for the indicated parameters, and the results of at least the most recent routine quality control completed on the system.

8. Exemption. A qualified expert performance evaluation on CBCT systems capable of operating at no greater than 100 kV or 20 mA shall be performed at intervals not to exceed 24 months, or an interval approved by the department.

9. Exemption. The registrant using fluoroscopy systems capable of CBCT shall meet LAC 33:XV.610.G, except LAC 33:XV.610.A.2-6 in LAC 33:XV.610.G.1.

H. Veterinary CT Systems. CT systems, including CBCT systems, solely used in nonhuman imaging shall meet the requirements of LAC 33:XV.610.C.1 (radiation protection surveys) and are otherwise exempt from the standards of LAC 33:XV.610.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2586 (November 2000), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§611. Dual-Energy X-ray Absorptiometry (DXA) (Bone Densitometry)

A. DXA systems shall be:

1. registered in accordance with Chapter 2 of these regulations; and

2. at a minimum, maintained and operated in accordance with the manufacturer’s specifications.

B. Operator Requirements. Operators shall complete training specific to patient positioning and the operation of the DXA system.

C. During the operation of any DXA system:

1. in the absence of a survey performed by or under the supervision of a qualified expert determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least two meters from the patient and DXA system during the examination.

D. Quality Assurance. In addition to the applicable requirements in LAC 33:XV.603.F.1, a facility performing DXA shall conform to the DXA system manufacturer recommendations and recommendations of recognized professional societies, such as the International Society for Clinical Densitometry or the American College of Radiology.

E. Records. The registrant shall keep the following records for a minimum of three years:

1. the maintenance and QC tests as prescribed by LAC 33:XV.611.A.2 and 611.D; and

2. operator training records as prescribed by LAC 33:XV.611.B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

§699. Appendices A, B, C, and D

Appendix A …

Appendix B

Design Requirements for an Operator's Booth

A. — B. …

1. When a door or movable panel is used as an integral part of the booth structure, it shall have an interlock that will prevent an exposure when the door or panel is not closed.

B.2. — D.1.a. …

b. the operator can have full view of any occupant of the room, and the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the

booth, then that door shall have an interlock controlling the exposure that will prevent the exposure if the door is not closed.

D.2. — D.4.b. …

Appendix C

Information to be Submitted by Persons

Proposing to Conduct Healing Arts Screening

Persons requesting that the department approve a healing arts screening program shall submit the following information for evaluation and approval.

A. — B. …

C. A detailed description of the X-ray examinations proposed in the screening program, i.e., type and number of views.

D. Description of the population to be examined in the screening program, i.e., age range, sex, physical condition, and other appropriate information.

E. — F. …

G. A description of the X-ray quality control program.

H. A copy of the protocol information for the X-ray examination procedures to be used.

I. — J. …

K. The name and address of the practitioner licensed in Louisiana who will interpret the radiograph(s).

L. Procedures to be used in advising the individuals screened and their practitioner of the healing arts or health care provider of the results of the screening procedure and any further medical needs indicated.

M. Procedures for the retention or disposition of the radiograph(s) and other records pertaining to the X-ray examination(s).

N. — P. …

Q. Frequency of screening of individuals.

R. The duration of the screening program.

Appendix D.

A. Each installation using a radiographic X-ray system and using analog image receptors (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

1. manually developed film:

a. processing tanks for manually developed film shall be constructed of mechanically rigid, corrosion resistant material;

b. the temperature of solutions in the tanks for manually developed film shall be maintained within the range of 60°-80°F (16°-27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		**Minimum Developing Time (Minutes)**
°C	**°F**	
26.7	80	2
26.1	79	2

Time-Temperature Chart		
Thermometer Reading (Degrees)		**Minimum Developing Time (Minutes)**
ºC	**ºF**	
25.6	78	2 1/2
25.0	77	2 1/2
24.4	76	3
23.9	75	3
23.3	74	3 1/2
22.8	73	3 1/2
22.2	72	4
21.7	71	4
21.1	70	4 1/2
20.6	69	4 1/2
20.0	68	5
19.4	67	5 1/2
18.9	66	5 1/2
18.3	65	6
17.8	64	6 1/2
17.2	63	7
16.7	62	8

Time-Temperature Chart		
Thermometer Reading (Degrees)		**Minimum Developing Time (Minutes)**
ºC	**ºF**	
16.1	61	8 1/2
15.6	60	9 1/2

c. devices shall be utilized for manually developed film that will:

i. indicate the actual temperature of the developer; and

ii. signal the passage of a preset time appropriate to the developing time required;

2. automatic processors and other closed processing systems:

a. films shall be developed by automatic processors and other closed processing systems in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		**Minimum Immersion Time***
ºC	**ºF**	**Seconds**
35.5	96	19
35	95	20
34.5	94	21
34	93	22

33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
*Immersion time only, no crossover time included.		

b. the specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor in a manner that provides sufficient and legible notice to persons present in these areas;

3. other requirements:

a. pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

b. the darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film;

c. darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed;

d. film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container;

e. film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of acceptable diagnostic quality;

f. outdated X-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed; and

g. film developing solutions shall be prepared in accordance with the directions given by the manufacturer of the chemicals, and shall be maintained in strength by replenishment or renewal so that full development of film is accomplished within the time specified by the manufacturer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2586 (November 2000), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 48:

Family Impact Statement

This Rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

Poverty Impact Statement

This Rule has no known impact on poverty as described in R.S. 49:973.

Small Business Analysis

This Rule has no known impact on small business as described in R.S. 49:978.1 - 978.8.

Provider Impact Statement

This Rule has no known impact on providers as described in HCR 170 of 2014.

Public Comments

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP068. Such comments must be received no later than March 4, 2022, at 4:30 p.m., and should be sent to Deidra Johnson, Attorney Supervisor, Office of the Secretary, Legal Affairs and Criminal Investigations Division, P.O. Box 4302, Baton Rouge, LA 70821-4302 or by FAX (225) 219-4068 or by e-mail to DEQ.Reg.Dev.Comments@la.gov. Copies of these proposed regulations can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP068. These proposed regulations are available on the Internet at https://www.deq.louisiana.gov/page/monthly-regulation-changes-2022%20.

Public Hearing

A public hearing will be held via Zoom on February 25, 2022, at 1:30 p.m. Interested persons are invited to attend and submit oral comments via PC, Mac, Linux, iOS or Android at https://deqlouisiana.zoom.us/j/9373792954 or by telephone by dialing 636-651-3182 using the conference code 725573. Should individuals with a disability need an accommodation in order to participate, contact Deidra Johnson at the address given below or at (225) 219-3985.

These proposed regulations are available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374; 201 Evans Road, Bldg. 4, Suite 420, New Orleans, LA 70123.

Courtney J. Burdette
General Counsel

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Richard "Scott" Blackwell
Richard.Blackwell@LA.GOV
Phone: (225) 219-3639

Dept.: Environmental Quality

Office: OEC/ERSD/Radiation

Return Address: P. O. Box 4312
Baton Rouge, LA 70821-4312

Rule Title: Chapter 6 X-Rays in the Healing Arts Update (LAC 33:XV.602, 603, 604, 605, 606, 607, 610, 611, and 699)

Date Rule Takes Effect: upon promulgation

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no implementation costs or savings to state or local governmental units.

The proposed rule will update the majority of Chapter 6 X-Rays in the Healing Arts. The regulations need updating to align with current manufacturer requirements and new x-ray technology and industry standards. The proposed rule will more closely align Louisiana regulations with current national standards.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no anticipated effect on revenue collections of state and local governmental units from this proposed action.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

This proposed action may have a minimal effect on costs to the regulated entities (x-ray registrants) due to possible additional time that it may take health physicists to perform the newly required quality control checks of x-ray units. Health physicists may have slightly increased income due to the need for them to perform more quality control testing of x-ray units. Consequently, the regulated entities that employ these health physicists may experience a slight increase in costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This proposed action will have no impact on competition and employment in the public and private sectors.

Signature of Agency Head or Designee	Legislative Fiscal Officer or Designee
Courtney J. Burdette, General Counsel Typed Name & Title of Agency Head or Designee	
Date of Signature	Date of Signature