

**RULES  
OF  
TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION  
DIVISION OF RADIOLOGICAL HEALTH**

**CHAPTER 0400-20-06  
USE OF X-RAY APPARATUS**

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**0400-20-06-.01 PURPOSE.**

This Chapter establishes requirements for the use of x-ray apparatus, except industrial radiography. The provisions of this Chapter are in addition to and not in substitution for other applicable provisions of these regulations.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

**0400-20-06-.02 SCOPE.**

Except as otherwise specifically provided, this chapter applies to all uses of x-ray apparatus in the healing arts, veterinary medicine, industry and educational institutions.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

**0400-20-06-.03 DEFINITIONS.**

- (1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
- (2) "Added filter" means the filter added to the inherent filtration.
- (3) "Aluminum equivalent" means the thickness of aluminum (Type 1100 alloy)<sup>1</sup> affording the same attenuation, under specified conditions, as the material in question.
- (4) "Analytical x-ray equipment" means any device that utilizes x-rays for the purpose of examining the microstructure of materials.
- (5) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, or type 1100 aluminum alloy<sup>1</sup> or other materials having equivalent attenuation.
- (6) "Automatic exposure control" means a device that automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation.

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<sup>1</sup> The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper. "Aluminum – Standards and Data," The Aluminum Association, New York, New York. (1969).

(Rule 0400-20-06-.03, continued)

- (7) "Beam axis" means a line from the source through the centers of the x-ray fields.
- (8) "Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.
- (9) "Certified components" means components of diagnostic x-ray systems that are subject to regulations promulgated under P.L. 90-602.
- (10) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.
- (11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.
- (12) "Contact therapy apparatus" means x-ray apparatus designed for therapy at very short treatment distances, 5 centimeters or less, usually employing tube potentials in the range of 20 to 50 kVp.
- (13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (14) "Diagnostic source assembly" means the tube housing assembly with a beam limiting device attached.
- (15) "Diagnostic type tube housing" means X-ray tube housing so constructed that at a distance of 1 meter from the target, the leakage cannot exceed 100 milliroentgens in 1 hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential. An acceptable method for the determination of the maximum leakage from an x-ray tube is to take measurements at 8 compass points in each of the 3 planes at right angles to each other at 1 meter from the target with the useful beam blocked with ten half-value layers (HVL) of attenuating material.
- (16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- (17) "Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.
- (18) "Entrance exposure rate" means the roentgens per minute at the point where the center of the useful beam enters the patient.
- (19) "Equipment" means X-ray equipment.
- (20) "Fail-safe design" means one in which all failures of indicator of safety components that can reasonably be anticipated cause the equipment to fail in a mode such that personnel are safe from exposure to radiation. For example: (a) if a light indicating X-RAY ON fails, the production of x-rays shall be prevented, and (b) if a shutter status indicator fails, the shutter shall close.
- (21) "Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (22) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiations.
- (23) "Fluoroscopic imaging assembly" means a component that comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housing, electrical

(Rule 0400-20-06-.03, continued)

interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

- (24) "General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.
- (25) "Gonadal shield" means a protective barrier for the gonads.
- (26) "Half-value layer" (HVL) means thickness of an absorber required to reduce a beam of radiation to one-half its incident exposure rate.
- (27) "Image intensifier" means a device that converts instantaneously by means of photo-emissive surfaces and electronic circuitry an x-ray pattern into a light pattern of greater intensity than would have been produced by the original x-ray pattern.
- (28) "Image receptor" means any device, such as a "fluorescent screen or radiographic film," that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.
- (29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.
- (30) "Kilovolts peak" (kVp) means the crest value in kilovolts of the potential difference of a pulsating potential generator. When only one-half of the wave is used, the value refers to the useful half of the wave.
- (31) "kWs" means kilowatt second which is equal to the product of kilovolts, amperes, and seconds or  $10^3$  kVp.mA.sec.
- (32) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (33) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:
- (a) The useful beam and
  - (b) Radiation produced when the exposure switch or timer is not activated.
- (34) "Leakage technique factors" means the technique factors associated with the tube housing assembly that are used in measuring leakage radiation. They are defined as follows:
- (a) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.
  - (b) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
  - (c) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.
- (35) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor,

(Rule 0400-20-06-.03, continued)

whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

- (36) "Misadministration" means an event that meets the criteria in Rule 0400-20-05-.145.
- (37) "Mobile equipment". See "X-ray equipment".
- (38) "Multipurpose radiographic equipment" means an x-ray machine designed or used for radiographic examinations of more than one part of the body, or one designed or used for both diagnosis and therapy.
- (39) "Normal operation" means operation under conditions suitable for collecting data as recommended by a manufacturer of the x-ray system. Recommended shielding and barriers shall be in place.
- (40) "Open beam x-ray equipment" means an analytical x-ray producing device designed in such a way that the primary beam is not completely enclosed by the tube housing-apparatus complex during normal operation.
- (41) "Phototimer" means a method for timing radiation exposures to image receptors by the amount of radiation that reaches a sensitive photo tube behind the receptor and that provides a means for precisely reproducing densities on these receptors.
- (42) "Primary beam". See "Useful beam" as defined in Rule 0400-20-04-.04.
- (43) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (44) "Portable equipment". See "X-ray equipment".
- (45) "Position indicating device" (PID) means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
- (46) "Protective apron" means an apron made of radiation absorbing materials equivalent to at least 0.25 millimeters of lead used to reduce radiation.
- (47) "Protective glove" means a glove made of radiation absorbing materials equivalent to at least 0.25 millimeters of lead used to reduce radiation exposure.
- (48) "Qualified individual" means an individual who has demonstrated to the satisfaction of the Division that he possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.
- (49) "Radiograph" means a permanent picture or image produced on a sensitive surface by a form of radiation other than visible light.
- (50) "Rating" means the operating limits as specified by the original component manufacturer.
- (51) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).
- (52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. It may also have been modified by a decrease in energy.

(Rule 0400-20-06-.03, continued)

- (53) "Shutter" means an adjustable device, generally of lead, fixed to an x-ray tube housing to intercept or collimate the useful beam.
- (54) "Source" means the focal spot of the x-ray tube.
- (55) "Source-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.
- (56) "Stationary equipment". See "X-ray equipment".
- (57) "Stray radiation" means the sum of leakage and scattered radiation.
- (58) "Technique factors" means the conditions of operation. They are specified as follows:
  - (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.
  - (b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.
  - (c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of the tube current and exposure time in mAs.
- (59) "Total filter" means the sum of the inherent and added filters.
- (60) "Tube" means an x-ray tube, unless otherwise specified.
- (61) "Tube housing-apparatus complex" means those parts of an analytical x-ray device in which x-rays are produced and utilized.
- (62) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.
- (63) "Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.
- (64) "Variable-aperture beam-limiting device" means a beam limiting device that has capacity for stepless adjustment of the x-ray field size at given SID.
- (65) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (66) "X-ray apparatus" means any device for the production of x-rays.
- (67) "X-ray control" means a device that controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment that controls the technique factors of the x-ray exposure.
- (68) "X-ray equipment" means an x-ray system, subsystem, or component thereof.
  - (a) Mobile means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
  - (b) Portable means x-ray equipment designed to be hand-carried.

(Rule 0400-20-06-.03, continued)

- (c) Stationary means x-ray equipment that is installed in a fixed location.
  - (d) Transportable means x-ray equipment to be installed in a vehicle or that may be readily disassembled for transport in a vehicle.
  - (e) "Hand-held" means portable X-ray equipment that is specifically designed to operate when held in a person's hand and is approved by the U.S. Food and Drug Administration (FDA).
- (69) "X-ray field" means 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 exposure rate is one-fourth of the maximum in the intersection.
- (70) "X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.
- (71) "X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location.
- (72) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.
- (73) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Chapter.
- (74) "X-ray tube" means any electron tube that is designed for the conversion of electrical energy into x-ray energy.

**Authority:** T.C.A. §§ 4-5-201, et seq.; 68-202-101, et seq.; and 68-202-201, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012. Amendments filed September 10, 2019; effective December 9, 2019.

#### **0400-20-06-.04 GENERAL SAFETY PRECAUTIONS.**

- (1) No person shall make, sell, lease, transfer, lend, repair, or install x-ray equipment or the supplies used in connection with such equipment unless such supplies or equipment, when properly placed in operation and properly used, will meet the requirements of these regulations. This includes but is not limited to such items as cones, collimators, filters, adequate timers, and fluoroscopic shutters (where applicable). Also, such person shall be registered with the Division pursuant to Rule 0400-20-10-.24.
- (2) Unless otherwise specified, each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with Rule 0400-20-05-.50, 0400-20-05-.55, 0400-20-05-.56 or 0400-20-05-.60, whichever applies.
- (3) No registrant shall operate or permit the operation of x-ray equipment unless the equipment and installation meets the requirements of these regulations.
- (4) The registrant shall assure that all x-ray apparatus under his control is operated only by individuals instructed in safe operating procedures and competent in safe use of the apparatus.

(Rule 0400-20-06-.04, continued)

- (5) Except for medical and dental units, no x-ray apparatus shall be left unattended or unsecured unless the control switch is turned "off," the power to the control switch disconnected, or the room, x-ray apparatus, or area housing the x-ray apparatus is locked.
- (6) Film development procedures recommended by the film manufacturer or other tested procedures shall be followed, which will insure maximum information content of the processed film with minimum radiation exposure. Except where automatic processors are used, it is required that an operable timer and thermometer be available and used for darkroom procedures. Darkrooms shall be light tight and shall contain safelights designed for the film being used.
- (7) The effectiveness of protective equipment shall not be impaired.
- (8) X-ray producing devices and associated equipment shall be maintained in such a condition as to ensure that the patient and attendants are not exposed to radiation unnecessarily.
- (9) The Division may waive compliance with the specific requirements of this rule for an existing x-ray apparatus or installation if:
  - (a) Such compliance would require replacement or substantial modification of the x-ray apparatus or installation; and,
  - (b) The registrant demonstrates, to the Division's satisfaction, achievement through other means, of radiation protection equivalent to that required by these rules.

**Authority:** T.C.A. §§ 4-5-201, et seq.; 68-202-101, et seq.; and 68-202-201, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012. Amendments filed September 10, 2019; effective December 9, 2019.

#### **0400-20-06-.05 MEDICAL X-RAY INSTALLATIONS.**

- (1) Therapeutic x-ray installations.
  - (a) Requirements for equipment and facility:
    1. The tube housing shall be of the therapeutic type.
    2. Adjustable beam limiting diaphragms, cones, or fixed diaphragms shall be provided to collimate the useful beam to the area under treatment.
    3. Fixed diaphragms or cones used to collimate the useful beam shall be so constructed as to provide the same degree of protection as the tube housing.
    4. Adjustable beam limiting diaphragm or cones shall not transmit more than 5 percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter.
    5. The radiation escaping through the filter slots shall not exceed an exposure rate of 1 R/hr at a distance of 1 meter or if the radiation from the slot is accessible to the patient, 30 R/hr at 5 centimeters from the external opening. Each removable filter shall be marked with its thickness and material.
    6. The x-ray tube shall be secured so that it cannot move in respect to the aperture. A mark on the housing shall show the location of the focal spot.

(Rule 0400-20-06-.05, continued)

7. A device shall be provided to immobilize the tube housing during stationary portal treatment.
8. A device shall be provided to terminate the exposure automatically after a preset time interval or preset exposure or dose limit. Means shall be provided for the operator to terminate the exposure at any time.
9. A filter indicator system shall be used on all therapy x-ray apparatus using changeable filters. It shall indicate from the control panel the presence or absence of any filter and it shall be designed to permit recognition of the filter in place. Color coded filters that are visible from the control panel qualify as an adequate indicator system.
10. Interlocks shall be provided so that when any door of the treatment room is opened either the x-ray apparatus will shut off automatically or the radiation exposure level within the room will be reduced to an average of not more than 2 milliroentgens per hour and an maximum of 10 milliroentgens per hour at a distance of 1 meter in any direction from the target. After such shut-off or reduction in output it shall be possible to restore the x-ray apparatus to full operation only from the control panel. For equipment operating at or below 60 kVp interlocks are not required.
11. The treatment room shall be so constructed that persons within the room may at all times be able to escape.
12. A visible signal which is actuated during the time x-rays are being generated shall be located outside and near each door to the treatment room.
13. There shall be on the control panel a device which indicates to the operator whether or not the tube is energized.
14. In the therapeutic use of x-ray apparatus constructed with windows of beryllium, or other material having an aluminum equivalent half-value layer less than 0.5 millimeter, the registrant shall use extreme care to insure that the unfiltered radiation reaches only that area of the patient intended and that the beam port is blocked at all times except when actually being used.
15. For contact therapy apparatus, the leakage radiation exposure at 5 centimeters from the surface of the tube housing shall not exceed 100 milliroentgens per hour.

(b) Conditions of operation:

1. The output of each therapeutic x-ray apparatus shall be calibrated by a qualified individual. The calibration shall be repeated after any change in or replacement of components of the x-ray generating equipment that could cause a change in x-ray output. Check calibrations shall be made at least once a year thereafter. Records of all calibrations shall be maintained by the registrant for inspection by the Division.
2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used whenever feasible. If the patient must be held by an individual, the individual shall wear a protective apron and he shall be positioned so that no part of his body will be struck by the useful beam and his body is as far as possible from the edge of the useful beam and his exposure shall be monitored and a record of such monitoring maintained for

(Rule 0400-20-06-.05, continued)

inspection by the Division. No pregnant women or persons under 18 years of age shall be used for this purpose.

3. Both the patient and control panel shall be under observation by the operator during patient irradiation.
4. All new installations and existing installations not previously surveyed shall have a radiation survey made by a qualified individual or registered inspector for the applicable class of x-ray unit. This shall be done after any change in the installation that might produce radiation levels in excess of those permitted by these regulations. Inadequacies found during the survey shall be corrected. A record of these surveys shall be kept on file for inspection by the Division.
5. Lead rubber, lead foil, or any other material used for limiting the treatment field shall transmit not more than 5 percent of the useful beam as measured when the maximum treatment filter for which the x-ray unit has been calibrated is in place.
6. Provision shall be made for oral communication with the patient from the control area.
7. No one other than the patient shall be in treatment room during treatment except as allowed in part 2. of this subparagraph except that for equipment operating at or below 60 kVp the operator and other persons may be permitted in the room during treatment provided that all such persons utilize protective aprons or their equivalent.

(2) Medical diagnostic x-ray installations.

(a) General requirements. Equipment:

1. The primary beam shall not be larger than clinically necessary. Cones, diaphragms, or adjustable collimators capable of restricting the primary beam to the area of clinical interest or an area within the limits imposed by the following conditions, whichever area is smaller, shall be used. The x-ray field size in the plane of the image receptor, whether controlled by cones, diaphragms, or adjustable collimators shall be such that neither the length nor the width of the x-ray field exceeds that of the image receptor by greater than 3 percent of the source-image receptor distance (SID) and that the sum of the length and width excesses be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor<sup>2</sup>. Cones, diaphragms, or adjustable collimators used to restrict the primary beam shall provide the same degree of protection as is required in the tube housing.
2. (i) Except when contraindicated for a particular diagnostic procedure, the aluminum equivalent of the total filtration (inherent plus added) in the useful beam shall not be less than that shown in Table RHS 3-1.

Table RHS 3-1 FILTRATION REQUIRED VS. OPERATING VOLTAGE

Operating voltage (kVp)	Total filtration (millimeters) Al equivalent
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<sup>2</sup> For purposes of these regulations the length and width measurements will be made through the center of the x-ray field. The length measurement will be made at an angle of 90 degrees to the width measurement. Thus for circular beams the length and width will be equal to the diameter.

(Rule 0400-20-06-.05, continued)

Below 50	0.5
50 - 70	1.5
Above 70	2.5

- (ii) If the thickness of the filter in the x-ray apparatus cannot be determined visually or the total filtration is unknown, it may be assumed that the requirements of subpart (i) of this part are met if the half-value layer is not less than that shown in Table RHS 3-2.

Table RHS 3-2 HALF-VALUE LAYER VS. OPERATING VOLTAGE

Design operating range (kilovolts peak) (kVp)	Measured potential (kVp)	Half-value layer (millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

- (iii) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.
  - (iv) For fluoroscopic equipment, the HVL measurement shall include the filtration contributed by the tabletop if the tabletop is placed permanently between the patient and the source.
3. The x-ray tube housing shall be of diagnostic type.
  4. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
  5. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
  6. Hand or head held fluoroscopic screens shall not be used.

(Rule 0400-20-06-.05, continued)

7. Machines equipped with beryllium window x-ray tubes shall contain keyed filter interlock switches in the tube housing that activate a device on the control panel that indicates the added filter in the useful beam if the total filtration permanently in the useful beam is less than 0.5 millimeter aluminum equivalent. The total filtration permanently in the useful beam shall be indicated on the tube housing.
  8. Beryllium window x-ray tubes shall not be used on multi-purpose radiographic equipment.
  9. 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.
  10. On installations made after March 1, 1978, where two or more tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly that has been selected.
  11. (Reserved)
  12. Tube housing assemblies shall be equipped with a means to assure mechanical support of the housing during exposures without drift or vibration.
  13. Where cones or diaphragms are used as beam limiting devices, each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed.
  14. In addition to other applicable requirements of this Chapter, diagnostic x-ray equipment certified under the Federal standards promulgated by the Department of Health and Human Services, in the Federal Register shall meet the following requirements:
    - (i) Each registrant shall retain, and shall present to the Division for examination when requested, all information provided by the manufacturer to the purchaser in accordance with the requirements of the applicable Federal standard and shall transfer this information to the subsequent owner of the equipment. See Rule 0400-20-06-.09, APPENDIX A.
    - (ii) Each registrant should keep a record of all maintenance and modifications performed on each diagnostic x-ray system containing any components certified under the applicable Federal standard during the period it is under his control, and, if kept, shall be transferred to the subsequent owner of the equipment.
    - (iii) No deviation from the requirements of these regulations will be considered a violation of these regulations if such deviation is permitted by a variance granted by the Food and Drug Administration, Department of Health and Human Services, or by a regulation promulgated pursuant to Public Law 90-602.
- (b) General requirements. Operation of equipment:
1. Patient or film holding

(Rule 0400-20-06-.05, continued)

- (i) Except where clinically contraindicated, restraining devices or mechanical supporting devices shall be used.
  - (ii) No person under eighteen (18) years of age and no pregnant women shall be used.
  - (iii) No individual shall be used on a consistent or routine basis.
  - (iv) Protective gloves and aprons with at least 0.25 millimeters of lead equivalency shall be provided and their use required of each person used for this purpose.
  - (v) No part of the body of the person utilized for this purpose shall be in the primary beam unless protected by 0.5 millimeter of lead equivalent material.
  - (vi) If occupationally exposed persons are utilized their exposure shall be monitored.
2. Gonadal protection, by use of gonadal shields, shall be provided and used for patients who have not passed the reproductive age, during each radiographic procedure in which the gonads are in the useful beam or proximate thereto, except for those cases in which the shield would interfere with the diagnostic procedure. The protection provided shall be at least equivalent to 0.25 millimeters of lead.
  3. Other than the patient being examined no one will be allowed in the room during the radiographic exposure unless:
    - (i) The location of all individuals in the room shall be such that no part of the body including the extremities not protected by 0.5 millimeter lead equivalent will be struck by the useful beam.
    - (ii) 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 millimeters lead equivalent.
    - (iii) Other patients in the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeters lead equivalent 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.
- (c) Radiographic Installations (includes photofluorographic units)
1. The operator shall be able to see the patient and the control panel at all times during an exposure.
  2. Radiographic equipment equipped with adjustable collimators shall contain light localizers that define the entire x-ray field. The size of the light field in the plane of the image receptor shall be such that no dimension of the light field differs from that of the x-ray field by greater than 2 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. The center of the light field shall be aligned with the center of the x-ray field to within 2 percent of the SID when the equipment indicates that the beam axis perpendicular to the plane onto which the x-ray and light fields are

(Rule 0400-20-06-.05, continued)

projected. See part (2)(a)1. of this rule for definition of length and width. The collimator shall also be equipped with a field size indicator that indicates numerically the dimensions of the x-ray field at the source-image receptor distances (SIDs) for which it is designed. Such numerical indication shall not deviate from the actual dimensions of the x-ray field at the SID by more than 2 percent of the SID when the equipment indicates that the axis of the beam is perpendicular to the plane of the image receptor. For equipment utilized in a manner that precludes the necessity of numerical indicators they shall not be required.

3. (Reserved)

4. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

5. Radiation Exposure Control Devices.

(i) Timers

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

- (I) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.
- (II) It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) X-Ray Control

- (I) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time except for:
  - I. Exposure of one-half second or less, or
  - II. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
- (II) Each x-ray control shall be located in such a way as to meet the following criteria:
  - I. For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure, or
  - II. For mobile and portable x-ray systems, a method of control shall be provided that will permit the operator to stand at least 2 meters from the patient, primary beam, and tube head assembly.

(iii) Automatic Exposure Controls (Phototimers). When an automatic exposure control is provided:

(Rule 0400-20-06-.05, continued)

- (I) A device shall be on the control panel that indicates when this mode of operation is selected;
  - (II) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
  - (III) The minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;
  - (IV) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
  - (V) A visible signal shall indicate when an exposure has been terminated at the limits described in item (IV) of this subpart, and manual resetting shall be required before further automatically timed exposures can be made.
- (iv) The exposure shall be reproducible. When 4 exposures are made at identical technique factors the value of the average exposure ( $\bar{E}$ ) shall be greater than or equal to 5 times the difference between the maximum exposure ( $E_{\max}$ ) and the minimum exposure ( $E_{\min}$ ), i.e.,
- $$\bar{E} \geq 5 (E_{\max} - E_{\min}).$$
- (v) The timer shall be reproducible. When 4 timer tests are performed with a timer setting of 0.5 seconds or less, the average time period ( $\bar{T}$ ) shall be greater than or equal to 5 times the difference between the maximum period ( $T_{\max}$ ) and the minimum period ( $T_{\min}$ ), i.e.,
- $$\bar{T} \geq 5 (T_{\max} - T_{\min}).$$
6. Radiation emitted from the x-ray tube of Capacitor Energy Storage Equipment when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
7. For stationary general purpose x-ray systems means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent.
- (d) Fluoroscopic installations

(Rule 0400-20-06-.05, continued)

1. The source to skin distance shall not be less than 30.5 centimeters on stationary equipment installed or reinstalled before July 1, 1972, and shall not be less than 38 centimeters on stationary equipment installed or reinstalled thereafter. The source to skin distance shall not be less than 30.5 centimeters on all mobile fluoroscopes. For image intensified fluoroscopes used for specific surgical applications a source to skin distance of 20 centimeters will be allowed provided the user's operating procedures indicate precautionary measures to be adhered to during this device's use and provided that these precautionary measures are followed by the registrant or his representative.
2. Equipment shall be so constructed that the entire cross-section of the useful beam is attenuated by a primary barrier permanently incorporated into the equipment. The tube mounting and the barrier shall be so linked together that the barrier always intercepts the beam. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.
3. The required lead equivalent of the primary barrier shall be at least 1.5 millimeters for 100 kVp, 1.8 millimeters for 125 kVp, and 2.0 millimeters for 150 kVp. This requirement may be assumed to have been met if the exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, does not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate<sup>3</sup>.
4. Collimators shall be provided to restrict the size of the useful beam to less than the area of the primary barrier. For conventional fluoroscopes, this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen with the screen properly centered in the beam at a distance of 38 centimeters from the panel or tabletop. Collimators shall provide the same degree of protection as is required in the x-ray tube housing. For image intensifiers, the useful beam shall be centered on the input phosphor within  $\pm 2$  percent of the SID and during fluoroscopy or cine-recording it should not exceed the diameter of the input phosphor. Means shall be provided by stepless adjustment to reduce the x-ray field size to 5 by 5 centimeters or less at the maximum SID.
5. For fluoroscopy, the radiation exposure as measured at the minimum target to skin distance shall be as low as practicable and shall not exceed 10 roentgens per minute except where clinically indicated. In cine-radiography, the exposure rates to which patients are normally subjected shall be determined periodically. An adequate period for such measurement shall be annually or after any change in the system that might affect the exposure rate. See subpart 13.(i) of this subparagraph for information on measuring exposure rate.

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<sup>3</sup> Compliance with this part will be determined as follows:

1. The exposure rate due to transmission through the primary barrier combined with radiation through the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
2. 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.
3. 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.

(Rule 0400-20-06-.05, continued)

6. The registrant shall provide protective aprons, and shall require their use by the physician, nurse, technician, and for all other persons within the fluoroscopic room, except the patient.
7. The registrant shall provide protective gloves, and shall require their use by the fluoroscopist during any procedure in which the fluoroscopist may be required to approach the primary beam with his hand or hands.
8. Conventional fluoroscopic screens shall not be used with mobile fluoroscopic equipment. Image intensification shall always be provided, and in the absence of a table top or panel, a cone or spacer frame shall limit the target to skin distance to not less than 30.5 centimeters.
9. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
10. A cumulative timing device actuated by the exposure switch shall be used that will indicate elapsed exposure time by either interrupting the production of x-rays or by emitting a continuous audible warning signal when the total exposure time exceeds a pre-determined limit not exceeding 5 minutes in one or a series of exposures.
11. Fluoroscopic table designs when combined with procedures utilized shall be such that no part of any staff or ancillary person's body shall be exposed to unattenuated direct scattered radiation that originates from under the table. The attenuation required shall be at least equivalent to that of 0.25 millimeters of lead.
12. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary person's body except the extremities shall be exposed to the unattenuated direct scatter radiation emanating from above the table top unless that individual is at least 2 meters from the center of the useful beam. This requirement cannot be met only by wearing a protective apron. Exceptions to this requirement may be made in some special procedures. The attenuation required here shall be at least equivalent to that of 0.25 millimeters of lead, (e.g., drapes, folding panel, or self-supporting curtains).
13. Additional requirements applicable to certified systems only.
  - (i) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute for equipment incorporating automatic exposure control or 5 roentgens per minute for equipment not incorporating automatic exposure control except during recording of fluoroscopic images or when provided with optional high level control. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
    - (l) Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use.

(Rule 0400-20-06-.05, continued)

- (II) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.<sup>4</sup>
  - (ii) For image intensified fluoroscopy, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed 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. Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along with the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.
  - (iii) For spot filming, in addition to other requirements of this section:
    - (I) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.
    - (II) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum at the greatest SID shall be equal to or less than 5 by 5 centimeters.
    - (III) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.
  - (iv) During fluoroscopy and cine-fluorography, x-ray tube potential and current shall be continuously indicated.
- (3) Dental radiographic installations
- (a) Extra-oral dental radiographic equipment shall be considered medical radiographic equipment for the purposes of these regulations.
  - (b) A device shall be used for collimating the primary beam and shall provide the same degree of protection as the tube housing. For intra-oral radiography, the primary beam, as measured at the point where it strikes the patient's face, shall be as small as clinically possible and not more than 7.6 centimeters in diameter. Collimating devices designed to provide rectangular collimation of the primary beam to the size of the dental film should be considered for use when practicable.

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<sup>4</sup> Compliance with this item shall be determined as follows:

1. For all measurements, the attenuation block with 1/8 inches lead sheet shall be placed in the useful beam between the point of measurement of the entrance exposure rate and the input surface of the fluoroscopic imaging assembly. Bottom surface of the block shall be at least 10 centimeters from the point of measurement of the entrance exposure rate.
2. Movable grids and compression devices shall be removed from the useful beam during the measurement.
3. If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.
4. If the source is above the table, the exposure rate 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.
5. In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(Rule 0400-20-06-.05, continued)

- (c) X-ray apparatus designed for intra-oral radiographic use shall be provided with means to limit the target to skin distance to not less than 18 centimeters if operable above 50 kVp or 10 centimeters if not operable above 50 kVp.
- (d) Unless operating intraoral dental radiographic equipment designed to be operated as a hand-held device pursuant to subparagraph (3)(r) of this rule, no one except the patient should be in the room when X-ray exposures are made. If for some reason it is necessary for operating personnel to be in the room with the patient during exposures, an exposure cord shall be provided that is sufficiently long to permit operating personnel to stand at least two meters from the patient and the tube head and in an area of minimal exposure to scattered and leakage radiation and outside of the primary beam.
- (e) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
1. The exposure shall be reproducible. When 4 exposures are made at identical technique factors the value of the average exposure ( $\bar{E}$ ) shall be greater than or equal to 5 times the difference between the maximum exposure ( $E_{\max}$ ) and the minimum exposure ( $E_{\min}$ ), i.e.,
 
$$\bar{E} \geq 5 (E_{\max} - E_{\min}).$$
  2. When a timer is provided it:
    - (i) Shall terminate the exposure after a preset time. This preset time shall be only that time necessary for a single exposure.
    - (ii) Shall be reproducible. When 4 timer tests are performed with a timer setting of 0.5 seconds or less, the average time period ( $\bar{T}$ ) shall be greater than or equal to 5 times the difference between the maximum period ( $T_{\max}$ ) and the minimum period ( $T_{\min}$ ), i.e.,
 
$$\bar{T} \geq 5 (T_{\max} - T_{\min}).$$
- (f) X-ray control (exposure switch)
1. A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less. A dead-man type control is preferred.
  2. This control shall cause an exposure only if the timer or automatic exposure control has been preset.
  3. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in progress.
- (g) Unless operating intraoral dental radiographic equipment designed to be operated as a hand-held device pursuant to subparagraph (3)(r) of this rule, neither the tube housing nor the Position Indicating Device may be hand held during an exposure.

(Rule 0400-20-06-.05, continued)

- (h) The film shall be held by an appropriate device or by the patient when an x-ray is made, or if necessary, by some other person not occupationally exposed to radiation. The fastest dental film available should be used.
- (i) Fluoroscopic screens shall not be used.
- (j) Filtration
  1. Except when contraindicated for a particular diagnostic procedure, the aluminum equivalent of the total filtration (inherent plus added) in the useful beam shall not be less than that shown in Table RHS 3-3.

Table RHS 3-3 FILTRATION REQUIRED VS. OPERATING VOLTAGE

Operating voltage (kVp)	Total Al filtration	(millimeters equivalent)
Below 50	0.5	
50 - 70	1.5	
Above 70	2.5	

2. If the thickness of the filter in the x-ray apparatus cannot be determined visually or the total filtration is unknown, it may be assumed that the requirements of part 1. of this subparagraph are met if the half-value is not less than that shown in Table RHS 3-4.

Table RHS 3-4 HALF-VALUE LAYER VS. OPERATING VOLTAGE

Design operating range (kilovolts peak) (kVp)	Measured potential (kVp)	Half-value Al	layer of equivalent)
Below 50	30	0.3	
	40	0.4	
	49	0.5	
50 to 70	50	1.2	
	60	1.3	
	70	1.5	
Above 70	71	2.1	
	80	2.3	
	90	2.5	
	100	2.7	
	110	3.0	
	120	3.2	
	130	3.5	
140	3.8		
	150	4.1	

3. For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

- (k) The x-ray tube housing shall be of the diagnostic type.

(Rule 0400-20-06-.05, continued)

- (l) The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (m) The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (n) Where 2 or more tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly that has been selected.
- (o) (Reserved)
- (p) Tube housing assemblies shall be equipped with a means to assure mechanical support of the housing during exposures without drift or vibration.
- (q) In addition to other applicable requirements of this Chapter, diagnostic x-ray equipment certified under the Federal Standards promulgated by the Department of Health and Human Services in the Federal Register shall meet the following requirements:
  - 1. Each registrant shall retain, and shall present to the Division for examination when requested, all information provided by the manufacturer to the purchaser in accordance with the requirements of the applicable Federal standard and shall transfer this information to the subsequent owner of the equipment. See Rule 0400-20-06-.09, APPENDIX A.
  - 2. Each registrant shall keep a record of all maintenance and modifications performed on each diagnostic x-ray system containing any components certified under the applicable Federal standard during the period it is under his control, and transfer to the subsequent owner of the equipment.
  - 3. No deviation from the requirements of these regulations will be considered a violation of these regulations if such deviation is permitted by a variance granted by the Food and Drug Administration, Department of Health and Human Services, or by a regulation promulgated pursuant to Public Law 90-602.
  - 4. Radiographic systems designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam such that:
    - (i) If the minimum source to skin distance (SSD) is 18 centimeters or more, the x-ray field shall be containable in a circle having a diameter of no more than 7 centimeters; and
    - (ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle have a diameter of no more than 6 centimeters.

(Rule 0400-20-06-.05, continued)

5. Notwithstanding subparagraph (j) of this paragraph all dental x-ray systems manufactured on or after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent.
- (r) The following requirements apply to any intraoral dental radiographic equipment designed to be operated as a hand-held device:<sup>5</sup>
1. The registrant shall provide and require individual personnel monitoring of external occupational dose via a whole body dosimeter and extremity dosimeters for both the right and left hands to all persons who may operate the hand-held device. The registrant may be relieved of the requirement of this part after one year of personnel monitoring if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely to receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rules 0400-20-05-.71 and 0400-20-05-.135.
  2. Registrants shall implement security and accountability procedures to prevent unauthorized use, misuse, or unauthorized removal of the hand-held device from its storage location. Immediately after learning of an incident of unauthorized use, misuse, or unauthorized removal from its storage location, a registrant shall report the incident to the Division at the contact point identified in part (3)(a)1. of Rule 0400-20-05-.141. The registrant shall maintain records of the security and accountability procedures described in this part. Said records shall be made available for review by the Division.
  3. The registrant shall ensure that:
    - (i) The operator prevents bystanders within a radius of at least six feet from the patient being examined with the hand-held device; and
    - (ii) Hand-held intraoral dental radiographic devices are not used for patient examinations in areas not designated as examination areas.
  4. The registrant shall incorporate specific information regarding hand-held devices into any initial and recurring training provided to the facility staff. The training shall contain, at a minimum, the following:
    - (i) Training on the proper operation of the hand-held device;
    - (ii) The requirements listed in parts 1. through 3. of this subparagraph; and
    - (iii) Instructions provided by the manufacturer in regard to equipment with unique features as required under 21 CFR 1020.30(h)(1)(i).<sup>6</sup>
  5. The registrant shall maintain records of the initial and recurring training provided to the facility staff described in part 4. of this subparagraph. Training records shall be made available for review by the Division and include:

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<sup>5</sup> This part is intended to apply to intraoral radiographic units that are hand-held. Any unit designed to be hand-held but operated as a fixed unit shall be subject to the requirements outlined in paragraph (3) of Rule 0400-20-06-.05.

<sup>6</sup> "A unit that is hand-held constitutes a unique feature that requires manufacturers to describe any safety procedures and precautions necessary to reduce operator exposure." (See Guidance for Industry and FDA Staff – Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use, December 24, 2008, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs).

(Rule 0400-20-06-.05, continued)

- (i) The date the training was provided;
- (ii) The name of each individual trained (printed) and their signature;
- (iii) The name and dated signature of the individual providing the training;
- (iv) The topics covered in the training (or an attachment of the training material); and
- (v) The duration of the training.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012. Amendments filed September 10, 2019; effective December 9, 2019.

#### **0400-20-06-.06 VETERINARY X-RAY INSTALLATIONS.**

(1) General requirements.

(a) Equipment

1. The primary beam for diagnostic purposes in radiography and fluoroscopy shall not be larger than clinically necessary. Cones, diaphragms, or adjustable collimators capable of restricting the primary beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required in the tube housing. See parts (2)(a)1. and 13. and (2)(c)2. and 7. of Rule 0400-20-06-.05 for minimum acceptable criteria for cones, diaphragms, or adjustable collimators.
2. Filtration
  - (i) The aluminum equivalent of the total filtration (inherent plus added), permanently in the useful beam shall not be less than that shown in Table RHS 3-1.
  - (ii) If the thickness of the filter in the x-ray apparatus cannot be determined visually or the total filtration is unknown, it may be assumed that the requirements of subpart (i) of this part are met if the half-value layer is not less than that shown in Table RHS 3-2.
3. The x-ray tube housing shall be of diagnostic type.
4. The effectiveness of protective equipment shall not be impaired.
5. A timer shall be provided that will terminate the exposure after a preset time.
6. The exposure switch shall be of a dead-man type.
7. If the operator is required to be in the room during exposures, the registrant shall require the operator to stand at least 2 meters from the animal for all exposures and outside the primary beam.
8. Hand or head held fluoroscopic screens shall not be used.

(b) Operation of equipment

(Rule 0400-20-06-.06, continued)

1. Animal or film holding.
  - (i) Except where clinically contraindicated restraining devices or mechanical supporting devices shall be used.
  - (ii) No individual under 18 years of age and no pregnant women will be used.
  - (iii) No individual shall be used on a consistent or routine basis.
  - (iv) Protective gloves and aprons with at least 0.25 millimeter of lead equivalency shall be provided and their use required of each individual used for this purpose.
  - (v) No part of the body of the individual utilized, for this purpose shall be in the primary beam unless protected by 0.5 millimeter lead equivalent material.
  - (vi) If occupationally exposed persons are utilized their exposure shall be monitored with the monitoring device place on the collar outside the leaded apron.
  - (vii) A record shall be maintained listing the name of the individual holding the film or animal and shall include the date of the examination and it shall be possible to determine the procedure for which the animal or film was held.
- (2) Specific requirements
  - (a) The following requirements apply to any veterinary intraoral dental radiographic equipment designed to be operated as a hand-held device: <sup>7</sup>
    1. The registrant shall provide and require individual personnel monitoring of external occupational dose via a whole body dosimeter and extremity dosimeters for both the right and left hands to all persons who may operate the hand-held device. The registrant may be relieved of the requirement of this subpart after one year of personnel monitoring if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely to receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rule 0400-20-05-.71 and 0400-20-05-.135.
    2. Registrants shall implement security and accountability procedures to prevent unauthorized use, misuse, or unauthorized removal of the hand-held device from its storage location. Immediately after learning of an incident of unauthorized use, misuse, or unauthorized removal from its storage location, a registrant shall report the incident to the Division at the contact point identified in part (3)(a)1. of Rule 0400-20-05-.141. The registrant shall maintain records of the security and accountability procedures described in this part. Said records shall be made available for review by the Division.
    3. The registrant shall ensure that:

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<sup>7</sup> This part is intended to apply to intraoral radiographic units that are hand-held. Any unit designed to be hand-held but operated as a fixed unit shall be subject to the requirements outlined in paragraph (3) of Rule 0400-20-06-.05.

(Rule 0400-20-06-.06, continued)

- (i) The operator prevents bystanders within a radius of at least six feet from the patient being examined with the hand-held device; and
    - (ii) Hand-held intraoral dental radiographic devices are not used for patient examinations in areas not designated as examination areas.
  4. The registrant shall incorporate specific information regarding hand-held devices into any initial and recurring training provided to the facility staff. The training shall contain, at a minimum, the following:
    - (i) Training on the proper operation of the hand-held device;
    - (ii) The requirements listed in parts 1. through 3. of this subparagraph; and
    - (iii) Instructions provided by the manufacturer in regard to equipment with unique features as required under 21 CFR 1020.30(h)(1)(i).<sup>8</sup>
  5. The registrant shall maintain records of the initial and recurring training provided to the facility staff described in part 4. of this subparagraph. Training records shall be made available for review by the Division and include:
    - (i) The date the training was provided;
    - (ii) The name of each individual trained (printed) and their signature;
    - (iii) The name and dated signature of the individual providing the training;
    - (iv) The topics covered in the training (or an attachment of the training material); and
    - (v) The duration of the training.
- (b) Fluoroscopic installations
1. Target to tabletop distance shall not be less than 30.5 centimeters.
  2. Equipment installed or reinstalled after July 1, 1972, shall be so constructed that the entire cross-section of the useful beam is attenuated by a primary barrier permanently incorporated into the equipment. The tube mounting and the barrier shall be so linked together that the barrier always intercepts the beam. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.
  3. The required lead equivalent of the primary barrier shall be at least 1.5 millimeters for 100 kVp, 1.8 millimeters for 125 kVp, and 2.0 millimeters for 150 kVp.
  4. Collimators shall be provided to restrict the size of the useful beam to less than the area of the primary barrier. For conventional fluoroscopes, this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen with the screen properly

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<sup>8</sup> "A unit that is hand-held constitutes a unique feature that requires manufacturers to describe any safety procedures and precautions necessary to reduce operator exposure." (See Guidance for Industry and FDA Staff – Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use, December 24, 2008, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs)

(Rule 0400-20-06-.06, continued)

- centered in the beam at a distance of 38 centimeters from the panel or tabletop. For image intensifiers, the useful beam shall be centered on the input phosphor and during fluoroscopy or cine-recording it should not exceed the diameter of the input phosphor.
5. For fluoroscopy, the radiation exposure as measured at the minimum target to skin distance shall be as low as practicable and shall not exceed 10 roentgens per minute except when clinically indicated.
  6. The registrant shall provide and require the use of a curtain of 0.25 millimeter lead equivalent that will hang from the screen and between the animal and fluoroscopist in both horizontal and vertical fluoroscopy, but it shall not substitute for the wearing of a protective apron.
  7. The registrant shall provide protective aprons, and shall require their use by the veterinarian, assistant and for all other persons within the fluoroscopic room.
  8. The registrant shall provide protective gloves, and shall require their use by the fluoroscopist during any examination in which the fluoroscopist may be required to approach the primary beam with his hand or hands.
  9. Conventional fluoroscopic screens shall not be used with mobile fluoroscopic equipment. Image intensification shall always be provided, and in the absence of a table top or panel, a cone or spacer frame shall limit the target to skin distance to not less than 30.5 centimeters.
  10. A shielding device of at least 0.25 millimeter lead equivalent for covering the bucky slot during fluoroscopy shall be provided.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012. Amendments filed September 10, 2019; effective December 9, 2019.

#### **0400-20-06-.07 ANALYTICAL X-RAY INSTALLATIONS.**

- (1) Equipment.
  - (a) The leakage radiation from the tube housing shall not exceed a radiation level of 2.5 milliroentgens in 1 hour at 5 centimeters from the surface of the tube housing at any specified tube rating.
  - (b) Radiation originating within the high voltage power supply (i.e., transformer and rectifiers) shall not exceed a radiation level of 0.5 milliroentgen in 1 hour at every specified rating at a distance of 5 centimeters from the housing of the power supply.
  - (c) A warning light with the notation "X-Ray On," or equivalent shall be located on the control panel and shall light only when the x-ray tube is activated. This light shall be a fail-safe design or administrative controls shall be exercised to ensure operations will not continue without a proper functioning warning light. On equipment installed after October 2, 1978, this device shall be a fail-safe design.
  - (d) The x-ray accessory apparatus shall include a beam trap or other barrier with sufficient shielding so that the dose rate due to the transmitted primary beam does not exceed 0.25 mrem/hr at 5 centimeters under normal operating conditions. The dose rate may be difficult to evaluate in the presence of scattered radiation, however, this requirement shall be considered met if the inherent shielding of the trap or barrier is at least

(Rule 0400-20-06-.07, continued)

equivalent to the thickness of lead specified in Table RHS 3-5 for the maximum rated anode current and potential.

Table RHS 3-5 THICKNESS OF LEAD REQUIRED FOR A PRIMARY BEAM BARRIER LOCATED 5 CENTIMETERS FROM THE FOCAL SPOT

Anode current (mA)	Thickness of lead (mm)		
	50 kVp	70 kVp	100 kVp
20	1.5	5.6	7.7
40	1.6	5.8	7.9
80	1.6	5.9	
100	1.7		

- (e) A light or indicator in a conspicuous location near the tube housing assembly shall be used to indicate when the x-ray tube is on. This light or other indicator shall be of fail-safe design or administrative controls shall be exercised to ensure operations will not continue without proper functioning of this light or indicator. On equipment installed after October 2, 1978, this device shall be of fail-safe design.
- (f) In addition to any signs or labels required in Rule 0400-20-05-.111, a sign or label shall be placed on or adjacent to each x-ray tube housing and shall be located so as to be clearly visible to any individual who may be working in close proximity to the primary beam path. The sign or label shall bear the words:
- “CAUTION - HIGH INTENSITY X-RAY BEAM”
- (g) Where couplings exist, e.g., between the x-ray tube and the collimator of the diffractometer, etc., they shall prevent radiation from escaping the coupling.
- (h) Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray accessory apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place. Shutters at unused ports shall be secured to prevent inadvertent opening.
- (i) Open beam x-ray equipment
1. All shutters shall be provided with a “shutter open” indication of fail-safe design.
  2. Radiation levels in the vicinity of controls and adjustments of the x-ray accessory apparatus used during normal operation shall be such that the operator’s exposure shall not exceed in one hour 37 mrem to the hands or 2 mrem to the whole body, gonads, bloodforming organs, or lens of the eye.
  3. A guard or interlock which prevents entry of any part of the body into the primary beam path should be utilized.
  4. The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.
  5. When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

(Rule 0400-20-06-.07, continued)

- (j) Enclosed beam x-ray equipment
  1. The radiation source, sample, detector and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.
  2. The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will continue without a proper functioning interlock.
  3. The exposure level at 5 centimeters from the tube housing apparatus complex shall not exceed 2.5 milliroentgens per hour during normal operation.
- (2) Operation of equipment.
  - (a) The registrant shall not permit any individual to operate or maintain analytical x-ray equipment until such individual has received instruction in and demonstrated competence as to:
    1. Identification of radiation hazards associated with the use of the equipment;
    2. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
    3. Proper operating procedures for the equipment;
    4. Symptoms of an acute localized exposure; and
    5. Proper procedures for reporting an actual or suspected exposure.
  - (b) Procedures and apparatus utilized in beam alignment shall be designed to minimize radiation exposure to the operator.
  - (c) Written operating procedures and emergency procedures pertaining to radiation safety shall be established for each facility and shall be conspicuously posted in a location near each unit of analytical x-ray equipment.
  - (d) Only trained personnel shall be permitted to install, repair, or make modifications to the x-ray generating apparatus and the tube housing apparatus complex.
  - (e) Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:
    1. Approved in advance by the radiation safety officer.
    2. Specified in writing and posted near the x-ray tube housing so that other individuals will know the existing status of the x-ray apparatus.
    3. Terminated as soon as possible.

(Rule 0400-20-06-.07, continued)

4. Recorded and the record maintained for inspection by the Division. This record should contain such information as date alteration was made, type of alteration, length of time unit remained in the altered condition, and signed by the individual who made the alteration and the individual who restored the unit to original condition.
  - (f) Tests of all safety devices such as interlocks, shutters, and warning lights shall be conducted at intervals not to exceed 3 months for all operable analytical x-ray equipment. Records of such tests shall be maintained for inspection by the Division.
  - (g) Interlocks shall not be used to de-activate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.
  - (h) Surveys and personnel monitoring shall be provided to insure compliance with the requirements of Chapter 0400-20-05 (See Rules 0400-20-05-.50, 0400-20-05-.55, 0400-20-05-.56, 0400-02-05-.60, 0400-20-05-.70, 0400-20-05-.71(1), 0400-20-05-.130, 0400-20-05-.132, and 0400-20-05-.135).
- (3) In addition to the requirements of paragraphs (1) and (2) of this rule, the following requirements apply to open-beam, hand-held, analytical X-ray devices:
  - (a) Procedures.

All registrants possessing open-beam, hand-held, analytical devices shall have available for review by the Division operating policies and procedures that contain measures to ensure that:<sup>9</sup>

1. Radiation protection is provided equivalent to that afforded in subparagraph (1)(d) of this rule. This shall be in the form of an operating procedure that contains, at a minimum:
  - (i) The operator's hands will not approach the primary beam;
  - (ii) The operator will not hold the sample during operation of the hand-held x-ray device;
  - (iii) The operator will not aim the primary beam at him/herself or at any individual during operation of the device; and
  - (iv) Before energizing the device, the operator will ensure that no person is within two meters of the device or sample being tested.
2. If the safety devices, which are known as the "X-ray On" warning light and the tube housing "X-ray On" indicator light, as outlined in subparagraphs (1)(c) and (1)(e) of this rule, are not of a fail-safe design, administrative controls shall be put in place in the form of an operating procedure that shall include, at a minimum:
  - (i) Discussion of the warning light(s) safety mechanism on the device, the rationale behind subparagraphs (1)(c) and (1)(e) of this rule, the absence of the fail-safe design on the device, and the potential risks to the operator should the warning light(s) fail;

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<sup>9</sup> This part is intended to apply to units that are hand-held. Analytical units designed to be hand-held but operated in a fixed configuration and not hand-held shall be subject to the requirements of subparagraph (1)(d) of this rule.

(Rule 0400-20-06-.07, continued)

- (ii) Training the operator to visually verify that the warning light(s) is correctly working when the device is known to be generating X-rays;
  - (iii) Training the operator to recognize warning light failure. For example: warning light(s) not functioning when the device is known to be generating X-rays, or if one of several warning lights is not operating;
  - (iv) Proper procedures for reporting an actual or suspected warning light failure; and
  - (v) If failure of the warning light, or any one of the warning lights if there are multiple warning lights, is confirmed, the analyzer will immediately be removed from service and returned to the manufacturer for repair. Return to service will not be permitted until necessary repair has been performed, and the maintenance record for the device updated. Such maintenance records shall be made available upon request by the Division.
3. Operator radiation exposure is as low as reasonably achievable. For example, use of ancillary equipment when possible, such as a sample holder.

(b) Extremity Monitoring.

The registrant shall provide and require individual personnel monitoring with extremity dosimeters for all operators of the hand-held device in compliance with Chapter 0400-20-05. Extremity monitoring may be discontinued after one year if the results of the personnel monitoring demonstrate that the operator of the hand-held device is not likely to receive a dose in excess of 10 percent of the limits in Rule 0400-20-05-.50, as outlined in Rule 0400-20-05-.71. The registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Rules 0400-20-05-.71 and 0400-20-05-.135.

(c) Training.

In addition to the training requirements of subparagraph (2)(a) of this rule, the registrant shall provide training for all users and operators on the requirements of subparagraph (a) and (b) of paragraph. Records of all user and operator training shall be maintained and made available for review by the Division. Training records shall include:

1. The date the training was provided;
2. The name of each individual trained (printed) and their signature;
3. The name and dated signature of the individual providing the training;
4. The topics covered in the training (or an attachment of the training material); and
5. The duration of the training.

**Authority:** T.C.A. §§ 4-5-201, et seq.; 68-202-101, et seq.; and 68-202-201, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012. Amendments filed September 10, 2019; effective December 9, 2019.

**0400-20-06-.08 X-RAY GAUGES.**

- (1) Equipment.

(Rule 0400-20-06-.08, continued)

- (a) A sign bearing the words, "Warning - X-Rays - Do not place hands in jaws of gauge," or equivalent, shall be so located that it is visible to any person operating, aligning, or adjusting a gauging device.
  - (b) A visible indication of the status of the shutter shall be provided, e.g., red light indicating beam on, green light indicating beam off. This device shall be of fail-safe design or administrative controls shall be exercised to ensure operations will not continue without a proper functioning warning device. On equipment installed after June 30, 1977, this device shall be of fail-safe design.
  - (c) Except whenever impracticable, an interlocking device which prevents the entry of any portion of an individual's body into the primary beam or causes the primary beam to be shut off upon entry into its path shall be provided.
  - (d) Unused tube ports shall be closed in such a fashion that accidental opening is not possible.
  - (e) In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding, to avoid exposure to any individual from the transmitted primary x-ray beam.
- (2) Operation of equipment.
- (a) Personnel working with open beam x-ray equipment shall be provided with finger or wrist personnel monitoring devices. Records of exposure shall be kept as required in Rules 0400-20-05-.130 and 0400-20-05-.135.
  - (b) When not in operation, the equipment shall be secured in such a way as to be accessible to, or operable by, only authorized personnel.
  - (c) A review of all safety devices shall be performed at least quarterly to insure their proper operation (i.e., signs, labels, interlocks, etc.). A record of this review shall be maintained for inspection by the Division.
  - (d) Prior to initial startup and subsequent to any change in any parameters affecting radiation safety and at least annually, surveys and monitoring to insure that operations are conducted safely shall be provided. Records of such surveys shall be kept as required by Rule 0400-20-05-.130 and paragraph (1) of Rule 0400-20-05-.132.

**Authority:** T.C.A. §§ 4-5-201, et seq.; 68-202-101, et seq.; and 68-202-201, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

#### 0400-20-06-.09 APPENDIX A.

Excerpt from Bureau of Radiological Health Standards for Certified Diagnostic X-ray Equipment. See subpart (2)(a)14.(i) and part (3)(q)1. of Rule 0400-20-06-.05.

- (1) Manufacturers of x-ray equipment shall provide for purchaser and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:
  - (a) All x-ray equipment.

For x-ray equipment to which this Chapter and 40 CFR 1020.31 and 1020.32 are applicable, there shall be provided:

(Rule 0400-20-06-.09, continued)

1. Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and
2. A schedule of the maintenance necessary to keep the equipment in compliance with this Chapter and 21 CFR 1020.31 and 1020.32.

(b) Tube housing assemblies.

For each tube housing assembly, there shall be provided:

1. Statements of the maximum rated peak tube potential, leakage technique factors, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;
2. Cooling curves for the anode and tube housing; and
3. Tube rating charts.

If the tube is designed to operate from different types of x-ray high voltage generators (such as single-phase self-rectified, single phase half-wave rectified, single-phase full-wave rectified, three-phase 6 pulse, three-phase 12 pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(c) X-Ray controls and generators.

For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

1. A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;
2. A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics, x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(s);
3. A statement of the technique factors that constitute the maximum line current condition described in part 2. of this subparagraph;
4. In the case of battery-powered generators, a specification of the minimum state of charge necessary for operation.
5. Generator rating and duty cycle;
6. A statement of the maximum deviation from the indication given by labeled control settings and/or meters during any exposure when the equipment is connected to a power supply as described in accordance with this paragraph. In

(Rule 0400-20-06-.09, continued)

the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated; and

7. A statement defining the measurement basis (or bases) upon which the exposure time, peak potential, tube current, and/or other technique factors are stated pursuant to parts 3. and 6. of this subparagraph.

(d) Variable-aperture beam-limiting device.

For each variable-aperture beam limiting device, there shall be provided:

1. Specifications of tube housing assemblies for which the device is designed or is compatible with respect to the requirements of this Chapter and 21 CFR 1020.31 (d) and (e); and
2. A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When 2 or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed February 22, 2012; effective May 22, 2012.

#### **0400-20-06-.10 PERSONNEL SECURITY SCREENING SYSTEMS USING X-RAY RADIATION.**

- (1) "Personnel security screening system" means radiation-generating equipment used for the sole purpose of screening an individual who is in custody of a law enforcement agency or persons accessing or in a vehicle accessing the secured facility perimeter in order to identify contraband items and weapons that would present a security threat within a secured facility perimeter.
- (2) X-ray devices used for personnel security screening shall be used only by law enforcement agencies at city, county, or state correctional detention facilities. No individual shall be exposed to the useful beam unless authorized by a law enforcement agency for security benefit. No individual shall be exposed to the useful beam for demonstration or frivolous purposes.
- (3) The X-ray system shall be manufactured, maintained, and operated solely for security screening purposes in strict compliance with, and fully according to, the most restrictive standards found in ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation," which is herein incorporated by reference. This ANSI publication may be examined and inspected at the TDEC Division of Radiological Health, WRS Tennessee Tower 15th Floor, 312 Rosa L. Parks Ave, Nashville, Tennessee 37243, and is available from the American National Standards Institute, Inc., at <http://www.hps.org/#>. The Division has determined that posting the publication on the Internet for purposes of public inspection and examination would constitute a violation of federal copyright law.
- (4) The law enforcement agency shall track radiation doses for each individual, as specified by ANSI/HPS N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation," to ensure the individual does not exceed the recommended dose limit.

**Authority:** T.C.A. §§ 4-5-201, et seq. and 68-202-101, et seq. **Administrative History:** Original rule filed September 10, 2019; effective December 9, 2019.