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Title 21 – Food and Drugs

Chapter I – Food and Drug Administration, Department of Health and Human Services

Subchapter J – Radiological Health

Part 1020 – Performance Standards for Ionizing Radiation Emitting Products

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§ 1020.40 Cabinet x-ray systems.

- (a) **Applicability.** The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.
- (b) **Definitions.** As used in this section the following definitions apply:
- (1) **Access panel** means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.
 - (2) **Aperture** means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.
 - (3) **Cabinet x-ray system** means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed *cabinet*) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.
 - (4) **Door** means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.
 - (5) **Exposure** means 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 (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.
 - (6) **External surface** means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.
 - (7) **Floor** means the underside external surface of the cabinet.

- (8) **Ground fault** means an accidental electrical grounding of an electrical conductor.
- (9) **Port** means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.
- (10) **Primary beam** means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.
- (11) **Safety interlock** means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.
- (12) **X-ray system** means an assemblage of components for the controlled generation of x-rays.
- (13) **X-ray tube** means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) **Requirements –**

(1) **Emission limit.**

- (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.
- (ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) **Floors.** A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) **Ports and apertures.**

- (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.
- (ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) **Safety interlocks.**

- (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.
- (ii) Each access panel shall have at least one safety interlock.
- (iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

- (iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.
- (5) **Ground fault.** A ground fault shall not result in the generation of x-rays.
- (6) **Controls and indicators for all cabinet x-ray systems.** For all systems to which this section is applicable there shall be provided:
 - (i) A key-actuated control to insure that x-ray generation is not possible with the key removed.
 - (ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.
 - (iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON".
 - (iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON".
- (7) **Additional controls and indicators for cabinet x-ray systems designed to admit humans.** For cabinet x-ray systems designed to admit humans there shall also be provided:
 - (i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.
 - (ii) No means by which x-ray generation can be initiated from within the cabinet.
 - (iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.
 - (iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.
 - (v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.
- (8) **Warning labels.**
 - (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

Caution: X-Rays Produced When Energized

- (ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

caution: Do Not Insert Any Part of the Body When System is Energized—X-ray Hazard

(9) *Instructions.*

- (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.
- (ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

- (10) ***Additional requirements for x-ray baggage inspection systems.*** X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

- (i) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.
- (ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

- (d) ***Modification of a certified system.*** The modification of a cabinet x-ray system, previously certified pursuant to § 1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

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