Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

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I. Introduction

On June 10, 2005, the Food and Drug Administration (FDA) published a final rule entitled "Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components" (70 FR 33997; subsequently referred to as "the rule"), which amended the performance standard for diagnostic x-ray systems and their major components. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28) to assist small entities to comply with these changes in the performance standard, which became effective June 10, 2006.[1] A subsequent amendment to the Radiological Health

[1] For further clarification on aspects of the performance standards for diagnostic x-ray equipment (21 CFR 1020.30 and 21 CFR 1020.32), see FDA's guidance entitled, "Policy Clarification for Certain Fluoroscopic Equipment Requirements" (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements).

Regulations (88 FR 3638;[2] January 20, 2023), removed certain reporting requirements for diagnostic x-ray systems and their major components and the current version of this guidance reflects these changes.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Questions and Answers on the Rule

1. To which products does this rule (21 CFR 1020.30; 1020.31; 1020.32; 1020.33) apply?

The rule applies to all medical diagnostic x-ray systems and their major components. This scope of application includes radiographic, fluoroscopic, and computed tomography (CT) diagnostic x-ray systems. The amendments added coverage of Image Receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006 and fluoroscopic Air Kerma Display Devices manufactured on or after June 10, 2006 to the list of components of a diagnostic x-ray system.

2. What new definitions were added to 21 CFR 1020.30(b)?

a) *Air kerma* means kerma in air (see definition of Kerma).

b) *Air kerma rate (AKR)* means the air kerma per unit time.

c) *Automatic exposure rate control (AERC)* means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

d) *C-arm fluoroscope* means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

e) *Cumulative air kerma* means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

f) *Fluoroscopic air kerma display device* means a device, subsystem, or component that provides the display of AKR and cumulative air kerma

[2] https://www.govinfo.gov/content/pkg/FR-2023-01-20/pdf/2023-00922.pdf

required by section 1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

g) *Fluoroscopic irradiation time* means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

h) *Fluoroscopy* means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term ‘‘radioscopy’’ in the standards of the International Electrotechnical Commission.

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

j) *Kerma* means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as ‘‘air kerma.’’

k) *Last-image-hold (LIH) radiograph* means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

l) *Lateral fluoroscope* means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

m) *Mode of operation* means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses,

source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

n) *Non-image-intensified fluoroscopy* means fluoroscopy using only a fluorescent screen.

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

p) *Solid state x-ray imaging device* means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

q) *Source-skin distance (SSD)* means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

3. What additional information is required by 21 CFR 1020.30(h)(5) to be provided to users regarding the imaging systems?

Imaging system information. For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

i. For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

ii. For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

4. How has the warning label (21 CFR 1020.30(j)) on the control panel changed?

Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

''Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.''

5. How have the minimum HVL requirements (21 CFR 1020.30(m)) changed?

The minimum HVL requirements for all x-ray systems (except dental systems designed for use with intraoral image receptors) manufactured on or after June 10, 2006, have been increased as specified according to 21 CFR 1020.30(m), Table 1.

The column titled "II-Other X-Ray Systems" in Table 1 shows the increased values.

TABLE 1

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[1]	I—Other X-Ray Systems[2]	II—Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1]Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2]Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[3]All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

6. What is the new requirement (21 CFR 1020.30(m)(2)) for optional filtration for certain fluoroscopic systems?

Optional filtration. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of section 1020.30(m)(1). The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

7. How has the requirement (21 CFR 1020.30(n)) for the maximum aluminum equivalent of material between the patient and image receptor changed?

For systems manufactured on or after June 10, 2006, the allowable amount of aluminum equivalent material between the patient and image receptor has been increased as specified in 21 CFR 1020.30(n), Table 2. The HVL for the x-ray beam used to determine the aluminum equivalent material is specified in Table 1 of 21 CFR 1020.30(m)(1).

TABLE 2

Item	Maximum Aluminum Equivalent (Millimeters)
1. Front panel (s) of cassette holders (total of all)	1.2
2. Front panel (s) of film changer (total of all)	2.3
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two articulated joints	2.3
8. Tabletop, cantileverd	2.3
9. Tabletop, radiation therapy simulator	5.0

8. What are the new requirements (21 CFR 1020.30(q)(2)) regarding documentation of owner modification of certified diagnostic x-ray components or systems?

The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of sections 1020.31, 1020.32, or 1020.33. The owner should record the date and the details of the modification in the system records and maintain this information, provided the modification of the x-ray system does not result in a failure to comply with sections 1020.31, 1020.32, or 1020.33.

9. Has the applicability of the rule to Radiographic equipment (21 CFR 1020.31) changed?

Yes. The provisions of 21 CFR 1020.31 apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

10. Has the applicability of the rule to Fluoroscopic equipment (21 CFR 1020.32) changed?

Yes. The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

11. Has the field-limitation requirement (21 CFR 1020.32(b)(4)(ii)) for fluoroscopic imaging assemblies with inherently circular image receptors been changed for equipment manufactured on or after June 10, 2006?

Yes. For fluoroscopy and radiography using fluoroscopic imaging assemblies with inherently circular image receptors, other than radiation therapy simulation systems, that are manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

A. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or

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

12. Has the field-limitation requirement (21 CFR 1020.32(b)(5)) for fluoroscopic imaging assemblies with inherently rectangular image receptors been changed for equipment manufactured on or after June 10, 2006?

Yes. For fluoroscopy and radiography using fluoroscopic imaging assemblies with inherently rectangular image receptors, other than radiation therapy simulation systems, that are manufactured on or after June 10, 2006, the following applies:

i. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

ii. The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

13. What are the new requirements (21 CFR 1020.32(g)(2)) regarding the minimum source-skin distance for source-image receptor distances of less than 45 cm?

For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in section 1020.30(h).

14. May fluoroscopic equipment be modified to comply with the new requirements (21 CFR 1020.32(h)(2)) for fluoroscopic irradiation-time display and signals?

Fluoroscopic equipment may be modified in accordance with §1020.30(q) to comply with the requirements of section 1020.32(h)(2). When the equipment is modified, it shall bear a label indicating the statement:

"Modified to comply with 21 CFR 1020.32(h)(2)."

15. For x-ray controls manufactured on or after June 10, 2006, what are the new requirements (21 CFR 1020.32(h)(2)) regarding fluoroscopic irradiation-time display and signals?

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

i. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in §1020.32(h)(2)(ii). The following requirements apply:
   A. When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.
   B. The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.
   C. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

ii. A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 second.

16. For fluoroscopic equipment manufactured on or after June 10, 2006, what is the new requirement (21 CFR 1020.32(j)) regarding display of last-image-hold?

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

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

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

3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of

fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

4) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by section 1020.30(h). The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions

17. For systems manufactured on or after June 10, 2006, what is the new requirement (21 CFR 1020.32(k)) for display of values of the air kerma rate (AKR) and the cumulative air kerma at the fluoroscopist's working position?

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

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

2) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

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

4) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to section 1020.30(h)(6)(iii).

   i. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in §1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v) for measuring compliance with air-kerma rate limits.
   ii. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

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

6) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

18. What additional information is required by 21 CFR 1020.30(h)(6) to be provided to users regarding the display of values of the air kerma rate (AKR) and the cumulative air kerma?

Displays of values of AKR and cumulative air kerma. For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the following shall be provided:

i. A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by §1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration.

ii. Identification of the distances along the beam axis:
   A. From the focal spot to the isocenter, and
   B. From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to section 1020.32(k)(4).

iii. A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to section 1020.32(k)(4)(ii).

19. Who may I contact for further information on this rule?

For questions about this document, contact Office of Health Technology 8 (OHT8): Office of Radiological Health at RadHealth@fda.hhs.gov.