Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment

Draft Guidance for Industry and Food and Drug Administration Staff

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This draft guidance document is being distributed for comment purposes only.

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For questions regarding this document, contact the Office of In Vitro Diagnostics and Radiological Health at 240-402-5149 and Scott Gonzalez at 301-796-5889 or by email at Scott.Gonzalez@fda.hhs.gov.

When final, this guidance will supersede FDA's guidance entitled "Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment" (HHS Publication FDA 89-8221 issued in March 1989).

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
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Preface

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Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides clarification to industry and FDA staff of the Federal Regulations that relate to diagnostic x-ray systems and their major components. This draft guidance, when finalized, will supersede FDA's guidance entitled "Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment" (HHS Publication FDA 89-8221 issued in March 1989).[1] "For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database.[2]

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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.

[1] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm095312.htm.
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

II. Background

CDRH is charged with the responsibility of enforcing regulations created under the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) (the Act). The Act was later recodified from Title 42 to Title 21 and incorporated into the Federal Food, Drug, and Cosmetic Act (FD&C Act) with the passage of the Safe Medical Devices Act of 1990. The relevant sections from the Radiation Control for Health and Safety Act were placed into Sections 531 through 542 of the FD&C Act (21 U.S.C. § 360hh through § 360ss) under Subchapter C entitled Electronic Product Radiation Control (EPRC). The regulations promulgated pursuant to the FD&C Act are covered in 21 CFR Subchapter J-Radiological Health. The term "Radiological Health Regulations," as used in this document, refers broadly to 21 CFR Subchapter J. These regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of "electronic products" as defined under 21 CFR 1000.3(j). General Performance Standards for Electronic Products are covered in 21 CFR Part 1010, while Specific Performance Standards for diagnostic x-ray systems are covered in "Diagnostic x-ray systems and their major components" (21 CFR 1020.30), "Radiographic equipment" (21 CFR 1020.31), "Fluoroscopic equipment" (21 CFR 1020.32), and "Computed tomography (CT) equipment" (21 CFR 1020.33), which cover aspects of the performance of each listed type of equipment and place specific requirements on the manufacturers, importers, dealers, distributors, and assemblers of the covered equipment. The term "Performance Standards" as used in this document refers to these five regulations.

III. Scope

Pursuant to the definitions in sections 201(h) [21 U.S.C. §321(h) and 531 [21 U.S.C. §360hh] of the FD&C Act, diagnostic x-ray systems are considered to be both medical devices and electronic products. As such, these devices are subject to the provisions of the FD&C Act that apply to medical devices (e.g., sections 510, 520, and of the FD&C Act [21 U.S.C. §§ 360 and 360j], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm) and their implementing regulations as well as the provisions of the FD&C Act that apply to electronic products, known as the EPRC (http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm), and their implementing regulations.

The substantive portion of this document consists of two sections. The first is the General Section (Section IV), which contains information of a general nature relating to diagnostic x-ray equipment. The second is the Specific Section (Section V), which contains information specific to particular sections of the Performance Standards for diagnostic x-ray systems which can be found in 21 CFR 1020.30 through 1020.33.

This document addresses only the requirements that apply to diagnostic x-ray equipment under the EPRC provisions of the FD&C Act and the regulations implementing those provisions. This document does not address requirements that may apply to such equipment as medical devices

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under provisions of the FD&C Act and its implementing regulations. For more information on the regulation of diagnostic x-ray systems as a medical device, see FDA's website.[3]

Manufacturers of diagnostic x-ray systems should be aware that CDRH intends to amend FDA's Performance Standards, as appropriate, to harmonize many of its requirements with those of the International Electrotechnical Commission (IEC) standards because FDA acknowledges the importance of simplifying compliance for global manufacturers. Manufacturers are advised to regularly check the FDA website for new developments on this topic.[4]

IV. General Information for Manufacturers of Diagnostic X-Ray Equipment

Section 531 of the FD&C Act (21 U.S.C. § 360hh) and implementing regulations in 21 CFR 1000.3(d) define "commerce" as:

a. commerce between any place in any State and any place outside thereof, and
b. commerce wholly within the District of Columbia.

Section 538(a)(1) of the FD&C Act (21 U.S.C. § 360oo) prohibits manufacturers from introducing, or delivering for introduction, into commerce any electronic product which does not comply with an applicable standard prescribed pursuant to Section 534 of the FD&C Act. FDA's policy regarding the introduction of an electronic product "into commerce" within the meaning of Section 538(a)(1) of the FD&C Act (21 U.S.C. § 360oo) is discussed in Compliance Policy Guide 390.100.[5]

As part of the requirements under the Radiological Health Regulations, manufacturers (as defined in 21 CFR 1000.3(n)) of diagnostic x-ray equipment which is intended for use on human patients must maintain records and provide reports to FDA (21 CFR Part 1002). These records and reports support the manufacturer's certification that their electronic products comply with all applicable requirements in the Performance Standards (see 21 CFR 1010.2). Manufacturers of diagnostic x-ray equipment must also include a label or tag permanently affixed to their electronic products that identify the manufacturer, location, and date of manufacture and state that the products are certified as meeting the requirements of the Performance Standards (see 21 CFR 1010.2 and 1010.3). Many diagnostic x-ray systems (as defined in 21 CFR 1020.30(b)) consist of components from different manufacturers; other systems use components from a single manufacturer. In either case, compliance with the Performance Standards is dependent upon proper installation and final testing of the complete system at the user location.

To allow for faster review, all required information, reports, and other submitted documentation to FDA should be written in the English language or accompanied by a complete English translation.

[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
[4] http://www.fda.gov/Radiation-EmittingProducts/default.htm
[5] https://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM337932.pdf

Additional information in question and answer format regarding assembler responsibilities is provided in FDA's guidance entitled, "Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment."[6]

In general, under the Performance Standards, manufacturers of diagnostic x-ray equipment must:

- Certify that each component complies with the applicable Performance Standards. Certification of compliance means the manufacturer guarantees the component will perform as required by the Performance Standards when it is assembled, installed, adjusted, tested, and maintained in accordance with the manufacturer's instructions (21 CFR 1020.30(c), 1020.30(g), 1020.30(h)(1)(ii)).

- Permanently inscribe or affix certification and identification labels on the component or system (as applicable) complete with the name and address of the manufacturer, date and place of manufacture, model designation, and serial number on each component (21 CFR 1010.3 and 1020.30(e)).

- Provide the assembler, and others who request it, at a cost not to exceed the cost of publication and distribution, with adequate instructions for assembly, installation, adjustment, and testing of the component to assure the product will comply with the Performance Standards when the instructions are followed (21 CFR 1020.30(g)). The instructions must also provide specifications for other components that are compatible with the component to be installed when compliance of the component or system depends on such compatibility. The specifications may describe physical characteristics of compatible components and/or may list, by manufacturer's name and model designation, specific components that are compatible (21 CFR 1020.30(c) and 1020.30(g)).

- Provide the purchaser with adequate instructions describing specific technical specifications of the equipment and any necessary radiological safety precautions and procedures which may be necessary because of unique features of the equipment as well as a schedule of the maintenance necessary to keep the equipment in compliance with the Performance Standards (21 CFR 1020.30(h)(1)).

V. Specific Topics of Importance to Manufacturers of Diagnostic X-Ray Equipment

A. Introduction into Commerce and Certification (see also questions 37, 38, 88, 92, 93, 96, 97, and 98)

[6] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM257783.pdf

The certification process for diagnostic x-ray equipment is a component-by-component process. 21 CFR 1020.30(a)(1)(i) identifies the certifiable components of a diagnostic x-ray system (referred to in this guidance, as "diagnostic x-ray components"). These diagnostic x-ray components may also qualify as medical devices under section 201(h) of the FD&C Act (21 U.S.C. 321(h)) and are also subject to the provisions of the FD&C Act that apply to medical devices. The component by itself may not be able to produce diagnostic x-rays, but is intended to be installed or assembled with other compatible components into a complete diagnostic x-ray system at the user location.

1. QUESTION: When is a diagnostic x-ray component or system considered to have been introduced into commerce?

   ANSWER: See the discussion of "introduction into commerce" provided in this guidance in Section IV - General Information for Manufacturers of Diagnostic X-Ray Equipment. As stated in the Compliance Policy Guide Sec. 390.100, if a diagnostic x-ray component or system intended for human use has been offered for sale or assembled by a person engaged in the business of assembling that product, FDA considers the component or system to have been introduced into commerce.[7]

2. QUESTION: Must an electronic product be certified before introduction into commerce?

   ANSWER: Yes. Section 538(a)(1) of the FD&C Act (21 U.S.C. 360oo) prohibits the introduction into commerce of any electronic product which does not comply with an applicable standard prescribed pursuant to section 534 of the FD&C Act (21 U.S.C. § 360kk), and section 534(h) of the FD&C Act requires every manufacturer of an electronic product to furnish, to the dealer or distributor at the time of delivery, a certification the product conforms to all applicable standards. Consequently, any diagnostic x-ray component or system introduced into commerce for use on human subjects must be certified to comply with the applicable Performance Standards before it is introduced into commerce (see also Section 534(a)(1) of the FD&C Act (21 U.S.C. § 360kk(a)(1))).

3. QUESTION: If a diagnostic x-ray system has been installed for use under an investigational device exemption (IDE), must it be certified?

   ANSWER: Yes. If a diagnostic x-ray component or system has been assembled for use on humans, including installation for use under an IDE (see Section 520(g) of the FD&C Act (21 U.S.C. 360j(g)) and 21 CFR part 812), it has been introduced into commerce and must both comply with all applicable standards prescribed pursuant to section 534 of the FD&C Act (21 U.SC. § 360kk) prior to introduction, and be certified (Sections 538(a)(1) and (5) of the FD&C Act (21 U.S.C. § 360oo(a)(1) and (5))).

4. QUESTION: After a diagnostic x-ray system or component has been sold and installed, who is responsible for ensuring continued equipment compliance with the Performance Standards?

[7] https://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM337932.pdf

ANSWER: The certifying manufacturer is responsible for designing systems and components to guarantee compliance with the Performance Standards for the life of the equipment when the equipment is properly maintained (21 CFR 1020.30(c)). A certified product that is maintained according to the maintenance schedule provided by the certifying manufacturer is expected to conform to the regulations and Performance Standards in effect on the date of manufacture (e.g., 21 CFR 1020.30(c) and 1020.30(h)). If evaluated today, for example, a product manufactured in 2004 is expected to be in compliance with the regulations in effect in 2004.

Because diagnostic x-ray equipment usually will remain in use for many years, the certifying manufacturer is required to provide a maintenance schedule that, if properly implemented by the user, will keep the equipment in compliance with the Performance Standards (21 CFR 1020.30(h)(1)(ii)). If the assembler installs the equipment following the instructions provided by the certifying manufacturer (21 CFR 1020.30(g)), and the user maintains the equipment according to the maintenance schedule provided by the certifying manufacturer (21 CFR 1020.30(h)(1)(ii)), the certifying manufacturer may be held responsible for manufacturer-related compliance issues until the equipment is permanently removed from service. However, the certifying manufacturer will not be held responsible for incorrect installations, incorrect repairs, or failure by other firms or the user to maintain the system properly (21 CFR 1020.30(c)).

5. QUESTION: A firm manufactures x-ray equipment for use in veterinary offices, pathology laboratories, and for training radiologic technologists when no human subjects are involved. Must this equipment be certified? Is the firm required to file a Form FDA 2579 ("Report of Assembly of a Diagnostic X-Ray System")?

   ANSWER: No to both questions. A "diagnostic x-ray system" is defined, for the purposes of the Performance Standards, as "an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization" (21 CFR 1020.30(b)). Because the electronic products are not intended for use on humans, they do not need to be certified. However, these systems are considered electronic products under 21 CFR Subchapter J, and the firm must comply with all of the electronic product radiation control requirements for equipment without a specific performance standard (21 CFR 1002.1(b)). This includes any reporting requirements in Table 1 of 21 CFR 1002.1 and reporting accidental radiation occurrences (AROs) to the FDA.

   The firm is not required to file Form FDA 2579. Form FDA 2579 is filed to report assembly of certified diagnostic equipment intended for irradiation of any part of the human body for the purpose of diagnosis or visualization. The completion and filing of the form is not required for any non-human application. Even though certified equipment is often installed in veterinary facilities, when such equipment will be used as dedicated veterinary equipment, it does not require certification to the Performance Standards.

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Note: Some state and local agencies may have more stringent reporting requirements, and the firm should check with them regarding their requirements.

6. QUESTION: Are there specific requirements for diagnostic x-ray systems installed in mobile vehicles?

   ANSWER: No. There are no specific requirements in 21 CFR 1020.30 for diagnostic x-ray systems installed in mobile vehicles. However, imaging systems installed in mobile vehicles may be subjected to adverse environmental conditions that do not occur in unmoving installations. FDA recommends that manufacturers provide specific instructions for assembly, testing, and maintenance of systems that are designed for, or routinely installed in, mobile vehicles that account for these adverse environmental conditions.

   NOTE: Stationary systems installed in mobile vehicles are bound by the requirements for stationary systems provided in the Performance Standards.

7. QUESTION: If a component is designed or modified so that it performs a function that is characteristic of a certifiable component, does it need to be certified with respect to that function?

   ANSWER: Yes. Any system, subsystem, or component that serves substantially the same function (i.e., performs the same function) as a certified component (see 21 CFR 1002.1 and 21 CFR 1020.30(a)) meets the definition of that component and therefore must be certified (21 CFR 1020.30(c)).

   For example, if software included with a digital detector controls the technique factors (e.g., duration of an exposure), then the software performs the same function as an x-ray control and therefore is itself an x-ray control. Because an x-ray control is a certifiable component, the software is subject to the requirements of the Performance Standards relevant to x-ray controls. These requirements include a statement of compatibility with other components in the system (21 CFR 1020.30(g)).

   Also, if the detector is marketed with a front panel (dust cover, etc.) that is not necessary for the digital detector's operation, the front panel performs the same function as a cassette holder with front panel. Because a cassette holder with front panel is a certifiable component (see 21 CFR 1020.30(a)(i)(A)), the front panel is subject to the requirements of the Performance Standards relevant to cassette holders with front panels. These requirements include maximum aluminum equivalence requirements under 21 CFR 1020.30(n) and the front panel must be certified as a cassette holder with front panel (21 CFR 1020.30(c)).

   These are examples and not an exhaustive discussion. For questions related to other design features, please contact the FDA.

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Note that adding functionality to a device may affect labeling applied to a component or subsystem. See the questions and answers in the "General Labeling" section below for more information on labeling requirements for various components and systems.

8. QUESTION: Must each manufacturer of certifiable components provide information regarding the compatibility of their products with other components?

   ANSWER: Manufacturers of certified components or systems must provide information to assemblers, purchasers and others who request it, at a cost not to exceed the cost of publication and distribution, including instructions for assembly, installation, adjustment, and testing (21 CFR 1020.30(g) and 1020.30(h)). When compliance of the component(s) or system depends on component compatibility, the information provided must include specifications of compatible components (21 CFR 1020.30(g)). Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components that are compatible. While it is permissible to list manufacturer model numbers to specify compatible components, that is not the only acceptable means for identifying compatible components. A manufacturer may also describe pertinent physical characteristics of the components to identify those which are compatible. However, manufacturers are not required to disclose trade secrets or confidential information.

9. QUESTION: Are cone-beam x-ray systems required to conform to the Computed Tomography (CT) performance standard (21 CFR 1020.33) even though certain sections don't seem appropriate for cone-bean technology?

   ANSWER: Dental cone-beam computed tomography (CBCT) devices are considered Computed Tomography systems because they depict the x-ray attenuation properties of a section through the body by the acquisition and computer processing of x-ray transmission data. They are therefore subject to the CT performance standard under 21 CFR 1020.33, including but not limited to the quality assurance requirements provided in 21 CFR 1020.33(d). If one or more provisions of the CT performance standard under 21 CFR 1020.33 do not appear appropriate for a CBCT device, the manufacturer should apply for a variance from such provision(s) as described in 21 CFR 1010.4.

B. Labeling (see also questions 45, 79, 99, and 100)

(1) General Labeling

10. QUESTION: Must labels be written in the English language?

    ANSWER: Yes. All required labels must be written in the English language (21 CFR 1010.2(b) and 1010.3(a)), with the exception of foreign equivalents to abbreviations such as "Co.," and "Inc." (21 CFR 1010.3(a)(1)).

11. QUESTION: A firm sells diagnostic x-ray systems, all of which consist of the same combination of components. May the firm place the certification and identification information

for the system, with specific component information (e.g., model number, serial number, and date of manufacture), in the user's manual rather than on the individual components?

ANSWER: No. The required labeling must be placed on each component or subsystem subject to certification (21 CFR 1010.2, 1010.3 and 1020.30(c)).

12. QUESTION: May a combination of certifiable diagnostic x-ray products be identified with a single certification label and a single identification label?

ANSWER: Yes, under the following circumstances, combinations of certified components may be labeled together:

a. high-voltage generators (HVG) contained within tube housing assemblies (THA),
b. beam-limiting devices (BLD) that are integral parts of THAs,
c. HVGs and x-ray controls when inseparable, combined in a single housing, and marketed under a single model designation,
d. combinations of components with written approval to single-label a specific combination of components (21 CFR 1020.30(c)), or
e. combinations of components where written approval of an alternate means of labeling (21 CFR 1010.3(b)) permits single labeling of that combination of components.

13. QUESTION: How should a manufacturer apply for FDA authorization to single label combinations of certifiable components not covered above in question 12?

ANSWER: A written request must be submitted to FDA as required by 21 CFR 1020.30(c). The written request should specify the components to be single labeled and include the reasons why the manufacturer believes the labeling request should be authorized.

Manufacturers interested in requesting permission to single label a combination of components should send their requests to the attention of the Director Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993-0002.

14. QUESTION: How will FDA evaluate requests submitted pursuant to 21 CFR 1020.30(c) to certify single label combinations of certifiable components?

ANSWER: The manufacturer must demonstrate that the combination of certifiable components is compliant with the applicable Performance Standards under a testing program (see 21 CFR 1010.2(c)) for the single label to denote product certification. Each request will be evaluated on a case-by-case basis, but the certifiable components should be contained in a single housing and marketed as a single certified entity, except for repair parts.

15. QUESTION: Items such as phototimers, automatic exposure controls, and positive beam limiting systems (including collimator, sensing tray, and electrical chassis), are made up of subassemblies located in various parts of the system, including in or on other certifiable

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components. Must each of these subassemblies be labeled with manufacturer identification, model, and certification information as specified in 21 CFR 1010.3 and 1020.30(e), or may one model number be assigned to the multiple parts?

ANSWER: Assignment of more than one model number and nameplate to the scattered parts of certifiable components is permissible but it is not required. FDA does not intend to object if only the essential part(s) of a certifiable component are labeled as specified under 21 CFR 1010.3 and 1020.30(e).

16. QUESTION: The use of laptop computers or desktop computers with off-the-shelf monitors that have software loaded to control diagnostic x-ray systems has become widespread. Are both the original and replacement computers required to be labeled with identification, certification, and warning labels?

ANSWER: Yes. We consider software that controls a diagnostic x-ray system loaded on a laptop or desktop computer to serve the same function as an x-ray control and to be subject to the same labeling requirements as any other diagnostic x-ray control as described in 21 CFR 1020.30(b).

The manufacturer of such diagnostic x-ray system control software may state that a personal computer and/or monitor meets their compatibility criteria. However, once a user installs a personal computer or monitor, which meets the x-ray system control software manufacturer's statement of compatibility, into a completed diagnostic x-ray system, the diagnostic x-ray system control software manufacturer continues to be responsible for compliance with the applicable requirements, and management of the risks of the x-ray control aspects of the diagnostic x-ray system.

The replacement of a diagnostic x-ray system control's monitor by a user may affect the component's compliance with applicable labeling requirements. The certification and identification labels (or the display of their contents) must be readily accessible by the user (see 21 CFR 1010.2 and 1010.3) and the required warning statement must be displayed on each computer and/or monitor used as a control panel (21 CFR 1020.30(j)). The labeling requirements for personal computers and/or monitors used as x-ray controls may be satisfied in several ways. Two examples of labeling methods that would satisfy this requirement are:

- Physical labels consistent with 21 CFR 1010.2, 1010.3, and 1020.30(j), accompanied by adequate instructions for placement and verification of the labels.

- Alternatively, FDA does not intend to object where these labels are displayed electronically as long as:
    - Each time the system is started, the screen displays the approved certification and identification labels; and
    - During use, the required warning label is continuously displayed on the screen. If the screen is used as both an acquisition and review work station, the warning

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need not be displayed when in the review mode, but must be continuously displayed when in the acquisition mode.

17. QUESTION: Device labeling regulations under 21 CFR 801 and 809 generally permit the use of symbols in device labeling without adjacent explanatory text if certain requirements are met.[8] Is this use of symbols found in standards such as ISO 7000 permitted in the mandatory labeling for certified x-ray components required by 21 CFR 1010.3(e) and 21 CFR 1020.30(e)?

    ANSWER: Yes. FDA does not intend to object to the use of certain symbols in the labeling required by 21 CFR 1020.30 consistent with the device labeling regulations under 21 CFR 801 and 809.

    For instance, certain FDA-recognized standards such as ISO 7000: *Graphical symbols for use on equipment* and IEC 60417: *Graphical symbols for use on equipment* include symbols which FDA does not intend to object to when used on labels required by the Performance Standards. Some examples of permissible symbols from ISO 7000:2014 include catalogue number, serial number, and date of manufacture.

    Because other required labels, including the certification label (21 CFR 1010.2) and warning label (21 CFR 1020.30(j)), require complete phrases written in English and cannot be adequately represented by symbols, symbols may not be used in those labels.

(2) Label Location

19. QUESTION: Items such as phototimers, automatic exposure controls, and positive beam limiting systems (including collimator, sensing tray, and electrical chassis), are made up of subassemblies located in various parts of the system including in or on other certifiable components. It is understood that FDA considers it reasonable to label only the essential part(s) of a major component (see question 15). Where should such labels be located?

    ANSWER: Table 1 below lists several major components and suggested label locations for each major component. If you have received written authorization from FDA (21 CFR 1020.30(c)) to sell two or more major components as a single-labeled device (i.e., one catalog item that is not intended to be subdivided for use with other components), only one label is required.

    NOTE: All tube housing assemblies must be labeled with the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates, since they are subject to frequent replacement (21 CFR 1020.30(e)(1)).

[8] https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling

Table 1. Suggested Label Locations for Major Components

Major Component	Label Location
Tube Housing Assembly	On housing, including under-table tubes
X-ray Control	On each x-ray control panel and control electronics cabinet
X-ray HV Generator	On generator housing
Fluoroscopic Imaging Assembly	On spot film device and image intensifiers
Table	On each table
Cradle	On each cradle
Film Changer	On changer (if separate control unit is provided, this must also be labeled)
Cassette Holder	On each cassette holder
Beam Limiting Device	On outside of each collimator

20. QUESTION: What is FDA's policy concerning the location of the certification and identification labels and the warning label for diagnostic x-ray systems?

ANSWER: Identification and certification labels must be legible and readily accessible to view when the product is fully assembled for use (21 CFR 1010.2(b) and 1010.3(a)). FDA interprets "legible and accessible to view" for diagnostic x-ray systems to be a location where a person can read the label without having to relocate the x-ray system or use a tool to remove or open panels, doors, etc. The identification and certification labels should be on the outside of the equipment and not on a side that is normally placed against a wall. For some components, such as a tube housing assembly mounted under a table, the identification and certification labels may not be visible from outside the completed system. In such a case, the identification and certification labels should be mounted on the component, although the component itself is not visible. If the identification or certification label is behind a door, panel, under a table, etc., in a location that is readily accessible without the need to unbolt, unlock, or relocate the x-ray system, wording should appear on the door, panel, etc., indicating the location of the identification and/or certification labels. (See 21 CFR 1010.2 and 1010.3 regarding general label requirements.)

The warning label serves to alert users to the hazards associated with the use of the equipment and, by its nature, should be conspicuous to the user. It should be situated so that a user of an x-ray machine can see the warning when he/she is preparing to initiate an exposure (21 CFR 1020.30(j)). To be consistent with the intent of the regulation, there should be a warning label visible at each location where technique factors may be set and/or where x-ray exposure may be initiated.

21. QUESTION: For aesthetic reasons, some manufacturers place certified components behind cosmetic covers and then place duplicate certification and identification labels on the covers. Is this acceptable?

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ANSWER: Yes, but only where the components themselves are also appropriately labeled. FDA considers this duplicate label placement to satisfy the "accessible to view" requirements of the Performance Standards (21 CFR 1010.2(b) and 1010.3(a)), as long as the manufacturer provides adequate assembly instructions to verify that the component label and the duplicate label on the outside casing are identical. The placement of the duplicate label(s) should be on the covering over the certified component and not at another location removed from the component itself. Manufacturers who wish to use such alternative labeling should notify FDA in their product reports (21 CFR 1002.10(j)) and provide copies of the assembly instructions that address proper label placement. This labeling scheme can cause problems when component replacement is necessary. The assembly instructions provided with replacement components should address this issue.

22. QUESTION: A firm manufactures fluoroscopic systems used for angiography and interventional procedures. The diagnostic source assembly (DSA) is covered by a plastic shield. The shield makes cleaning of the DSA easier. The certification and identification labels on the tube housing assembly and beam limiting device are covered by the shield. There is a panel on the shield that can be removed with a screwdriver that would allow access to the certification and identification labels if needed. Is this acceptable?

    ANSWER: No. Because the panel requires a screwdriver to open, the labels are not considered accessible to view. Since the certification and identification labels are not accessible to view under normal use (21 CFR 1010.2(b), 1010.3(a), and 1020.30(e)), this is not acceptable and would not comply with the regulations. Acceptable solutions may include designing the panel to be removable without the use of tools, placing the labels behind a clear shield so that they remain accessible to view, or designing robust labels such that their information remains legible despite cleaning practices and placing them without the protective shield.

23. QUESTION: A firm has been asked to install a diagnostic x-ray system in a facility where a wall will prevent anyone from seeing the certification and identification labels on the x-ray table. Is this acceptable?

    ANSWER: No. Even if the x-ray table was otherwise properly labeled, the proposed placement would render the assembly noncompliant (21 CFR 1010.2(b), 1010.3(a), and 1020.30(e)) because the labels will not be accessible to view.

24. QUESTION: Sections 21 CFR 1020.30(c) and 21 CFR 1020.30(e) require that labels be accessible to view when the equipment is installed. Since the installation of equipment is frequently performed by personnel other than manufacturer representatives, how can the manufacturer assure label visibility after assembly?

    ANSWER: The manufacturer must provide instructions to the assembler regarding proper placement of components so that the labels are visible and accessible when the installation is completed to assure the equipment complies with the regulations (21 CFR 1020.30(g)).

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(3) Certification Labels

21 CFR 1010.2(a) requires every manufacturer of an electronic product for which an applicable standard is in effect to furnish to the dealer or distributor, at the time of delivery, the certification that such product conforms to all applicable Performance Standards unless FDA has approved an alternate means to provide certification (21 CFR 1010.2(d)). Such certification must be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use (21 CFR 1010.2(b)). Each certifiable component of a diagnostic x-ray system must have its own certification label unless the system falls under the provisions for single labeling (21 CFR 1020.30(e)). Single labeling questions and answers are provided in the Section "General Labeling" above.

25. QUESTION: Is there specific wording required to meet the certification labeling requirement in 21 CFR 1010.2(a)?

    ANSWER: No. The regulation concerning certification (21 CFR 1010.2(a)) does not specify the wording of the certification label; it states that "Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter."

    Two examples of suggested wording that satisfy 21 CFR 1010.2(a) include:

    - "Complies with DHHS radiation performance standards, 21 CFR Subchapter J"
    - "Product complies with applicable DHHS standards under Subchapter C - Electronic Product Radiation Control of Chapter V of the Federal Food, Drug and Cosmetic Act."

26. QUESTION: May a manufacturer use the words "at the time of manufacture" in the certification label to indicate that the certification statement applies to the regulations in effect at the time of manufacture?

    ANSWER: Yes, if the phrase is qualified appropriately. Some manufacturers use the term "at the time of manufacture" in their certification statement because the regulations are amended from time to time. However, the addition of this phrase can cause some confusion as to whether it refers to compliance or to the regulation.

    If the phrase "at the time of manufacture" is placed on the certification label then the words "in effect" or "applicable" should be included with the phrase to clearly indicate that the certification statement means that the component complies with the regulations in effect at the time of manufacture. Two examples of acceptable wording are:

    - "Complies with DHHS radiation performance standards, 21 CFR Subchapter J, in effect at time of manufacture."; or

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- "Product complies with applicable DHHS standards in effect at time of manufacture under Subchapter C - Electronic Product Radiation Control of Chapter V of the Federal Food, Drug and Cosmetic Act."

27. QUESTION: Since shipping containers of components being imported into the U.S. are typically not opened at the time of customs inspection, is any certification labeling required on the outside of these shipping containers?

    ANSWER: No. However, the importer must file a declaration (Form FDA 2877) upon entry of the product into the U.S. (19 CFR 12.91(b)).

(4) Identification Labels

28. QUESTION: How should the manufacturer be identified on component identification labels?

    ANSWER: 21 CFR 1010.3(a)(1) requires that the full name and address (in English) of the certifying manufacturer be stated on each certifiable component, in the form of a label or tag permanently affixed to or inscribed on the product. Under the EPRC provisions of the FD&C Act, the certifying firm (whether manufacturer, importer or assembler) is the responsible manufacturer for compliance of the certified component.

    If the product is sold under a label other than that of the certifying manufacturer, the full name and address of the selling individual or company may be placed on the label as the manufacturer as long as prior to introduction of the product into commerce, the CDRH Director has been provided sufficient information to identify the manufacturer of the product (21 CFR 1010.3(a)(1)). This label must also contain the date of manufacture of the component (21 CFR 1010.3(a)(2)). Labels on certified components that are medical devices must contain the phrase "Manufactured for ___", or "Distributed by ___" (or other wording that expresses the facts) when the device is sold under a label other than that of the component manufacturers label (21 CFR 801.1(c)).

29. QUESTION: Under 21 CFR 1010.3(a)(2)(ii), the format for the date of manufacture is "Manufactured: (Insert Month and Year of Manufacture)." May manufacturers use other formats instead, such as 12/2/2009, 2-Dec-09, or 2009-12-02? May they use "Date of Manufacture:" instead of "Manufactured:"?

    ANSWER: The regulation specifies the format for the date of manufacture (21 CFR 1010.3(a)(2)(ii)). This format may not be modified. The month and year of manufacture must be provided clearly and legibly, as follows:

    MANUFACTURED: (INSERT MONTH AND YEAR OF MANUFACTURE)

    The date of manufacture must have the month spelled out, and the year as a four-digit number (Example: December 2009) (21 CFR 1010.3(a)(2)(ii)). Manufacturers may add the actual date

of manufacture, as long as the correct month and year format is used (Example: MANUFACTURED: December 2, 2009).

FDA does not intend to object to the formats "DATE OF MANUFACTURE", "DATE MANUFACTURED", and "MANUFACTURED DATE."

30. QUESTION: What is the "place of manufacture" as used in 21 CFR 1010.3?

    ANSWER: The place of manufacture is the location where the certifiable component or system is produced. A code may be used to identify the place of manufacture if the CDRH Director has previously been provided the key to such code (21 CFR 1010.3(a)(2)(i)).

31. QUESTION: A firm manufactures diagnostic x-ray components and systems at several locations. The firm would like to include its corporate office name and address on the identification label. Is the firm required to also identify the place of manufacture? May it use a code on the label to identify the place of manufacture?

    ANSWER: Yes to both questions. The firm is required to identify the place of manufacture (21 CFR 1010.3(a)(2)). It may use a code to identify the place of manufacture, provided that it has supplied FDA with a listing of the codes, along with the name and address of the place of manufacture associated with each code (21 CFR 1010.3(a)). See also question 28.

32. QUESTION: It is understood that 21 CFR 1010.3(a)(1) and (2) require that manufacturers include their full name, address and place of manufacture on their electronic product identification tags or labels. May a manufacturer place its Uniform Resource Locator (URL) on its electronic product labels instead?

    ANSWER: No. The Performance Standards do not permit manufactures to place the URL information on a label *instead of* the specified information. The product label must include the information required in the regulations (21 CFR 1010.3(a)(1) and (2)).

    However, as discussed in FDA's guidance entitled "Guidance for Industry and FDA Staff - Addition of URLs to Electronic Product Labeling",[9] FDA recommends, when feasible, that manufacturers add their URL to their electronic product tag or label, in addition to the identification information required under 21 CFR 1010.3(a)(1) and (2).

33. QUESTION: 21 CFR 1020.30(e) requires manufacturers of diagnostic x-ray components that are subject to the Performance Standards to permanently inscribe or affix to each component the model number and serial number (identification labels) of the component. How does the FDA interpret this requirement?

[9] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM228556.pdf

ANSWER: 21 CFR 1020.30(e) specifies that a model number and serial number shall be inscribed or affixed to a component, and that the word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. A model designation should describe only one certified component, and it should not be used to describe an assemblage of components except as specified in 21 CFR 1020.30(e) or as specifically authorized by the FDA. See also question 13.

34. QUESTION: Is specific wording required to meet the labeling requirement for specific component identification?

ANSWER: Yes, in addition to the identification requirements of 21 CFR 1010.3, 21 CFR 1020.30(e) describes additional identification labeling requirements for major components of diagnostic x-ray system by specifying the listing of model and serial numbers. The specified format calls for the word "model" or "type" to appear on the label. Tube housing assemblies require additional information on their identification label. The name of manufacturer, the model number, and the serial number of the tube insert must also appear on the identification label (21 CFR 1020.30(e)(1)). The reloading of the tube insert in a previously certified tube housing assembly constitutes manufacture of a new tube housing assembly; this requires the manufacturer to remove, cover, or deface any previously affixed tube insert inscriptions, tags, or labels that are no longer applicable and apply new tube insert labels (21 CFR 1020.30(e)(2)).

(5) Warning Labels

The *control panel* is the means used by the operator to set technique factors (21 CFR 1020.30(b)). The prescribed warning statement must be present on the control panel, and this label must be legible and accessible to view and should be viewable by the operator during adjustment of technique factors (21 CFR 1020.30(j)) (see question 20). The control panel may be physically co-located with the control (i.e., mounted directly to the cabinet) or separated from the control (i.e., a satellite or remote panel). The control panel may consist of a single operator interface or multiple operator interfaces.

35. QUESTION: Has the wording for the warning label (21 CFR 1020.30(j)) on the control panel changed as a result of the June 10, 2006 amendments to the Performance Standard?

ANSWER: Yes. The change adds "maintenance schedules" to the required wording of the warning label as prescribed in 21 CFR 1020.30(j) as follows:

a. New controls manufactured on or after June 10, 2006:

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

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b. Old controls manufactured prior to June 10, 2006:

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

NOTE: Warnings that differ slightly from the standard but are more forceful and restrictive in content meet the intent of the regulations. However, it is important that each aspect of the warning label (i.e. safe exposure factors, operating instructions, and maintenance schedules) be addressed in the warning.

36. QUESTION: 21 CFR 1020.30(j) requires a warning label on the control panel. Modern control panels may incorporate or be wholly replaced by a computer that serves as a user interface for purposes of adjusting technique factors and for the initiation of x-ray exposure. Can a manufacturer propose to display the required warning statement on the computer monitor screen?

ANSWER: Yes. FDA acknowledges that the cited regulation does not specifically address computerized control of x-ray production. However, we believe that the definition can be applied to controls and control panels utilizing a computer as a user interface.

Software may incorporate certification and identification statements within the code that are reflective of labels affixed to the x-ray control (e.g., on the electronics cabinet or operator console). Software performing x-ray control functions should also incorporate a means to electronically display the required warning statement on each computer/terminal used as a control panel unless a permanent warning label is present. See also question 20.

C. Date of Manufacture (See also question 29)

37. QUESTION: Several of the applicable Performance Standards differ based on whether or not the equipment was manufactured before June 10, 2006. How does a manufacturer determine if its system is required to comply with the updated Performance Standards?

ANSWER: An x-ray system must comply with the revised performance standards that are in effect for equipment manufactured on or after June 10, 2006, when:

1) The complete system is certified (21 CFR 1002.1 Table 1 – Footnote 4) and the system's date of manufacture falls on or after June 10, 2006; or

2) All of the certified components in the system were manufactured on or after June 10, 2006, as provided by each of their identification labels.

Note that if a system's date of manufacture falls before June 10, 2006 and a certified component with a date of manufacture on or after June 10, 2006 is used to replace an existing component in this system, the new component must comply with the applicable revised performance standards; however the system is not required to comply with all of the revised performance

standards as a result of installing the single new certified component. However, if a certified component with a date of manufacture before June 10, 2006, is installed into a certified system manufactured on or after June 10, 2006, then the system is still required to conform to all of the revised performance standards.

Example 1: An air kerma display manufactured in 2007 could be used to replace an air kerma display on a fluoroscopic x-ray system manufactured in 2005. This new air kerma display must be certified to conform to the performance standards applicable on its date of manufacture (ex., 21 CFR 1020.32(k)). However, the fluoroscopic x-ray system would not be required to conform to other revised performance standards applicable on or after June 10, 2006 as a result of installing the single new certified air kerma display.

Example 2: A fluoroscopic x-ray system was manufactured in 2007 and certified as a system using a certified air kerma display which was manufactured in 2005. Because the x-ray system was certified as a system and the system's date of manufacture is in 2007, the system is still required to conform to all of the revised performance standards applicable on or after June 10, 2006 even though the revised performance standards didn't apply to the air kerma display as of its own date of manufacture.

For computerized tomography (CT) systems manufactured on or after September 3, 1985, the date of manufacture of the system is defined as the date of manufacture of the CT gantry as provided by the identification labeling (21 CFR 1020.30(a)(3)).

38. QUESTION: When an existing diagnostic x-ray system is disassembled or removed from its original location and reassembled at a different location does its "date of manufacture" change?

ANSWER: No. A system that is disassembled and reassembled with the same components retains its previous date(s) of manufacture.

For additional information on assembly of diagnostic x-ray equipment, see FDA's guidance entitled "Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment."[10]

D. Measurements

39. QUESTION: There are many references in 21 CFR Subchapter I to test methods used to determine compliance with the Performance Standards. (See 21 CFR 1020.30(k), (l), (m)(3), (n), 1020.31(b)(2), (c)(3), (d)(2)(iii), (e)(4), (g)(3), (h)(2), (l), (m)(3), 1020.32((a)(2), (b)(1), (d)(3)). Is a manufacturer required to develop its quality control testing program to use these test methods exactly?

[10] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM257783.pdf

ANSWER: It is the manufacturer's responsibility to ensure that its testing program ensures that diagnostic x-ray equipment conforms to the applicable Performance Standards (21 CFR 1010.2(c)) once assembled according to the Information to be provided to assemblers (21 CFR 1020.30(g)). The testing methods referenced in the Performance Standards describe how FDA determines compliance with the Performance Standards when performing testing under 21 CFR 1005.10. It is the component manufacturer's responsibility to use test methods that provide assurance that after assembly into a finished x-ray system, its products will comply with all applicable performance standards when tested using the test methods provided in the Performance Standards. It is also the component manufacturer's responsibility to maintain records pertaining to its quality control testing (21 CFR 1002.30).

40. QUESTION: Is it permissible to round off measured values obtained during testing if the measured values are slightly in excess of numerical limits stated in the Performance Standards and the rounding would allow the values to fall within the regulatory limits?

    ANSWER: No. The regulatory limits in the Performance Standards are absolute values and as such, they cannot be exceeded. Rounding measured test results to obtain compliant values is not acceptable. For example, during testing of a fluoroscopic system, a measured maximum air kerma rate (after taking into account test measurement uncertainties) of 88.1 mGy per minute was obtained. Since the limit for the applicable requirement is 88 mGy per minute for this system, the measured value of 88.1 mGy per minute exceeds the limit in the standard, and the unit is not compliant. We recommend manufacturers (including assemblers) employ action limits more stringent than the regulatory limit to assure that equipment meets all numerical limits in the relevant Performance Standards.

41. QUESTION: What is meant by the expression "measurement criteria" as related to "technique factors" in 21 CFR 1020.30(h)(3)(viii)?

    ANSWER: The regulations define technique factors such as peak tube potential, tube current, etc. (21 CFR 1020.30(b)). However, the definitions are general in nature and more precise information is needed to interpret the technique factors. Specifically, the criteria used to obtain the indicated technique factors must be given (21 CFR 1020.30(h)(3)(viii)). For example, when measuring exposure time for three-phase equipment, one manufacturer may specify the measurement by defining it as the time between the beginning and end of the exposure cycle, while another manufacturer may define it in some other way. In some cases, the measurement criteria may vary among models produced by the same manufacturer. A statement of the measurement criteria used must be provided in the manufacturer's literature to allow meaningful comparisons (21 CFR 1020.30(h)(3)(viii)).

42. QUESTION: The linearity requirement of 21 CFR 1020.31(c) is interpreted to apply to the x-ray system rather than individual components. Some systems are composed of components that may have different maximum limiting specifications. If so, is the linearity requirement of the system in a compliance test restricted to the maximum value as specified by the manufacturer's rating of the limiting component?

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ANSWER: Yes. The requirement in 21 CFR 1020.31(c) applies to the x-ray system, and testing compliance for linearity of the maximum milliampere-second product selection or maximum current setting of the system is limited by the manufacturer's rating of the limiting component.

43. QUESTION: When measuring leakage from the diagnostic source assembly, may the main beam be blocked at the exit end of the beam-limiting device?

ANSWER: Yes. Note that, as defined in 21 CFR 1020.30(b), leakage radiation "means radiation emanating from the diagnostic source assembly except for . . . [t]he useful beam;" and useful beam is defined in 21 CFR 1020.30(b) as "radiation which passes through the tube housing port and the aperture of the beam-limiting device . . . ." This means radiation passing through the aperture of the beam-limiting device is not leakage radiation and therefore is not subject to the leakage requirement. Thus, the proposal of blocking the aperture at the exit end of the beam-limiting device is appropriate.

E. Models (See also question 33)

44. QUESTION: A firm manufactures several slightly different versions of certain component models. Must each version have its own unique model number?

ANSWER: The answer depends on the differences among the versions. 21 CFR 1000.3(o) defines model as "any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer." If the different versions have different structural or electrical design characteristics, including compatibility issues, they must have different model numbers (21 CFR 1020.30(e)). However, if the differences are cosmetic (such as different paint colors), it is acceptable to use the same model number for the different versions.

45. QUESTION: Under 21 CFR 1020.30(e), each certifiable component must have a model and serial number. May manufacturers use any alphanumeric format in standard English characters for these numbers, such as "BLK012", "100245", or "ALMM"?

ANSWER: Any alphanumeric format is acceptable for model and serial numbers, as long as the model number and the serial number are unique to that component, or approved single-labeled systems or single-labeled sub-system as authorized by FDA.

F. Product Reports

46. QUESTION: Should reports be submitted in English?

ANSWER: Yes, all required information and reports should be in the English language to allow for faster review by FDA.

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47. QUESTION: Who is responsible for submitting annual reports?

ANSWER: The manufacturer of an electronic product, including the manufacturer of a certifiable component, is responsible for filing all required reports as specified in Table 1 under 21 CFR 1002.1. The manufacturer's designated U.S. agent or the importer who is an employee of, or contractor to, the manufacturer may submit the reports on behalf of a foreign manufacturer.

48. QUESTION: Are manufacturers permitted to update product reports in their annual reports?

ANSWER: It depends. 21 CFR 1002.13(c) states that new models of a model family do not require supplemental reports prior to introduction into commerce if they do not involve changes in radiation emission from the product or are not required for compliance with a performance standard. These model numbers should be reported in quarterly updates to the annual report (21 CFR 1002.13(c)). However, when a manufacturer updates a product report, FDA recommends that it do so through either: (1) the submission of a new product report as described in 21 CFR 1002.10, or (2) supplements to the affected product report as described in 21 CFR 1002.11.

49. QUESTION: A manufacturer changed the kilovolts peak (kVp) accuracy specifications of one of the models of an x-ray control it manufactures from ± 10% to ± 5%. It is understood that the manufacturer needs to report the change to FDA. Should it file a new product report or a supplemental report?

ANSWER: Since the firm has changed the performance specifications for the x-ray control, it must report this change prior to the introduction into commerce of the new model (21 CFR 1002.11(b)). FDA recommends that the firm submit a supplement under to the initial product under 21 CFR 1002.11 rather than a new product report. The supplement should include the submission of test data to demonstrate compliance with the new specifications.

G. Assembly (See also questions 5, 6, 23, and 38)

For additional assembler information see FDA's guidance entitled "Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment."[11]

47. QUESTION: It is understood that the Form FDA 2579, "Report of Assembly of a Diagnostic X-ray System" is used by assemblers to report the installation of diagnostic x-ray systems and/or their major components. In a case where purchasers or their employees install certified components or systems, do the purchasers then become "assemblers," as defined in the regulations? Must they complete and file Form FDA 2579?

[11] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM257783.pdf

ANSWER: Yes, in this situation, the purchasers or their employees become assemblers. 21 CFR 1020.30(b) defines an assembler as "any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services." Therefore, anyone who installs certified components or systems meets the definition of an assembler (21 CFR 1020.30(b)), and must file a Form FDA 2579 (21 CFR 1020.30(d)(1) unless they meet one of the exceptions to the reporting requirements provided under 21 CFR 1020.30(d)(2). For additional details and exceptions on when to file Form FDA 2579, see FDA's guidance entitled "Assembler's Guide to Diagnostic X-Ray Equipment."[12] Information on obtaining Form FDA 2579 may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm. There is also an option for electronic submission of Form FDA 2579. For more information, see FDA's website.[13]

49. QUESTION: Must a Form FDA 2579 be filed when an assembler installs used certified equipment that have been donated?

ANSWER: Yes. The regulations make no distinction regarding the method of acquisition of the equipment. When an assembler installs certified equipment for use on humans, they are required to file Form FDA 2579 (21 CFR 1020.30(d)(1)), regardless of how the equipment is acquired.

50. QUESTION: What date should be used as the "date of installation" on the Form FDA 2579?

ANSWER: The date of installation of an x-ray system or component is considered to be the date the x-ray system is released by the assembler to the facility or user for use on humans. Assemblers have fifteen (15) days from the date of installation to complete and distribute Form FDA 2579 before they are considered to be in violation of 21 CFR 1020.30(d)(1). The Form FDA 2579 should properly indicate the actual date of installation, and not the date on which the assembler completes and distributes the Form FDA 2579.

51. QUESTION: What are the manufacturer's and assembler's responsibilities relative to final testing of a newly-assembled x-ray system or component before it is released to the user?

ANSWER: Manufacturer's Responsibilities: Manufacturers certify that each of their products meet all applicable requirements when installed according to their instructions for assembly, installation, adjustment, and testing. Descriptions of any testing that must be performed after installation in order to ensure compliance with the applicable Performance Standards should be

[12] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM257783.pdf

[13] http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107879.htm

included in these instructions. This information shall be provided to assemblers (21 CFR 1020.30(g).

Step-by-step instructions and a thorough explanation of the required test equipment should be provided. The instructions should include a requirement to record those key data that will permit demonstration at a later date that all specified tests were performed and that the equipment was installed and tested in compliance with the assembly instructions. Manufacturers who rely on the results from tests performed during assembly to support their certification but do not include final compliance testing in their assembler instructions may have their quality control and testing programs disapproved (21 CFR 1010.2(c)).

Assembler's Responsibilities: Assemblers of diagnostic x-ray equipment must perform all testing specified in the assembly instructions provided by the component or system manufacturer(s) at the time of installation (21 CFR 1020.30(d)). Assemblers who fail to perform, and document the results of, final compliance tests as required by the manufacturer(s) may be considered by the FDA to have issued a false and misleading certification and may be subject to regulatory action by the FDA. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was performed according to the component manufacturer's instruction (21 CFR 1020.30(d)).

52. QUESTION: An assembler determines that the available rated line voltage and/or range of line voltage regulation is not within the manufacturer's specified requirements. May this installation be completed?

    ANSWER: No. The installation, as described, is not permitted. The manufacturer must provide assembly instructions adequate to assure compliance of its components with the applicable Performance Standards (21 CFR 1020.30(c)) which must include a statement of the rated line voltage and the range of line-voltage regulation (21 CFR 1020.30(g)(1)), and the assembler shall assemble, install, adjust and test the certified components according to the instructions of the manufacturer (21 CFR 1020.30(d)). This assembly cannot be performed according to the manufacturer's instructions and should not be completed.

53. QUESTION: A firm manufactured and sold a fluoroscopic C-arm system that was fully compliant with the Performance Standards if installed and assembled according to its instructions. However, this particular system was incorrectly installed and assembled, and is noncompliant with the Performance Standards. Is the manufacturer responsible for correcting the noncompliant system?

    ANSWER: No. Manufacturers are not responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person (21 CFR 1020.30(c)). However, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of the Performance Standards (21 CFR 1020.30(g)).

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54. QUESTION: A firm manufactured, sold, and installed a fluoroscopic C-arm system that was fully compliant with the Performance Standards when it was assembled. However, the owner's service engineer adjusted the tube output to increase the air kerma rate. The maximum air kerma rate after the adjustment was found to be 120 mGy per minute and as a result, the system fails to comply with 21 CFR 1020.32(d)(2)(ii). The facility's medical physicist notified the assembler that the system needs to be adjusted to comply with the Performance Standards. Is the assembler or manufacturer responsible for adjusting the system at no cost to the user?

    ANSWER: No. If the user's service engineer did not adjust the system by following the assembly, installation, adjustment, and testing (AIAT) instructions, the manufacturer is not responsible for the failure to comply (see question 53). However, if the user adjusted the system by following the assembly, installation, adjustment, and testing (AIAT) instructions, and the resulting air kerma rate did not meet the requirement provided in 21 CFR 1020.32(d)(2)(ii), the manufacturer is responsible for the failure to comply and must act according to 21 CFR 1003.10 including notification to the Secretary (21 CFR 1003.20), notification to affected persons (21 CFR 1003.21), and unless exempted from notification requirements (21 CFR Subpart D), repurchase, repair, or replace the system at no cost to the user (21 CFR 1004).

55. QUESTION: Section 21 CFR 1020.31(b)(2), "Measuring Compliance" appears to limit an assembler to install systems where only plus or minus 1 percent (1%) line-voltage regulation is available. Is this correct?

    ANSWER: No. The plus or minus 1 percent (1%) line-voltage regulation in 21 CFR 1020.31(b)(2) is an FDA test condition only. This means if the line voltage regulation (expressed as a percent) for one measurement departs from the mean value of line voltage regulation for all 10 measurements (expressed as a percent) by more than 1 percent, the test result is not valid for determining compliance. See question 39.

(1) Assembly Instructions (See also questions 51, 53, and 54)

Manufacturers of components listed in 21 CFR 1020.30(a)(1) are required to provide assemblers with adequate instructions for assembly, installation, adjustment and testing of those components (21 CFR 1020.30(g)). The instructions must be adequate to assure that the products will comply with the applicable provisions of the Performance Standards when assembled, installed, adjusted and tested as directed (21 CFR 1020.30(g)). Manufacturers of diagnostic x-ray systems and components must provide these instructions to assemblers and, upon request, to other interested parties at a cost not to exceed the cost of publication and distribution (21 CFR 1020.30(g)). However, manufacturers are not required to disclose trade secrets or confidential information.

In addition, manufacturers of x-ray equipment, including components, are required to provide to purchasers, and upon request, to others manuals or instruction sheets with the information required under 21 CFR 1020.30(h).

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Additional information is available in FDA's guidance entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems."[14]

56. QUESTION: Section 21 CFR 1020.30(g) requires manufacturers to provide adequate instructions to complete a compliant installation of their component(s) into a diagnostic x-ray system. However, assembly of a manufacturer's system may require the use of unique software programs to assure a compliant assembly. Must the manufacturer provide access to these software programs as part of the information to be provided to assemblers?

    ANSWER: Yes. If assembly, installation, adjustment, and testing of the certified components requires the use of unique software programs then access to those software programs should be provided to assemblers and, upon request, to others at a cost not to exceed the cost of publication and distribution (21 CFR 1020.30(g)). If adequate instructions to complete a compliant installation can only be conveyed by other modes (e.g., instructional videos or in-person training) then those forms of instructions should similarly be provided at a cost not to exceed the cost of publication and distribution.

    Some manufacturers bundle the unique software programs covered by 1020.30(g) with other types of proprietary software; in some instances, the proprietary software cannot be deleted from the bundled information. Nothing in section 1020.30 prohibits bundling software information or programs; however, the practice does not relieve manufacturers of their responsibilities under the performance standard to provide the necessary documentation or software at a cost not to exceed the cost of publication and distribution.

57. QUESTION: Section 21 CFR 1020.30(g) requires manufacturers to provide adequate instructions to complete a compliant installation of their component(s) into diagnostic x-ray systems. It is understood that if software is required to assure a compliant assembly, the manufacturer is required to provide the software. However, does 21 CFR 1020.30(g) apply to ancillary software developed by the manufacturer that may be helpful but is not required for such an installation?

    ANSWER: No. Some manufacturers have developed proprietary software beyond that required by 21 CFR 1020.30(g) for use as an aid during the assembly process. They are not required to provide such additional ancillary software.

    Additional information is available in FDA's guidance entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems."[15]

58. QUESTION: Are manufacturers required by the Performance Standards to provide maintenance and repair instructions to users or others?

[14] http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf
[15] http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf

ANSWER: No. The Performance Standards only require manufacturers to provide a schedule of maintenance (if any) necessary to maintain compliance with Performance Standards (21 CFR 1020.30(h)(1)(ii)). For more direction regarding information disclosure by manufacturers to assemblers, see FDA's guidance entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems."[16]

59. QUESTION: How does the FDA interpret the phrase "cost not to exceed the cost of publication and distribution" as used in 21 CFR 1020.30(g)?

ANSWER: Manufacturers may charge for the cost of producing each additional package or unit of instructions. The charge can incorporate factors such as the cost of paper, labor, use of a copying machine, shipping cost, or other costs associated with each package the manufacturer provides under the Performance Standard. For software, recoverable charges equivalent to printed materials would include such factors as the cost of the labor (e.g., technical and clerical) of producing such additional package or unit, computer disks, and packaging materials used to produce each additional unit of software.

60. QUESTION: Some manufacturers always include the assembly of their x-ray equipment as part of the initial purchase. Are such manufacturers required to provide assembly instructions to anyone who requests copies?

ANSWER: Yes. Assembly instructions must be provided to assemblers and, upon request to others at a cost not to exceed the cost of publication and distribution (21 CFR 1020.30(g)). Even though the manufacturer may perform the initial assembly, the system could subsequently be moved or sold and might need to be dismantled and then re-assembled by an assembler.

H. Accidental Radiation Occurrence

61. QUESTION: Does the requirement in 21 CFR 1002.20 concerning the reporting of "accidental radiation occurrences" apply to foreign manufacturers of products sold in the U.S.?

ANSWER: Yes. Foreign manufacturers of products sold in the U.S. are subject to the reporting requirements provided in 21 CFR 1002.20, and all of the requirements applicable to foreign manufacturers of products sold in the U.S.

I. Records

62. QUESTION: Sections 21 CFR 1002.30(a)(1) and (a)(2) call for maintaining records pertaining to (1) quality control procedures, and (2) test results. How do these requirements apply to foreign manufacturers and where does FDA expect the records to be maintained?

[16] http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/IndustryGuidance/UCM136731.pdf

ANSWER: Because all manufacturers are required to have quality control and testing programs (21 CFR 1010.2(c)), they are responsible for generating and maintaining records of the results of these programs. As long as the records are available within a reasonable timeframe during FDA inspections of the manufacturing facility, it does not matter where the records are stored.

J. Defects (See also questions 53 and 54)

63. QUESTION: Does FDA consider a failure which prevents a diagnostic x-ray system from producing x-rays to meet the definition of a "defect" as described in 21 CFR 1003.2(b)(3)?

ANSWER: If the failure to produce x-rays is the result of the design, production, or assembly of the x-ray system and the system appears ready to emit x-rays on command but fails to emit x-rays, then the failure will be considered a defect by FDA under 21 CFR 1003.2(b)(3) because the product fails to accomplish the intended purpose.

64. QUESTION: Does FDA consider a non-radiation related failure (e.g., broken wheel or drive mechanism failure on a mobile x-ray system), which causes the device to fail to accomplish the intended purpose, to meet the definition of a "defect" as used in 21 CFR 1003.2(b)(3)?

Answer: No. For diagnostic x-ray systems, FDA considers only those occurrences that are the results of the design, production, or assembly of the x-ray system and related to the emission of radiation including the failure to emit radiation when expected, to be defects under the failure to accomplish the intended purpose designation in 1003.2(b)(3). In this case, the broken wheel or drive mechanism failure may be the result of the design, production, or assembly of the system but it is not related to the emission of radiation and, therefore, does not meet the definition of a defect.

65. QUESTION: Does a burned-out x ray tube that does not produce x rays fall under the definition of a "defect" as used in 21 CFR 1003.2(b)(3)?

ANSWER: Under 21 CFR 1003.2(b)(3), a defect is defined as a product which "as a result of its design, production or assembly… fails to accomplish the intended purpose." Because x-ray tubes have an expected lifetime that is influenced by the age and use of the tube, the failure of an x-ray tube due to such causes will generally not be considered a defect under 21 CFR 1003.2(b)(3) by FDA but rather a normal and expected failure of the x-ray tube. However, an x-ray tube which burned out prematurely as a result of the design, production or assembly of the tube housing assembly or other components in the system may be considered a defect under 21 CFR 1003.2(b)(3). See also question 64.

66. QUESTION: Is a tube with an excessively large focal spot considered a "defect" under 21 CFR 1003.2 (i.e., the tube fails to meet the manufacturer's specifications for focal spot size)?

ANSWER: If a tube is sold with a focal-spot size that exceeds its specifications, then there is a defect - the product does not meet its own specifications relating to the emission of electronic product radiation (21 CFR 1003.2(b)(1)). If the tube met specifications when it was sold, but no

longer meets the specifications due to age or misuse, that failure to meet specifications may or may not be considered a defect.

The manufacturer bears the burden of proof in establishing that a defect or noncompliance is due to a cause other than faulty manufacture. This may include information to distinguish between normal wear and damage resulting from misuse of the equipment. For example, a certain amount of normal wear will occur in electronic products. If such normal wear results in radiation emitted by the product exceeding the limit prescribed in an applicable standard, the manufacturer may be charged with noncompliance because of his failure to design the product to maintain an acceptable level of radiation leakage over its useful life. See FDA's Compliance Policy Guide (CPG) 390.200.[17]

67. QUESTION: A manufacturer has found that some diagnostic x-ray systems that it shipped are noncompliant with the beam quality requirements under 21 CFR 1020.30(m)(1) because the manufacturer failed to install an aluminum filter plate in these systems. The manufacturer knows that other systems tested at its manufacturing facility passed this requirement with the filter plate installed, and therefore installing filter plates will correct the noncompliant systems. Would it be acceptable for the manufacturer to start correcting the noncompliant installed systems concurrent with notification to FDA?

    ANSWER: Yes. Upon discovery of a defect or failure to comply with an applicable performance standard, a manufacturer shall immediately notify the FDA in accordance with 21 CFR 1003.20 (see 21 CFR 1003.10(a)). Implementation of a corrective action plan may begin prior to the plan's approval by FDA. However, if the plan fails to correct the noncompliance or defect, or if FDA does not approve the corrective action plan, the manufacturer may be required to perform additional actions (21 CFR 1004.2 and 1004.6). To avoid these problems, a manufacturer should contact FDA regarding its corrective action plan prior to the plan's implementation.

68. QUESTION: What procedure does FDA follow upon discovering that a diagnostic x-ray system or component fails to comply with the regulations or has a defect?

    ANSWER: FDA notifies the manufacturer of the defect or failure to comply by providing the following in writing:

    a. How FDA determined that the product was noncompliant/defective (21 CFR 1003.11(a)(2));
    b. Details about the noncompliance including a reference to the specific regulation(s) with which the product is noncompliant (21 CFR 1003.11(a)(1));
    c. In the case of a defect, details about why the product is defective;
    d. A reasonable period of time during which the manufacturer may present its views and evidence to establish that there is no failure of compliance or that the alleged defect does

[17] https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM073911

not exist or does not relate to the safety of the use of the product by reason of the emission of electronic product radiation (21 CFR 1003.11(a)(3)); and

e. The manufacturer's obligation to repair, replace, or refund the cost of electronic products.

K. Fluoroscopy (See also question 54)

69. QUESTION: On June 10, 2006, several new requirements became effective for fluoroscopic x-ray systems manufactured on or after that date. If new components manufactured on or after that date are added to a fluoroscopic system manufactured before June 10, 2006, are the new requirements applicable to the system?

    ANSWER: No, the new requirements that became effective for fluoroscopic x-ray systems manufactured on or after June 10, 2006, are only applicable if:

    1. The complete system is certified and the system's date of manufacture falls on or after June 10, 2006; or

    2. All of the certified components in the system were manufactured on or after June 10, 2006, as provided by each of their identification labels.

70. QUESTION: The regulatory changes that became effective June 10, 2006 require fluoroscopic systems manufactured on or after that date to have a "last image hold" display and equipment to "clearly indicate" whether a live image or the "last image hold" is displayed (21 CFR 1020.32(j)(3)). How does FDA interpret the requirement to "clearly indicate" which image is being displayed?

    ANSWER: Any readily recognizable and distinguishable wording, icon, or image that is prominently displayed on the images or at the location where the "image hold" and "live image" information is displayed, in conjunction with clear explanations and descriptions in the information to be provided to users (21 CFR 1020.30(h)(1)(i)) (e.g., manuals or instructions) will satisfy the requirement under 21 CFR 1020.32(j)(3).

71. QUESTION: 21 CFR 1020.32(k) specifies that fluoroscopic systems manufactured on or after June 10, 2006 must display at the fluoroscopist's working position both the air kerma rate (AKR) and the cumulative air kerma. Would the display of the dose area product (DAP) (also called kerma-area product) and the cumulative DAP satisfy these requirements?

    ANSWER: No. Display of the DAP and cumulative DAP provide significantly different information relating to the x-ray field and do not satisfy 21 CFR 1020.32(k).

72. QUESTION: If a fluoroscopic system uses an under-table tube, and is also capable of spot-film exposures, is the tube considered a radiographic tube when used for spot-film exposures? If it is considered a radiographic tube, where should the indicator be placed to show that it was selected for an exposure as required by 21 CFR 1020.31(k)?

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ANSWER: The under-table tube is considered a radiographic tube when used for spot-film exposures, but a separate indicator is not required. 21 CFR 1020.31(k) applies to the situation where two or more tubes are controlled by the same exposure switch. Even though the tube is typically controlled by a separate exposure switch when used for radiography, it is not a separate tube. Therefore, the separate indication required by 21 CFR 1020.31(k) does not apply to the scenario proposed in the question.

73. QUESTION: A fluoroscopic x-ray system was manufactured after May 19, 1995 and the system limits the air kerma rate (AKR) to 88 mGy per minute (10 R per minute) by limiting the maximum peak tube potential. However, the fluoroscopic AKR could exceed the 88 mGy per minute limit momentarily (less than two seconds) if the operator changes to a higher mA setting while x-rays are being produced. This occurs during the time that the peak tube potential is driven down to a value sufficient to limit the AKR to 88 mGy per minute. The alternative would be to terminate production of x-rays during this time, but that could lead to a loss of important diagnostic information. The audible signal for high-level control (HLC) mode is set so that anytime the AKR exceeds 88 mGy per minute, the signal is activated. Is such a system acceptable?

    ANSWER: No. For fluoroscopic equipment manufactured on or after May 19, 1995, AKR greater than 88 mGy per minute are allowed only during activation of HLC or during recording of fluoroscopic images (21 CFR 1020.32(d)(2)(iii)). A special means of HLC activation is required (21 CFR 1020.32(d)(2)(iii)(C)). When HLC is activated the audible signal must also be activated, regardless of the actual air kerma rate (21 CFR 1020.32(d)(2)(iii)).

74. QUESTION: A manufacturer is planning to provide a high-level control (HLC) mode switch for fluoroscopy that does not require continuous pressure for activation. The manufacturer feels this would be safer because it would avoid accidental use of HLC by operators, free the operator from using a hand or foot consciously and allow them to concentrate on the clinical procedure, and would still provide a visual and audible warning immediately if the previous operator had left the unit in HLC mode. Is this acceptable?

    ANSWER: No. HLC mode shall be operable only when continuous manual activation of the fluoroscopic HLC switch is provided by the operator (21 CFR 1020.32(d)(2)(iii)(C)). A switch that activates the HLC mode without continuous pressure could activate HLC mode indefinitely, and does not provide the positive means required in the Performance Standards (21 CFR 1020.32(d)(2)(iii)(C)).

75. QUESTION: In certain fluoroscopy systems, the peak tube current is not user selectable. It remains constant and the average current changes automatically by varying pulse width and frequency (frame rate). In these systems, where peak tube current is held constant, will a label that provides the specified tube current meet the requirement of 21 CFR 1020.32(f)?

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ANSWER: No. 21 CFR 1020.32(f) requires continuous indication of both x-ray tube potential and tube current during any fluoroscopic exposure. A label is not an acceptable substitute for a continuous indication and is noncompliant with 21 CFR 1020.32(f).

76. QUESTION: The June 10, 2006 regulatory changes in the fluoroscopic regulations included a change under 21 CFR 1020.32(h)(2). A preset timer having a maximum cumulative time of 5 minutes is no longer required. Since this timer is not required for new equipment, may a manufacturer remove or disable the 5 minute preset feature from older equipment when customers request this modification?

ANSWER: Yes, as long as the fluoroscopic system is modified appropriately. The regulatory changes that became effective on June 10, 2006 removed the requirement for the 5 minute preset timer limit, but replaced it with new requirements for several additional features as specified in 21 CFR 1020.32(h)(2). Under 21 CFR 1020.30(q)(2), the owner of a diagnostic x-ray system may modify the system as long as the modification does not create a failure to comply with any requirements in effect at the time the affected system or component was manufactured. Simply removing or disabling the timer would create such a problem. However, under 21 CFR 1020.32(h)(1)(i) this modification is permitted if the system is also modified to meet the requirements of 21 CFR 1020.32(h)(2), and if a label stating "Modified to comply with 21 CFR 1020.32(h)(2)" is affixed to the control.

L. Specific components

(1) Beam Limiting Devices (see also questions 12, 15, 19, 78, and 98)

77. QUESTION: To produce a radiograph in a particular panoramic dental system, the diagnostic source assembly and film cassette rotate about the patient's head at a fixed source-image receptor distance (SID) while the film is advanced through the film holder. A narrow slit in the film cassette holder allows the useful x-ray beam to pass through while blocking scatter radiation from the exposed and unexposed sections of the film. This produces a laminographic view of the patient's jaw and teeth. Is such a design consistent with the requirements of 21 CFR 1020.31?

ANSWER: Yes. However, for the panoramic unit described above, the image receptor size is equal to that portion of the film instantaneously exposed through the slot in the cassette holder, rather than the entire image receptor. This means that for dental panoramic type units designed with a fixed SID and one image receptor size, the dimensions of the portion of the x-ray beam whose intensity is equal to or greater than 25 percent of the maximum intensity of the x-ray field (21 CFR 1020.30(b)) at the front plane of the cassette holder must be limited to the dimensions of the film instantaneously exposed through the slot in the cassette holder (21 CFR 1020.31(f)(2)) and the center of the x-ray field must be aligned with the center of the slot in the cassette holder within 2 percent of the SID. Alternatively, means may be provided to both size and align and x-ray field such that the x-ray field at the front plane of the cassette holder does not extend beyond any edge of the slot in the cassette holder.

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For dental panoramic type units in which the SID is variable, the x-ray beam dimensions where the intensity is equal to or greater than 25 percent of the maximum intensity of the x-ray field (21 CFR 1020.30(b)) at the front plane of the cassette holder shall not exceed the dimensions of the slot by more than 2 percent of the SID (21 CFR 1020.31(f)(4)). Alternatively, means may be provided to both size and align and x-ray field such that the x-ray field at the front plane of the cassette holder does not extend beyond any edge of the slot in the cassette holder.

78. QUESTION: A firm plans to manufacture and assemble cephalometric attachments designed for use with conventional intraoral dental x-ray equipment. What beam limitation requirements are applicable to the resulting system?

    ANSWER: When a certified cephalometric BLD is added to any existing diagnostic x-ray system, means must be provided to limit and align the x-ray field to the image receptor as specified in 21 CFR 1020.31(f)(2) or (f)(4), depending on whichever regulation is applicable. Therefore, if the means for alignment is dependent on other apparatuses or certified components being installed (e.g., head positioners, cassette holders), it may be necessary to install a complete cephalometric system. If the resulting cephalometric system is designed to be operated at one SID and one image receptor size, 21 CFR 1020.31(f)(2) is applicable; otherwise, 21 CFR 1020.31(f)(4) is applicable.

(2) Controls (See also questions 20, 35, and 36)

79. QUESTION: Users have requested that manufacturers install a remote exposure switch to permit the operator to be located further away from the x-ray beam and patient than normally would be permitted by the use of a retractable cord. The remote exposure switch would be provided in a separate box, on which are mounted the exposure switch, a light indicating that power is on to the entire control, and a light that indicates exposure. Is such an installation allowed by the regulations?

    ANSWER: Yes, as long as the following requirements are met:

    - The warning label (21 CFR 1020.30(j)) and technique factors to be used before an exposure begins must be visible and legible from any position where the remote exposure switch is mounted (21 CFR 1020.31(a)(1));

    - At the remote location, the beam-on indicators required by 21 CFR 1020.31(j) are provided (both a visual indication of x-ray production and a signal audible to the operator to indicate that the exposure has terminated); and

    - The instructions for assembly governing this remote switch option clearly address the two conditions above (21 CFR 1020.30(g)).

80. QUESTION: When a diagnostic x-ray system with a single x-ray control is used to control the operation of two or more diagnostic source assemblies (DSAs), how should the system indicate which tube or tubes have been selected?

ANSWER: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated before initiation of the exposure (21 CFR 1020.31(k)). This indication must be provided on both the x-ray control and at or near the tube housing assembly that has been selected (21 CFR 1020.31(k)). This could be accomplished with a graphical representation of the x-ray system at the x-ray control which indicates the active tube with lights or color accents. Alternatively, clear language may be presented to the user at the x-ray control such as "under-table tube active" or "over-table tube active".

81. QUESTION: When a diagnostic x-ray system with a single x-ray control is used to control the operation of two or more DSAs, does the linearity requirement (21 CFR 1020.31(c)) apply between the two DSAs?

ANSWER: No. If two or more DSAs are operated from the same control, each combination of DSA and control will be considered as a separate system for the purpose of determining applicability of the linearity requirement. Therefore, linearity is applicable for each such "system" combination, but not between the two "systems."

(3) Filters

82. QUESTION: How have the minimum half-value layer (HVL) requirements (21 CFR 1020.30(m)) changed since June 9, 2006?

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

The shaded-gray column in Table 2 below (Table 1 of 21 CFR 1020.30(m)) shows the increased values.

Table 2. Minimum HVL requirements (21 CFR 1020.30(m) TABLE 1)

X-Ray Tube Voltage (kilovolt peak)		**Minimum HVL (mm of aluminum)**		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[18]	I—Other X-Ray Systems[19]	II—Other X-Ray Systems[20]
Below 51	30	1.5	0.3	0.3

[18] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[19] 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.
[20] 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.

	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

85. QUESTION: 21 CFR 1020.30(m)(1) specifies that, for diagnostic x-ray systems, "positive means" must be provided to ensure the minimum filtration beam quality requirement is met for each exposure. In systems having variable filtration capability, where special radiographic techniques require temporary disengagement of the filter and/or mirror optic system, would a special tool with appropriate warnings and instructions that would disengage the filtration elements meet the requirements of "positive means"?

ANSWER: No. FDA does not believe a special tool would qualify as being a "positive means." By "positive means" FDA suggests that the manufacturer design the equipment so that exposure is inhibited until the proper filtration is in the beam (21 CFR 1020.30(m)(1)). Although special tools may be used to remove the filter during servicing, the operator should not have to routinely add and/or remove it during normal use. In the case of a diagnostic x-ray system that is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector that will prevent x-ray emissions if the minimum required filtration is not in the beam.

NOTE: A requirement to provide optional additional filtration is provided in 21 CFR 1020.30(m)(2) for certain fluoroscopic systems manufactured on or after June 10, 2006.

86. QUESTION: Do the Performance Standards cover use of a filter of varying thickness (beam-shaper) to obtain a uniform exposure at the surface of the film during an examination?

ANSWER: No. The Performance Standards do not place requirements on such filtration, but they do set requirements in Table 1 of 21 CFR 1020.30(m)(1) (see question 84) for minimum beam quality. FDA will test systems for compliance with the compensation filter in place and the beam-limiting device opened to the widest setting to make the half-value layer

determination. Since the filtration is not uniform across the useful beam, the region of minimum thickness will be the value used to determine compliance.

87. QUESTION: A manufacturer produces an x-ray system rated nominally at 70 kVp and has established a kVp tolerance of plus or minus 5 percent (±5%). If the measured kVp of the system is 73, and referencing Table 1 of 21 CFR 1020.30(m)(1), must the minimum half-value layer (HVL) be at least 2.6 mm of aluminum (by linear interpolation from the "above 70" kVp section) or 1.9 mm of aluminum (by linear extrapolation from the "51 to 70" kVp designed operating range)?

    ANSWER: 1.9 mm of aluminum is an acceptable value. In 21 CFR 1020.30(h)(3) and 1020.31(a)(4) each manufacturer is required to establish and state its own technique factor accuracy specifications. If a machine is designed to operate only in the range of 51 to 70 kVp, the appropriate range in Table 1 for determining HVL compliance is the 51 to 70 kVp range, regardless of whether the measured kVp exceeds 70 or falls below 51 kVp. If the measured kVp value falls outside of this range, the manufacturer should determine the correct HVL by linear extrapolation from Table 1 under 21 CFR 1020.30(m)(1). The manufacturer should extrapolate from the values for HVL given for the two kVp values (within the designed operating range) that are closest to the measured kVp. In this example, the HVL value for 73 kVp should be extrapolated from the 51 to 70 kVp operating range and the correct minimum HVL is 1.89 mm of aluminum.

    If a system is designed to operate in multiple kVp ranges, the appropriate range for determining HVL compliance is dictated by the selected operating tube potential.

(4) Image Receptors

88. QUESTION: Under 21 CFR 1020.30(a)(1)(i)(F), the June 10, 2006 update of the Performance Standards now includes "Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006," as certifiable diagnostic x-ray components. How does FDA interpret this change and what requirements are applicable to the covered products?

    ANSWER: FDA currently limits the applicability of 21 CFR 1020.30(a)(1)(i)(F) to only those electrically-powered image receptors that are used as fluoroscopic image receptors. This includes image receptors that are used for a combination of both fluoroscopy and radiography. FDA does not intend to enforce the requirements under 21 CFR 1020.30(a)(1)(i)(F) to image receptors that are electrically powered or connected to radiographic only systems at this time.

    NOTE: Additional requirements may apply to image receptors if they perform additional functions where requirements are specified in the Performance Standards. See question 7 where adding x-ray control functionality to a digital detector is discussed as an example.

89. QUESTION: What additional information is required to be provided to users regarding image receptors that are electrically powered or connected?

ANSWER: For x-ray systems, manufactured on or after June 10, 2006 that produce images using a fluoroscopic image receptor, the following information is required by 21 CFR 1020.30(h)(5) and "must 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."

For additional information on requirements for these image receptors, see FDA's guidance entitled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices."[21]

90. QUESTION: Would it be permissible to control a light localizer with two switches performing the following functions:

    a. When switch number 1 is activated, the light intensity is equal to about 100 lux at 100 cm; and

    b. When both switches are activated, the light intensity is equal to about 160 lux at 100 cm, and it is timed so that after 30 seconds, the intensity decreases to about 100 lux?

    Would such a system meet the requirement in 21 CFR 1020.31(d)(2)(ii)?

    ANSWER: No. 21 CFR 1020.31(d)(2)(ii) requires that whenever the light localizer is activated, the intensity must be equal to or greater than 160 lux at 100 cm or the maximum SID, if less than 100 cm.

91. QUESTION: 21 CFR 1020.31(d)(2)(ii) and 21 CFR 1020.31(d)(2)(iii) place requirements on the intensity and edge contrast that must be provided when light field localizers are incorporated into general purpose x-ray systems. What requirements, if any, are applicable to special purpose x-ray systems such as mammography, podiatry, and cephalometric systems incorporating light localizers?

    ANSWER: The answer depends on how the light field is used. If the light field device is intended for use only as a centering light and is not intended by the manufacturer or perceived by the user as visually defining the perimeter of the x-ray field, then no specific illumination

[21] https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm073781.pdf

intensity or light field contrast requirements apply. However, if the light field is intended for use by the manufacturer or perceived by the user to visually define the perimeter of the x-ray field, then the illumination intensity requirement of 21 CFR 1020.31(d)(2)(ii) and the light field edge contrast requirements of 21 CFR 1020.31(d)(2)(iii) are applicable.

(5) Mechanical Tomographic Systems

92. QUESTION: Traditionally, a tomographic attachment for a standard radiographic x-ray system consists of a mechanical interconnecting arm, a drive system, and electrical switches, one of which initiates exposure and another of which terminates the exposure. Thus, the tomographic device becomes an exposure timing device. However, its accuracy may be suspect because of mechanical friction or accuracy of attachment by the user.

    If the exposure termination switch is removed, the exposure timing function would revert to the x-ray control, to be set by the user. Would the tomographic attachment then no longer be a certifiable component?

    ANSWER: Yes.

93. QUESTION: A manufacturer markets a mechanical tomographic kit to be added to its x-ray table. However, since the kit is capable of controlling exposure time, it is subject to the Performance Standards. The manufacturer's instructions specify that the console timer must be set to terminate the exposure before the exposure switch in the tomographic attachment would terminate it, thus making the tomographic exposure control serve merely as a back-up. Therefore, the manufacturer concludes that the tomographic timer would not need to be certified. Would this be a satisfactory approach?

    ANSWER: No. Tomographic attachments that control the exposure time are required to be certified (21 CFR 1020.30(a)(1)(i)(A)). This is true even of tomographic controls used as back-up timers. See also question 7.

94. QUESTION: Are exposures made during the operation of radiographic systems in a tomographic mode subject to the reproducibility and linearity requirements of 21 CFR 1020.31(b) and (c)?

    ANSWER: Yes. The reproducibility and linearity provisions of 21 CFR 1020.31(b) and (c) are applicable during the tomographic mode of operation.

(6) Source-image receptor distance (SID) Indicators

95. QUESTION: 21 CFR 1020.31(e)(1) states that "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." A manufacturer proposes meeting the requirement for indicating SID by placing microswitches at discrete operating locations and providing: (1)

user instructions specifying the position of each microswitch and the corresponding SID to the permanently-mounted image receptor, and (2) installation of an "exposure ready light" on the beam-limiting device. This light would only be illuminated when a microswitch is activated. The microswitches are frequently used to provide discrete SIDs with a wall-mounted image receptor, and are occasionally used to provide discrete SIDs with an under-table image receptor. Would such a configuration satisfy the applicable requirements?

ANSWER: No. A statement of the SID(s) in the user instructions alone is not sufficient. All stationary general purpose radiographic systems must be equipped with means to provide numerical indication of any and all SIDs (21 CFR 1020.31(e)(1)) at which the system is designed to operate when the x-ray beam is perpendicular to the plane of the image receptor. The SID value must be indicated on the system (21 CFR 1020.31(e)(2) and (3)).

(7) Timers (See also questions 92 and 93)

96. QUESTION: A firm wants to manufacture and sell replacement electronic timers for installation into existing x-ray controls. Are there any specific requirements for these timers?

ANSWER: Yes. FDA considers such timers to be x-ray controls (21 CFR 1020.30(a)(1)(i)(A)) and, as such, must be certified (21 CFR 1020.30(c)). Replacement timers require adequate labeling, statements of accuracy, and compatibility information (21 CFR 1020.30(g)). The labels must be legible and readily accessible to view when the product is fully assembled (21 CFR 1010.2 and 1010.3). See also question 20.

(8) Tube Housing Assemblies (See also questions 12 and 34)

97. QUESTION: A manufacturer produces a number of x-ray tube housing assemblies to be used solely for testing purposes and never to be used on patients. The manufacturer also has tube housing assemblies that are used in trade show displays that will never be sold for patient use and are not intended to be connected to produce x rays. Does the manufacturer have to certify these tube housing assemblies?

ANSWER: No. The intent of electronic product certification for x-ray systems and components is to assure that patients and users are protected from unnecessary electronic product radiation. Since these tube housing assemblies will not be used to irradiate any part of the human body for the purpose of diagnosis or visualization, then they are not considered major components of a diagnostic x-ray system (21 CFR 1020.30(b)) and they do not have to be certified. FDA recommends that manufacturers mark the tube housings clearly as to their intended purpose, make them non-functional, or include assembly instructions to indicate that the tube housings are not to be used on patients.

98. QUESTION: The Performance Standards limiting x-ray leakage (21 CFR 1020.30(k)) and capacitor discharge system standby radiation (21 CFR 1020.31(l)) apply to the diagnostic source assembly, which includes the tube housing assembly (THA) and the BLD). How does a

manufacturer who wishes to certify only a BLD or THA perform certification testing on this component?

ANSWER: The manufacturer must ensure that the THA or BLD it is certifying is compatible with the components with which it is intended to be used (21 CFR 1020.30(g)). This firm, or the manufacturer of the other components (if the components are manufactured by different firms), must test the THAs or BLDs with those devices with which compatibility is specified (21 CFR 1020.30(g)). Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. A firm which specifies compatibility with other components should perform periodic direct testing of the component combinations to confirm continuing compatibility. Once established, compatibility may be specified in terms of manufacturer name and model number or in terms of generic physical characteristics. See also question 8.

99. QUESTION: If a manufacturer replaces a tube insert in a THA, does it need to change the date of manufacture on the THA's identification label? What about any other required labeling on the housing?

ANSWER: Yes. With the exception of quick-change tubes, replacing the tube insert in a THA requires that the THA show a new date of manufacture (21 CFR 1020.30(e)(1), (e)(2) and (e)(3)). The previous label must be removed, covered, or defaced so that only the new date is shown (21 CFR 1020.30(e)(2)). In the event that any other information is different, such as name and address of manufacturer or model or serial number, this information also must be changed in the same manner (21 CFR 1020.30(e)(1), (e)(2) and (e)(3)). See also question 34.

100. QUESTION: Does the answer to question 99 (above) change if the system contains a single-labeled group of components that includes the tube housing assembly that is to be re-loaded?

ANSWER: If there is a single-labeled group of components that includes a tube housing assembly that needs replacement, then there are two options:

a. Re-label the single-labeled group of components (date of manufacture, model number and serial number if applicable, tube insert model information and change of certifying manufacturer if applicable) to meet 21 CFR 1020.30(e)(1). The date used should be the date of replacement of the tube insert, not the original date of manufacture. (21 CFR 1020.30(e)(2)).

b. If adding the tube insert does not affect any aspect of compliance, an additional label may be used to provide tube insert model information and change of manufacturer if applicable.

101. QUESTION: Do repairs to a tube housing assembly, including repairs that require the temporary removal and reinstallation of the same insert, constitute the manufacture of a new tube housing assembly?

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ANSWER: No. Any repair done on any tube housing assembly that does not include insertion of a different tube insert in a previously certified tube housing is considered repair (21 CFR 1020.30(d)(2)(iii)) and does not constitute the manufacture of a new tube housing assembly. However, any time that the integrity of the THA shielding has been compromised, FDA recommends that evidence be provided to the user to assure continued compliance of the tube housing assembly with leakage and compatibility requirements.

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