Contains Nonbinding Recommendations

Guidance for Industry and Food and Drug Administration Staff

Assembler's Guide to Diagnostic X-Ray Equipment

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This document supersedes Assembler's guide to diagnostic x-ray equipment: responsibilities of assemblers, distributors, and dealers of diagnostic x-ray equipment under the federal performance standard (DHHS Publication FDA 81-8144, November 1980)

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Food and Drug Administration
Center for Devices and Radiological Health
Office of Communication, Education, and Radiation Programs
Division of Mammography Quality and Radiation Programs
Diagnostic Devices Branch

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to www.regulations.gov. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and Food and Drug Administration Staff

Assembler's Guide to Diagnostic X-Ray Equipment

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The Center for Devices and Radiological Health (CDRH) is charged with the responsibility for enforcing regulations created under the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) (the Act). The Act was later moved to the Food, Drug, and Cosmetic Act (FD&C Act) with the passage of the Safe Medical Devices Act of 1990 in a new section entitled Electronic Product Radiation Control (EPRC) section under Subchapter V – Part C. The regulations written under the Act are covered in 21 CFR Chapter I, Subchapter J and the Diagnostic X-ray Performance Standards for Electronic Products. These regulations cover the manufacturing, importing, and installation of equipment that emits electronic product radiation to achieve its intended purpose or as a byproduct of meeting its intended purpose. Specific regulations under "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) 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" will be used in this document to refer to these regulations collectively known as the Performance Standards for Diagnostic x-ray systems and their major components. This document addresses only requirements that apply to Diagnostic X-ray equipment under the EPRC provisions of the FD&C Act. This document does not address requirements that apply to such equipment under the medical device provisions of the FD&C Act.

As a part of the requirements under the Performance Standards, manufacturers of diagnostic x-ray equipment that is used on human patients must provide reports to CDRH that document that these products comply with all applicable requirements in the Performance Standards covered in 21 CFR 1020.30, 1020.31, 1020.32, and 1020.33. They must also affix labels to the products that declare they are certifying those products to meet the regulations (21 CFR 1010.2). Many diagnostic x-ray systems consist of components from different manufacturers while other systems use components from a single manufacturer. Whether these systems comply with the Performance Standards is dependent upon proper installation and final testing of the complete system at the user location, which FDA considers the final step in the manufacture of these systems.

FDA's guidance documents, including this 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.

General Responsibilities of Manufacturers of Diagnostic X-Ray Equipment

21 CFR 1000.3(n) defines a manufacturer as "*any person engaged in the business of manufacturing, assembling, or importing electronic products.*"

In general, manufacturers must:

1. Certify that each component complies with the 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)).
2. Place certification and identification labels 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).
3. Provide the assembler with instructions for assembly, installation, adjustment, and testing of the component sufficient to assure the product will comply with the Performance Standards when the instructions are followed. 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)).
4. Provide the purchaser with instructions describing specific technical specifications of the equipment and any necessary radiological safety precautions and procedures. This information must include a recommended maintenance schedule required to keep the equipment in compliance with the Performance Standards (21 CFR 1020.30(h)).

General Responsibilities of Assemblers of Diagnostic X-Ray Equipment

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.*" This is true even if the individual is not normally in the business of installing such equipment.

Although the above clearly specifies that the "assembler" is also a "manufacturer", the Performance Standards have different requirements for each.

Assembler responsibilities, outlined in 21 CFR 1020.30, are applicable to all assemblers of diagnostic x-ray systems and/or components installed into any system used on live human patients.

"1020.30(d) *Assemblers' responsibility. An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by Sections 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.*

> *(1) Reports of assembly. All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under Sections 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of Sections 1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.*"

The Assembly of Certified Diagnostic X-ray Equipment

1. QUESTION: The Performance Standards require manufacturers of diagnostic x-ray products to file various reports with CDRH. Since assemblers are defined as being manufacturers, must they file all reports required of manufacturers?

ANSWER: No. The Performance Standards permit the assembler, who only installs components or systems manufactured by others, to meet most of the reporting and recordkeeping requirements by filing the report of assembly (Form FDA 2579; also, see

guidance for filing e2579s below) specified in 21 CFR 1020.30(d)(1) and keeping copies for at least five years (21 CFR 1002.1(c)(4)). The only other reporting requirement placed on such assemblers is found under 21 CFR 1002.20 which requires assemblers to file reports of situations where accidental radiation occurrences have occurred or may occur.

2. QUESTION: What is an accidental radiation occurrence (ARO)?

ANSWER: An ARO means "*a single event or series of events that have/has resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.*" (21 CFR 1000.3(a))

3. QUESTION: Must an assembler report AROs?

ANSWER: Yes. If an assembler becomes involved with or aware that such a situation exists or may exist, he/she must notify the Center for Devices and Radiological Health (21 CFR 1002.20). Such notification shall be addressed to the Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports, Office of Communication, Education, and Radiation Programs, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993, and the reports and their envelopes shall be distinctly marked "Report on 1002.20" and shall contain all of the following information where known:

(1) The nature of the accidental radiation occurrence,

(2) The location at which the accidental radiation occurrence occurred,

(3) The manufacturer, type, and model number of the electronic product or products involved,

(4) The circumstances surrounding the accidental radiation occurrence, including causes,

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Center for Devices and Radiological Health, the names of the persons involved,

(6) The actions, if any, taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence,

and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

The assembler should also notify (1) the user, (2) the State and local radiation control authorities, and (3) the component manufacturer. The reports may also be submitted using eSubmitter following the instructions in item 6. "Adverse Event Reporting," at http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ucm202505.htm

Classification of Components and Systems by Certification Status

There are two broad classifications of components that must be considered before bringing them together into a complete system. Components are classified by the certification status of each and they are either certified or uncertified. Systems are classified as certified, uncertified, or mixed.

4. QUESTION: What are certified components?

ANSWER: Certified components are specified components manufactured after an effective date (as published in the Performance Standards) that a manufacturer has designed, manufactured and tested to meet the applicable requirements of 21 CFR 1020. Each manufacturer reports its products to the FDA and certifies that, when installed and tested according to manufacturer instructions, the resulting system will meet all applicable requirements. The manufacturer must affix a certification label to each component to indicate that the component complies with the Performance Standards. Each component manufactured after its specified effective date must be certified.

5. QUESTION: What is an "uncertified component"?

ANSWER: CDRH defines an "uncertified component" as a diagnostic x-ray component that was manufactured before August 1, 1974, and not certified before that date by the manufacturer.

NOTE: Some manufacturers chose to certify equipment before the effective date of the Performance Standards. FDA allowed this certification if the manufacturer met the requirements before the August 1, 1974 effective date. These certified components should have been labeled with a date of manufacture before the effective date and bear a certification label.

6. QUESTION: What is a certified x-ray system?

ANSWER: A certified system is one that is assembled of all certified compatible components that are designed to function together as a system meeting all applicable requirements in 21 CFR 1020.

7. QUESTION: What is an uncertified x-ray system?

ANSWER: An uncertified system is one that is assembled of all uncertified components.

8. QUESTION: What is a mixed system?

ANSWER: Mixed systems are complete systems composed of both certified and uncertified components.

9. QUESTION: What components are subject to the Performance Standards?

ANSWER: The following specific components are included along with any other components that behave in substantially the same way (i.e., serve the same function) as those listed. For example, x-ray timers are not listed below, but they are certifiable components requiring inclusion in the report of assembly because they serve substantially the same function as components listed in the regulations (see as 21 CFR 1002.1 Table 1, and 1020.30(a)).

- Tube housing assemblies (tube housings with x-ray tube installed),
- X-ray controls (includes exposure timers when housed separately),
- X-ray high-voltage generators (transformers with other appropriate elements),
- Fluoroscopic imaging assemblies manufactured before April 26, 1977 or after June 10, 2006,
- Tables,
- Cradles,
- Film changers,
- Cassette holders (includes vertical frames, cephalometric film holders, any cassette holder with a front panel; excludes film trays within tables),
- Beam-limiting devices (BLDs) (collimators, diaphragms, cones, etc.),
- Spot film devices and image intensifiers manufactured after April 26, 1977,
- Cephalometric devices manufactured after February 25, 1978,
- Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978,
- Cumulative air kerma display devices in x-ray systems manufactured on or after June 10, 2006,
- Air kerma rate (AKR) display devices in x-ray systems manufactured on or after June 10, 2006,
- Electrically powered fluoroscopic image receptors in x-ray systems manufactured on or after June 10, 2006.

10. QUESTION: Can I legally modify a certified component or system and, if so, do I need to file the manufacturer reports with the FDA?

ANSWER: If you are an owner of a diagnostic x-ray system and use the system in a professional or commercial capacity or are acting under the instructions of such an owner, you may, under certain conditions, modify certified components and/or systems without filing the reports required of plant-based manufacturers. Certified components or systems

may be modified, provided that the modification does not result in the failure of the x-ray component or system to comply with the Performance Standards (see 21 CFR 1020.30(q)). Modifications that adversely affect the compliance of a component or system are permitted only when a variance has been granted in accordance with the regulations (see 21 CFR 1010.4).

An owner who modifies his/her x-ray system without affecting compliance (including compatibility) need not submit the reports usually required of manufacturers and/or assemblers, but is required to record the date and the details of the modification and retain that information.

11. QUESTION: What does the FDA mean when referring to the "repair" of a component or system?

ANSWER: Repair of a certified component or system means the act of bringing a malfunctioning item back to the original manufacturer's specification.

Restrictions on Assembly of Components

The certification status of the components in a system influences the ability of an assembler to legally install additional components into an existing system.

12. QUESTION: What requirements are applicable to assembly and reassembly of diagnostic x-ray systems?

ANSWER: The rules covering the assembly and reassembly of these systems are addressed in 21 CFR 1020.30(d). The important points to remember are:

1. A new system, consisting of all unused components, may only be assembled with all certified or all uncertified (manufactured before August 1, 1974) components.
2. A complete x-ray system may be assembled from all uncertified (manufactured before August 1, 1974) components, without restriction, if all components were never previously assembled into an x-ray system.
3. A complete x-ray system may be assembled from all certified components, without restriction, if all components have documented necessary compatibility.
4. An existing x-ray system that contains all uncertified components may be reassembled. Additional or replacement components must all be uncertified or all certified. (This excludes repair or exact replacement of uncertified components.)
5. An x-ray system that contains one or more certified components may be reassembled. Additional or replacement components must all be certified. (This excludes repair or exact replacement of uncertified components.)
6. Exchange of an uncertified component for an identical uncertified component, or reinstallation of any component following repair of the component to its original condition, is not considered assembly or reassembly for the purposes of the Performance Standards.

13. QUESTION: May one or more uncertified components from a previously existing system be sold and later reassembled with certified components to form a complete system?

ANSWER: Yes. A previously existing uncertified system may be upgraded by replacing or adding certified components and being introduced into commerce. Replacement of uncertified elements by certified elements within existing systems is considered an upgrade of the system. After the introduction of the first certified component into a system, all subsequent components must be certified unless an exact replacement for an existing uncertified component (repair) is installed. All certified components must be compatible as required by the Performance Standards (21 CFR 1020.30(d)).

14. QUESTION: May an assembler legally replace all but one component in an existing uncertified x-ray system with certified components?

ANSWER: Yes. The certified components would be considered replacement components and may be assembled with the existing uncertified component; however, the certified components must be compatible as required (21 CFR 1020.30(d)).

15. QUESTION: A practitioner is planning to buy an existing uncertified or mixed radiographic system and intends to later add certified fluoroscopic capability. Is this allowed?

ANSWER: Yes. Existing systems comprised of all certified, all uncertified, or mixed components may be reassembled following resale. The addition of certified components or subsystems is permitted during assembly of a preexisting system or at a later date since such changes are considered upgrades (21 CFR 1020.30(d)).

16. QUESTION: What does "accessory component" mean? Must the installation of such components be reported to the FDA?

ANSWER: Accessory component means: (21 CFR 1020.30(b))

1. A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system, or
2. A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting apertures, or
3. A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions (21 CFR 1020.30(d)(2)(ii)). An example of a certified accessory component which needs no reporting is a table top cassette holder without a front panel.

If the manufacturer of such accessory components has certified the product and reported to the FDA as required in 21 CFR 1002.10, no report of assembly is required.
Components falling into categories 1 or 2 (above) do not require filing a report of assembly for subsequent use of the accessory within other compatible systems within the same facility. However, permanent relocation of a certified accessory component into a compatible system(s) at a new address does require submission of another report of assembly to certify compatibility and installation in accordance with the manufacturer's instructions. Accessory components in category 3 (above) deserve special attention in that their use within a system(s) does not require assembly. If the manufacturer of such accessory components has reported to the FDA that no specific assembly is required then the assembler's reporting and certification requirements of 21 CFR 1020.30(d) are not applicable.

17. QUESTION: What does "compatibility" mean when referring to components and why is it important?

ANSWER: Many diagnostic x-ray systems are assembled from individual components. Many times these components may be manufactured by different firms and at different times, often years apart. To assure that they will work together to form a system compliant with the Performance Standards, a statement of compatibility is required from each component manufacturer.

There are three definitions of compatibility that apply to diagnostic x-ray systems.

a. Operational or Functional Compatibility
   Prior to the effective date of the Performance Standards, any combination of components could be interconnected provided the operational functions of the system were not impaired to an extent objectionable to the user. This definition of compatibility differs from the Performance Standard's implied definition of compatibility (1020.30(g) and (h)). Installations based only on operational or functional compatibility are no longer acceptable for installations involving certified components.

b. Manufacturer Specified Compatibility
   As implied by the name, this type of compatibility is specified by manufacturers of certified diagnostic x-ray components. It means that when compatible components are brought together, following the manufacturer’s assembly and testing instructions, the finished subassembly or system will meet the requirements of the Performance Standards. According to these standards, it is the responsibility of the manufacturers of individual components or systems to specify the compatibility of certified components (see 21 CFR 1020.30(g) and (h)). If none of the manufacturers state compatibility, either by specific model designation or a description of pertinent physical characteristics, then the components are described as noncompatible and, if installed, should be so stated on the assembler's forms. Operational compatibility, although important, does not justify the assembly of certified components not stated to be compatible by the manufacturers, since it is not known if they will perform in

accordance with the Performance Standards. An installation involving a noncompatible, certified component is allowed only when a compatible component is not commercially available and in conjunction with an approved variance (21 CFR 1010.4).

c. Noncompatible
Any components that rely on the performance or characteristic(s) of other components for which no compatibility has been stated are considered to be noncompatible.

NOTE: When the terms "compatible" or "compatibility" appear in this document, it is intended that they reference the manufacturer specified compatibility unless otherwise indicated.

18. QUESTION: Is it necessary that compatibility be stated between all of the components installed in a diagnostic x-ray system?

ANSWER: No. Compatibility statements are required of component manufacturers only when the interconnection or use together of those components depends on their compatibility (21 CFR 1020.30)(g) and (h)). An example requiring a compatibility statement is a high voltage generator used with a control. An example when the compatibility statement is not required is an x-ray table installed with a permanently mounted wall cassette holder. NOTE: If these were installed into a system having positive beam limitation (PBL), each would require a statement of compatibility with the PBL collimator, but not with each other.)

19. QUESTION: How should an assembler determine if there are any compatible components for a particular situation?

ANSWER: An assembler, in attempting to determine commercial availability of a component, should, at a minimum, take the following steps to find a compatible component: (1) Consult the information supplied by the manufacturer of the certified component being installed to see if the manufacturer has made a determination of compatibility regarding the component or an alternate model for the system in question; if unsuccessful, (2) consult the manufacturer(s) of the component(s) of the system not meeting the specification for compatibility to determine if alternate components exist which would be compatible and perform the intended functions. If the lack of compatibility was simply an oversight, contact one or more of the manufactures to determine if they are willing to state compatibility; if unsuccessful, (3) contact CDRH for assistance in identifying a compatible component.

20. QUESTION: What is meant by "commercial availability" and how does an assembler determine commercial availability?

ANSWER: A component is "commercially available" if it can be supplied by any manufacturer within a reasonable time period.

21. QUESTION: If there are no commercially available compatible components, is it permissible to interconnect components for which no statement of compatibility exists?

ANSWER: This depends on the certification status of the components involved. Certified components which are not compatible may not be interconnected without a variance from the Performance Standards (see 21 CFR 1010.4). The interconnection of certified and uncertified components for which compatibility has not been stated may be completed if they meet the criteria for operational compatibility to upgrade existing uncertified or mixed systems.

Problematic Assembly Situations

22. QUESTION: If the manufacturer's instructions to the assembler are inadequate, confusing or incorrect in any way, is the assembler obligated to complete the installation?

ANSWER: If the instructions are unclear, the assembler should advise the manufacturer that there is some confusion related to a particular installation and request clarification. The "Comments" section of the report of assembly form is an appropriate means of informing FDA of such problems. Installation should be postponed if the problem could result in the assembled equipment being noncompliant with the Performance Standards.

23. QUESTION: May an assembler refuse to connect equipment to a user's power source?

ANSWER: Yes. The assembler of the x-ray control is required to assemble, install, adjust, and test the certified component in accordance with the manufacturer's instructions. Connection of the unit MUST be refused if the required power specified by the manufacturer is not available (21 CFR 1020.30)(d)).

Temporary Installations

24. QUESTION: A component occasionally needs to be removed from a system for an extended time for repair. Is it acceptable to temporarily install a compatible replacement component so that the facility can resume using the system?

ANSWER: Yes. A compatible replacement component may be installed to temporarily replace a component while it is being repaired. If the original component is uncertified, the loaner component may be either certified or uncertified. If the original component is certified, the loaner must be certified (21 CFR 1020.30)(d)). Upon installation of a certified loaner component, the assembler is not required to file a report of assembly provided the loaner component is (1) clearly labeled as a temporarily installed component and (2) bears a temporary tag or label with the statement shown in the response to Question 27 below, (or a temporary report of assembly stating the component involved is temporary) signed and dated by the assembler affirming compliance with all applicable requirements of the Performance Standards (see 1020.30(d)(2)). Even though a report of assembly is not required, the FDA considers the installation of a certified loaner component to be the introduction of the

component into commerce and the dealer, distributor, and manufacturer are still required to maintain all of the records specified under 21 CFR 1002.40.

Reports of Assembly

25. QUESTION: What is a "Report of Assembly of a Diagnostic X-ray System"?

ANSWER: A report of assembly is a form (form number FDA 2579; see Question 28 for electronic reporting) required by the FDA to document that an assembler has installed the system or component according to the manufacturer's instructions. The Performance Standards require that anyone who assembles a certified component into a human-use diagnostic x-ray system report that assembly to the FDA (except as outlined below) (21 CFR 1020.30)(d)). This applies regardless of whether the assembler installs an entire system or adds or replaces a single certified component into an existing system. It also applies to users of systems who install a certified component into an x-ray system, even for their own use. Many diagnostic x-ray systems consist of separate components that only become a system at the user location. This means that the installation of the component(s) into an x-ray system is the last step in the manufacturing process. The form serves as documentation that the equipment installed is certified, compatible with other components in the system, was installed and tested following the manufacturer's instructions, and is of the type called for by the Performance Standards.

26. QUESTION: Are there any exceptions to the requirement to file reports of assembly?

ANSWER: Yes. The Performance Standards have provisions for some exceptions to the assembler reporting requirements and they are included under 21 CFR 1020.30(d)(2). In addition, assemblers are not required to report the assembly of uncertified components into an existing system. These exceptions will apply if the system is being moved, sold, or repaired.

21CFR 1020.30(d)(2) states:

> "*Exceptions to reporting requirements. Reports of assembly need not be submitted for any of the following:*
>
> *(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system,*
>
> *(ii) Certified accessory components that have been identified as such to CDRH in the report required under Sections 1002.10 of this chapter,*
>
> *(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported, or*

(iv) (A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
"This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer."
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section."

NOTE: The exception in 1020.30(d)(2)(i) applies to those tube housing assemblies that are equivalent to those being replaced. If the tube housing assembly differs from the one it is replacing, the assembly should be reported to FDA. The exception in 1020.30(d)(2)(ii) applies only to certified components reported to FDA by the manufacturer where no specific assembly is required. It also must state in the assembler/user information that no assembly or installation is required.

27. QUESTION: Is there an alternative to filing the printed Form FDA 2579 to report an assembly?

ANSWER: Yes. Instead of filing a paper version of the form, CDRH allows electronic submission of the information required on the FDA 2579 form through its CeSub eSubmitter software application through the FDA Electronic Submissions Gateway (ESG). Once the e2579 submission is complete, the submitter will receive an acknowledgment of receipt via e-mail. You may download this software application from http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm. If you would like to take advantage of this provision, please visit http://www.fda.gov/esg/ to register as a trading partner and obtain an ESG account. If you have any questions regarding the registration process or the Gateway in general, please contact the help desk as indicated on the website.

Using the eSubmitter software is currently voluntary. If you are unable to take advantage of electronic reporting, you may continue to submit the paper versions of the Form FDA 2579. Paper versions of the forms may be requested by following the instructions listed at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

28. QUESTION: What does the filing of the report of assembly mean regarding the assembler responsibility?

ANSWER: In signing the form, an assembler takes legal responsibility for the following:

- the certified components installed were:
  (a) adjusted and tested according to the instructions provided by the manufacturer(s),
  (b) of the type required by the manufacturer(s),
  (c) of the type called for by the Performance Standards (21 CFR Part 1020)
  (d) not modified to adversely affect performance, and
  (e) installed in conformance with provisions of 21 CFR Part 1020,
- all instruction manuals and other information required by 21 CFR 1020 for this assembly were furnished to the purchaser, and
- the assembler will submit to the FDA, the State, and the user, within 15 days of the date of assembly, the information required on the Form FDA 2579, either through FDA's CeSub eSubmitter application (refer to Question #28) or using the paper form.

29. QUESTION: What is meant by the expression "were of the type required by the manufacturer(s)" as referenced on the Form FDA 2579?

ANSWER: Every manufacturer of a certified component is required to state the compatibility requirements with other components that may be included in a final assembled system. The type required by the manufacturer(s) means that assemblers must meet these compatibility requirements when matching components for a complete system (21 CFR 1020.30)(d)).

30. QUESTION: What is meant by the expression "the type called for by the diagnostic x-ray performance standard" as referenced on the Form FDA 2579?

ANSWER: "The type called for by the diagnostic x-ray performance standard" means that the assembler has installed certified components in a given system (except for situations mentioned above where pre-August 1, 1974 uncertified components may be installed) and that all compatibility issues have been met.

31. QUESTION: Some requirements in the Performance Standards regarding the type of components called for in a system are different for "general purpose x-ray systems" and those that are considered as "other than general purpose." How can an assembler determine if a system is a "general purpose" system or not?

ANSWER: An x-ray system, designed for and limited by its design for diagnostic purposes to only one of the following body regions, is classified as "other than general purpose" for the purposes of 21 CFR 1020.31.

1. Extremities,
2. Head or head and neck,
3. Thoracic,
4. Abdominal,
5. System designed for cystographic, urologic, or other specialized exams of the kidney, bladder, and/or urinary tract,
6. Dental x-ray system designed for use with intraoral and/or extraoral image receptors,
7. Cephalometric x-ray system or dental x-ray system designed for use with extraoral image receptors whenever special cephalometric devices are attached,
8. An x-ray system designed specifically for chest or spinal radiography when installed:
    a. with a single fixed source-to-image-receptor distance (SID) along the horizontal axis, or
    b. with two SIDs along the horizontal axis when exposure at one of the two SIDs is restricted to image receptors with a dimension greater than 50 centimeters (20 inches).
9. Mammographic x-ray system,
10. Therapy simulation x-ray system,
11. System designed for and installed in operating rooms,
12. Pantomographic x-ray system,
13. Conventional tomographic x-ray system (when used in the tomographic mode of operation).

NOTE: Computed tomography (CT) systems are not considered general-purpose radiographic systems. Any x-ray system, other than a CT system, which by its design is not limited to radiographic examination of a specific anatomical region and does not meet the requirements listed above, is considered to be "general purpose" for the purposes of 21 CFR 1020.31.

When to File a Report of Assembly (Form FDA 2579 or e2579)

32. QUESTION: I sometimes install certified diagnostic x-ray components and systems in veterinary facilities. Must I submit the report of assembly for these installations?

ANSWER: No. The Performance Standards only require filing the form to report assemblies of certified diagnostic equipment intended for irradiation of any part of the human body for the purpose of diagnosis or visualization. Veterinary equipment does not require certification to the Performance Standards, but certified equipment is often installed in veterinary facilities. The completion and filing of the form is not required for any non-human application. Some states and local agencies may have more stringent reporting requirements and you should check with them regarding their requirements.

33. QUESTION: Our firm is frequently asked to remove diagnostic x-ray systems from facilities. This is sometimes in preparation for installation of new equipment and other times the equipment is being removed with no replacement. Does such removal of this equipment require the reporting on a report of assembly?

ANSWER: No. FDA does not require notification of the removal of either certified or noncertified x-ray equipment from facilities. Some states do require notification, but the report of assembly should not be used for this purpose. You should contact the appropriate state agency for guidance on its requirements.

34. QUESTION: If, as an assembler, I legally install only an old component that was not required to be certified into a system, must I file a report of assembly?

ANSWER: No, unless the uncertified component is the master control. When you legally install only uncertified components into a system, filing a report of assembly is not required. If uncertified components are installed at the same time as certified components, the report of assembly is required, but does not need to include the uncertified components other than the master control. The master control is used to identify the system and must be listed regardless of certification status.

35. QUESTION: If certified components are transferred from one x-ray system to another in the same facility, does the assembler have to file a report of assembly?

ANSWER: Yes. If certified components are installed or reassembled (other than reinstallation of repaired components) into any diagnostic x-ray system, a report of assembly is required (21 CFR 1020.30)(d)). Certified accessory components are excluded from this requirement when moved or interchanged between systems provided the initial installation was reported in a report of assembly.

36. QUESTION: If I install a temporary "loaner" component into a system, am I required to file a report of assembly?

ANSWER: If a loaner component is installed, no report of assembly is required, nor is such a report required when the original component is reinstalled. A report of assembly is not required when the loaner component is removed and the original repaired component is reinstalled into the system. It should be noted that even though the report of assembly is not required, the FDA considers the installation of a certified loaner component to be the introduction of the component into commerce and the dealer, distributor, and manufacturer are still required to maintain all of the records required under 21 CFR 1002.40.

NOTE: When a certified loaner component is removed and replaced with another certified component that was not previously installed in the system, but will now remain with the system, the installer must submit a new report of assembly (21 CFR 1020.30)(d)). This applies when the replacement component is a new component or an exchange component of the same type (exact replacement other than tube housing assemblies).

37. QUESTION: May uncertified or mixed x-ray systems be moved from one part of a hospital to another or from one office to another?

ANSWER: Yes. Uncertified and mixed systems may be reassembled in another location.

38. QUESTION: Would reinstallation of a repaired certified component into its original system require a report of assembly?

ANSWER: No. In the case of the repair of a certified component, if the same component is repaired and reinstalled into the original system, a report of assembly is not required. However, the installation of any certified component that was not previously a part of the system requires the assembler to follow the manufacturer's instructions and test procedures and to file a report of assembly. A report of assembly is required even if the component is replaced with the same exact model of component. Section 1020.30(d)(2)(i) exempts "Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system" from the requirement to file a report of assembly, however, the exception applies only to those tube housing assemblies that are equivalent to those they are replacing. If the tube housing assembly differs from the housing assembly it is replacing, then the assembly should be reported to FDA.

39. QUESTION**:** Is a report of assembly required for the installation of self-contained (mobile, portable, some dental, etc.) systems containing certified components?

ANSWER: It depends. In most cases the answer is yes, the form must be filed. However, there are a few x-ray components or systems, typically limited to portable or hand-held systems, not requiring assembly upon delivery. For such components or systems, the manufacturer designed the system so that it would be operational and compliant upon delivery (i.e., “no assembly required”). If the manufacturer has stated in its product report submitted to the FDA and in its assembler/user information that no assembly or installation is required, then no report of assembly is required. The individual manufacturer is responsible for certifying these systems and reporting the product to FDA. The manufacturer may require the user to perform checks or tests on the system before using the system on patients. Instructions for conducting those checks or tests must be provided to the assembler (in this case, the user). If only checks or tests are required as mentioned above and no actual assembly is required, no report of assembly is needed.

40. QUESTION: Our firm does not sell diagnostic x-ray equipment. However, we do rent and/or lease such equipment to end users. Do we need to file the report of assembly when we install these systems?

ANSWER: Yes. Leased and loaned components installed at the user's facility are considered owned by the users for a definite time period. As a result, installation and recordkeeping requirements are identical to those for any permanent assembly. However, for certified components on loan, filing a report of assembly is not required provided the units

are labeled as temporarily installed components. If such labeling is not used, then the assembly would have to be reported in the usual way.

41. QUESTION: Our firm occasionally installs demonstration units that are on temporary loan for a facility's assessment prior to committing to a purchase. These units would be installed, used for a short time and then removed. Is it necessary to file a report of assembly for these short term installations?

ANSWER: CDRH considers such units to be similar to "loaner" components or systems that may be temporarily installed while a permanent component/system is undergoing repair. A temporary loaner component or a demonstration unit, under consideration for purchase by a facility, may be used on patients for a limited time before an assembler will be required to submit a report of assembly. Such units should not be used for more than 30 calendar days without filing the report of assembly with the FDA. Documentation should be maintained at the facility and by the manufacturer/dealer/distributor/assembler certifying that the manufacturer's assembly instructions were followed and the installed components were of the type called for by both the Performance Standards and the manufacturer. Such documentation could be a statement such as that specified in 21 CFR 1020.30(d)(2)(iv)(A), substituting "system" for "component", a completed report of assembly (not submitted to the FDA but maintained as specified above), or similar statements/documentation. If a report of assembly is used for such documentation, but not submitted to FDA, we recommend that a comment be entered on the form describing its temporary nature and expected duration of the installation. If a demonstration unit remains at a facility beyond 30 days, then a completed report of assembly should be promptly submitted. For a loaner component, we expect that all repair/replacement will be completed within the 30 day period and appropriate forms submitted. If the repair/replacement cannot be completed within 30 days, a strong justification should be submitted to the FDA District office with a request for extending the temporary installation.

The above applies only to the filing of the report of assembly with the FDA. States may have more stringent requirements regarding the use and reporting of these systems. Systems used for mammography have additional requirements that must be met before use on patients, so the Mammography Quality Standards Act regulations (see 21 CFR 900) should be consulted for such systems. The above opinion does not relieve the manufacturer, dealer, and/or distributor from their respective responsibilities under 21 CFR 1002.30 and/or 21 CFR 1002.41.

42. QUESTION: Would reinstallation of a repaired certified component require an assembler's report?

ANSWER: No. In the case of the repair of a certified component, if the same component is repaired and reinstalled into the original system, a report of assembly is not required. However, the installation of any certified component that was not previously a part of the system requires the assembler to follow the manufacturer's instructions and test procedures and to report such assembly. If the component is replaced by an exact match, the assembly

must also be reported. Note that 1020.30(d)(2) specifically exempts "Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system" from the requirement to file an report of assembly, however, the exception applies only to those tube housing assemblies that are equivalent to those they are replacing. If the tube housing assembly differs from that it is replacing, then the assembly should be reported to FDA.

43. QUESTION: If I replace a certified component with an exact replacement must a report of assembly be filed?

ANSWER: Yes. Note that 1020.30(d)(2) specifically exempts "Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system" from the requirement to file a report of assembly .

44. QUESTION: If I install a tube housing assembly into an existing system, must I file a report of assembly?

ANSWER: If the tube housing assembly is identical to the original it is replacing, no report of assembly is required. However, the assembly of new or existing tube housings must be reported when installing a new system or relocating a previously existing system and, if the tube housing assembly installed differs from that being replaced.

45. QUESTION: When tube housing assembly reloading is done in a location other than the primary manufacturing site does this location become a separate manufacturer? Does this location have to file a product and/or an annual report? Reloading instructions and procedures at this location would be equivalent to those used at the primary manufacturing site.

ANSWER: The replacement of an x-ray tube in a used, previously certified tube housing constitutes manufacture of a new tube housing assembly. The manufacture and field reloading operations of previously certified tube housings should be included in the parent company's annual report. The field office doesn't have to file separately with the FDA because it is the responsibility of the parent manufacturer to do so. However, if the tube reloading location is an independent operation, then the requirements for product and annual reports would apply to that location.

46. QUESTION: Changes to the Performance Standards went into effect on June 10, 2006 covering digital image receptors that are electrically powered or connected to the system. When we install these components, do we need to file a report of assembly? If so, how do we enter the information on the form?

ANSWER: A report of assembly is required for electrically powered image receptors intended for use with fluoroscopic systems (including fluoroscopic systems used for both fluoroscopy and radiography). When completing the paper Form FDA 2579, select the most correct descriptors from those in block 3 AND "DIGITAL," then in block 4 select "OTHER"

and specify the component information in the "COMMENTS" space. If you are submitting an e2579 online, the component is listed under section 4 and may be selected in the normal fashion. The submission of a report of assembly is not currently required for radiographic-only digital image receptors. Such an addition to a radiographic only system is considered as an owner modification to a certified system and is allowed with the understanding that it will not cause any violation of the applicable Performance Standards and that records of the modification are retained by the owner as previously discussed (see QUESTION 10). An announcement will be circulated if a change in this policy is made.

47. QUESTION: The June 10, 2006 Performance Standards changes included provisions covering cumulative air kerma displays and air kerma rate displays. When we install these components, do we need to file a report of assembly? If so, how do we enter the information on the current form?

ANSWER: Yes, a report of assembly is required to report the installation of these certified components. When completing the paper FDA 2579, select the most correct descriptors from those in block 3b, in block 4h select "OTHER" and specify the component information in the "COMMENTS" space. If you are submitting an e2579 online, the component(s) are listed under section 4h and may be selected directly.

48. QUESTION: Must I file a report of assembly when I move a certified or mixed system without a change in the ownership of the system?

ANSWER: Yes. Whenever a certified or mixed system is moved (or reassembled), with or without a change in ownership, the report of assembly must be filed.

49. QUESTION: If an assembler realizes that he/she has made an error on an already submitted report of assembly, how should the assembler correct the error?

ANSWER: The assembler should make the necessary changes and explain the changes in the "COMMENTS" on the copy of the FDA 2579, copy the form and distribute the copies to the FDA, State, and user. Updates to reports submitted using eSubmitter can be filed by following the directions on the eSubmitter system.

Completing the Report of Assembly (Form FDA 2579)

50. QUESTION: The report of assembly seems to imply that a distinction exists between the terms "assembly" and "reassembly." Please address and clarify any distinction between "assembly" and "reassembly."

ANSWER: CDRH does make a distinction between the two terms. "Assembly" means the installation of an unused system or unused component into a system. "Reassembly" means the installation of a group of components (including any new upgrade components) that were previously assembled and used as an "x-ray system." Note that the Performance Standards

do not make this distinction and the assembly or reassembly of certified components is always considered as "assembly" for assembler reporting purposes.

51. QUESTION: The report of assembly seems straightforward, but are there any general guidelines that might help with completing the form?

ANSWER: The table below provides some "hints" regarding completion of the report of assembly.

Form Block and Section	Title	Hint/Definition
1	Equipment Location	Actual equipment installation location: Street, Building, Suite, Floor as appropriate for the business
2	Assembler Information	Actual office location of firm, if user/owner installed enter office contact location
3.a	This report is for assembly of certified components:	Select "NEW ASSEMBLY" if a complete, unused system is being installed Select "REASSEMBLY" if a complete system is being installed at a new location without a change in ownership. Select "REASSEMBLY - MIXED SYSTEM" if a complete system containing certified and uncertified components, either used or new, is being installed in a new location with a change in ownership. Select "REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM" if one or more certified components are installed to replace existing components in a system (Note: Selection of both this answer and "AN ADDITION TO AN EXISTING SYSTEM" may be used if applicable). Select “AN ADDITION TO AN EXISTING SYSTEM” if one or more certified components are added to an existing system (Note: Selection of both this answer and "REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM" may be used if applicable).
3.b	*Intended Uses*	You may select as many items as necessary to completely describe the intended system use. For example, if the system is a general purpose radiographic/fluoroscopic system using digital imaging; select General purpose radiography, General purpose fluoroscopy, and Digital. You should attempt to determine all of the listed uses that may be appropriate for the given facility. Questioning the chief technologist or the most responsible individual at the facility should be sufficient.
	- General Purpose Radiology	Single image capture of human anatomical structure
	- General Purpose Fluoroscopy	Real-time imaging of human anatomical structure
	- Tomography (other than CT)	Three-dimensional study of human anatomical structure
	- Angiography	Cardiac structure and function study
	- Podiatry	Study of the structure of the human foot
	- Urology	Study of the structure of the human urinary system

	- Mammography	Study of the structure of the human breast
	- Chest	Study of the structure of the human chest region
	- Chiropractic	Study of the structure of the human spine
	- CT Head scanner	Three-dimensional study of the human head
	- CT Whole Body Scanner	Three-dimensional study of the entire human anatomical structure
	- Head-Neck (medical)	Study of the structure of the human head and neck regions
	- Dental-Intraoral	Study of human oral cavity for dental purposes
	- Dental-Cephalometric	Study of the structure of the human head for dental purposes
	- Dental Panoramic	Study of the entire human oral cavity for dental purposes
	- Radiation Therapy Simulator	Radiographic or fluoroscopic systems used to visualize/define human anatomical structures in preparation for radiation therapy
	- C-arm Fluoroscopic	Fluoroscopic x-ray system with a fixed spatial relationship between the diagnostic source assembly and the image receptor, capable of rotation about the imaging area of interest
	- Lateral Fluoroscopic	Fluoroscopic x-ray system in which the diagnostic source assembly and the image receptor are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.
	- Digital	System or component incorporating a means of electronically acquiring imaging information as numeric values, rather than using film-screen technology or an image intensifier
	- Bone Mineral Analysis	Study and spectroscopic analysis of human bone structure
	- Other...	Identify the specific intended use here (as specified in the instructions.)
3.c	X-Ray system is	Stationary: Any system installed in a fixed location, including systems that are permanently installed in vans or other conveyances Mobile/portable: Any system mounted on a permanent base incorporating wheels or casters (mobile systems) or designed to be hand-carried (portable systems)
3.d	Master Control is in Room	Describe where the main control panel is located: i.e., room number, hallway, for portable or mobile systems enter portable or mobile - no fixed location.
3.e	Date of Assembly	Enter the date the assembly was completed (i.e., when the unit is turned over to the facility as ready for use on patients). This is not the date the facility formally accepts the unit.
4	Component Information	Enter the information as outlined below. If any portion of the information is not found, enter "NOT GIVEN" and explain in the "COMMENTS" section.
4.a	Master Control	Select "NEW" only if the control is unused. This would include controls previously installed into a mobile or portable system by the manufacturer, requiring no on-site assembly by the assembler and not previously used
4.b	Control Manufacturer	Enter the information from the control manufacturer identification label. Do not use logo information that may appear on the control or the system.
4.c	Control Model Number	Enter the information from the control identification label where it may appear as a "model" or "type" designation.
4.d	Control Serial Number	Enter the information from the control manufacturer identification label.
4.e	Date Manufactured	Enter the information from the control date of manufacturer label,

		shown as month (spelled out without abbreviation) and year (four digits).
4.f	CT System Model Name	Enter information only for a CT (including cone beam 3D imaging systems) system, as it appears on the CT gantry.
4.g	Selected Components	Enter the requested information for each beam limiting device, table, or CT gantry newly installed under this Assembler Form. Enter the information exactly as it appears on the component labeling; if labeling is missing or obscured, then explain in the "COMMENTS" section.
4.g	Beam Limiting Device	
	Tables	
	CT Gantry	
4.h	*Other Certified Components*	Enter the quantity (number) of certified components newly installed under this report. For “OTHER” describe the component(s) in the comments field following the instructions
	X-Ray Control	
	High Voltage Generator	
	Vertical Cassette Holder	Select this option only if permanently mounted or a front panel is provided
	Tube Housing Assembly	Do not select this option if the tube housing assembly also contains a high voltage generator
	Dental Tube Head	Select this option only if the tube housing assembly also contains the high voltage generator. Otherwise, select "Tube Housing Assembly"
	Cradle	
	Film Changer	Select this option only if a front panel is provided
	Image Intensifier	
	Spot Film Device	
	Fluoroscopic Imaging Assembly	
	Cephalometric Device	Select this option also for add-on wall cassettes with alignment devices for use on standard intraoral dental systems
	Image Receptor	Do not select this option if only a traditional image intensifier is being installed. Image intensifiers should be listed under the "Image Intensifier" section
	Image Receptor Support Device	Select this option only for applicable mammographic installations
	Fluoroscopic Air Kerma Display Device	Select this option for systems incorporating a means to display air kerma rate and cumulative air kerma
	Other	Any certified component not listed elsewhere on the form. Enter the number of such items here and describe each such component as specified in the instructions
5	Name	PRINTED NAME: Print the name of the individual responsible for installation, calibration, and testing of the equipment. If more than one assembler is involved, enter only the name of the most responsible individual. SIGNATURE: Enter the signature of the responsible individual identified in the "PRINTED NAME" box
	Date	Enter the date the form is signed (this may or may not be the same as the date of assembly)

6	Comments	Enter items as requested above and any other issues such as inadequate assembly instructions, potentially hazardous situations encountered, and any comments you deem appropriate.

52. QUESTION: As an independent contractor, I perform assemblies for several distributors as well as performing direct repair/relocation operations for facilities. How should I complete block 2, "ASSEMBLER INFORMATION" on the report of assembly?

ANSWER: When operating as the sole assembler, always use your identifying name and address in Block 2. When operating as a subcontractor, completion of block 2 should reflect any existing agreement between both parties. In the event that no agreement exists, you should complete the form with your identifying information.

Additional questions should be directed to the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance. Contact information is located at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm.