Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

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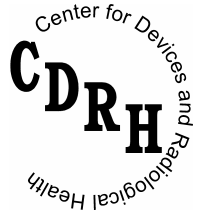

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Diagnostic Devices Branch
Division of Enforcement B
Office of Compliance

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability 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 FDA Staff

Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems

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

This document provides guidance to assemblers and manufacturers of diagnostic x-ray systems regarding the disclosure of specifications for assembly, installation, adjustment, and testing (AIAT). The guidance clarifies the scope and terms of the information disclosure provision and explains how affected parties should view cost and software issues. This revision further clarifies that manufacturers should provide, upon request, AIAT information for each certified component used for the controlled production of x-rays.

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.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the

issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

SUMMARY:

Manufacturers of diagnostic x-ray systems are subject to information disclosure obligations so that assemblers or other interested parties may obtain, upon request, information regarding the assembly, installation, adjustment, and testing (AIAT) of an x-ray system to ensure it meets federal performance standards. (21 Code of Federal Regulations sec. 1020.30(g)) The AIAT information should be provided at a cost not to exceed the cost of publication and distribution. The information helps to ensure compliance with performance standards that are intended to reduce unnecessary x-ray exposure to the patient and operator. With the evolution of new technology for x-ray systems and related major components, the Food and Drug Administration (FDA) has received new questions about the scope of the information disclosure obligation for manufacturers, and whether computerization of that information affects the disclosure provision and how to calculate its cost.

Background

FDA protects the public health from unnecessary exposure to electronic product radiation by, among other things, requiring that electronic products meet performance standards. (Section 532 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii)) Federal regulations regarding the disclosure of AIAT information protect the public health by preventing unnecessary exposure to x-rays from diagnostic x-ray systems. This disclosure obligation became effective on August 1, 1974. (38 Federal Register 15444) During that time, AIAT documentation for operational activities has evolved from the use of written manuals to computer software programs.

Assembly of Components

Assembly procedures can affect whether a diagnostic x-ray system complies with federal performance standards. Accordingly, the manufacturing process is not complete until the assembler has installed the component(s) into an x-ray system. The standard defines "manufacturer" to include "assembler." This means that the component manufacturer can only certify to a component's ability to function in compliance with the standard when the system is properly assembled and installed according to the manufacturer's instructions. A manufacturer's labeled certification of a component, coupled with adequate and complete assembly, installation, adjustment, and testing (AIAT) instructions, should provide the assembler with all of the information necessary to ensure the products will comply with applicable performance standards when assembled, installed, adjusted and tested, as directed by the instructions. Delivering a diagnostic x-ray system fully assembled does not relieve manufacturers of their obligations under 21 CFR 1020.30(g) to provide assemblers and others with AIAT materials.

Installation of Components

The component manufacturer should also provide AIAT instructions that describe how to install the assembled components so the unit meets applicable performance standards. For example, in order to install components properly as part of a system, the assembler needs to fix and align the relationship between the x-ray source and the related components of the diagnostic system. This activity involves adjustment and testing to ensure compliance with performance standards. If the assembler follows the AIAT instructions and the certified component does not meet the performance standard, the component manufacturer should, at no cost to the user, repair or replace the violative component(s), or refund the cost of the component.

Legal Responsibility

Manufacturers and assemblers each bear legal responsibility for their roles in the manufacture and commerce of products subject to section 1020.30. (See sections 535(e) and 538 of the act (21 U.S.C. 360ll(e), 360oo).) As a practical matter, close cooperation between the manufacturer and the assembler furthers the interests of both parties by controlling legal liability for noncompliant or defective x-ray equipment.

Guidance

The manufacturer can certify that the components or system manufactured meet the applicable federal performance standard only when they are assembled, installed, adjusted, and tested according to instructions. The assembler certifies that the system and its components were assembled, installed, adjusted, and tested according to the manufacturer's instructions. Reliable certification, then, depends upon the manufacturer's providing adequate and complete instructions to the assembler.

An x-ray system is an assemblage of components for the controlled production of x-rays. The information disclosure obligation applies to each individually certified component produced by a manufacturer and is independent of the manufacturer’s decision to deliver a fully assembled x-ray system or subsystem. The regulation establishes that manufacturers of certified components should provide to assemblers and others, upon request, AIAT information for the certified components of a diagnostic x-ray system. (21 CFR 1020.30(a)(1)) This means that AIAT information should exist for each certified component produced by a manufacturer and be available to others upon request.

Explanation of Terms

The agency would like to explain the meaning of four terms that comprise AIAT to help manufacturers and assemblers establish clear expectations about what information is subject to disclosure.

Assembly: To fit together the parts or pieces of a component or system.

Discussion: New x-ray components and accessories are shipped to a final destination in various boxes and crates. These components must be unpacked and properly assembled before the unit can be used to make x-rays. The typical major component of a diagnostic x-ray system cannot simply be removed from the box and used by the operator. For example, various parts, such as printed circuit boards and switches, may require assembly into the control console of an x-ray control unit in a medical facility. Assembly also includes the re-assembly of components that were not replaced but must be re-connected to the new component. Correct electrical and hardware connections with all of the equipment must be made before using the system. Such connections are considered assembly. Complete assembly instructions in written form or software programs that automate the assembly process should be disclosed to the assembler to the extent they are part of the assembly procedures.

Software programs may incorporate information that does not relate to assembly or re-assembly activities. Such programs are not subject to disclosure. For example, the console's central processing unit may include unrevealed, protected software programs that create a log of assembly activities related to computer operations. Should the manufacturer wish to check the assembly history on a particular system, this log would provide information, independent of the assembler's report, about when activities occurred and perhaps about the identity of the replaced components. This information does not fall within the scope of the AIAT disclosure requirements. However, the incorporation of non-AIAT information or software does not change obligation of the manufacturer to release the required AIAT information. It is incumbent upon the manufacturer to provide adequate AIAT information to the assembler.

It is important to note that the term "assembly" and "installation" should not be used interchangeably. The term "installation" includes other activity not covered in the assembly activity.

Installation: To set up for use by verifying that proper assembly and adjustments were made to assure compliance with federal performance specifications.

Discussion: The unit should not be used on humans until the installation is completed in accordance with the manufacturer's instructions, including any additional adjustments and testing needed to verify compliance with performance specifications. For example, to complete the installation of an x-ray system, the assembler combines (or assembles) the various certified components, e.g., tube housing assembly, beam-limiting device, and x-ray control, into an interdependent operating system. The assembler should be sure that the components work in coordination with each other and do not cause any of the interdependent components to operate outside of the equipment manufacturer's specified tolerances or outside of applicable federal performance specifications, which are detailed in the regulations. (21 CFR 1020.30 - 1020.33)

The manufacturer's documentation or software programs provide information on how the major components should be configured to meet applicable federal performance standards. However, a manufacturer may also have software programs that operate with specifications that are narrower

than federal performance standards, which they use for internal quality assurance purposes. In addition, the firm may have developed a particular sequencing of installation that operates in conjunction with system accessories that do not directly or indirectly impact electronic radiation emissions specifications. This information does not fall within the scope of AIAT disclosure requirements.

Adjustment: To bring various component parts up to a true or more effective relative position for performance purposes.

Discussion: Adjustment covers activities performed on various components to make sure they work as a system within applicable federal performance standards. For example, adjustments to the electrical circuitry are often needed to ensure the system does not operate outside of its performance specifications. Calibration of the equipment's operational parameters is achieved by adjusting the electrical or mechanical features of the component.

The manufacturer's documentation or software that provides adjustment information also serves a critical function so assemblers can ensure the component(s) will comply with the applicable performance standards. Adjustment information would include any relevant calibration references. However, the manufacturer may have incorporated a proprietary software program that continuously monitors the performance of the system and alerts the manufacturer if the system may need adjustment in the future, even though it is currently operating within the performance standard. This information does not fall within the scope of AIAT disclosure requirements.

Testing: A critical examination, observation, or evaluation of such conditions or operations through procedures provided by the manufacturer that will prove the unit meets specifications.

Discussion: The regulations define the performance requirements for diagnostic radiographic exposure reproducibility such that the coefficient of variation of radiation exposures shall not exceed 0.05. (21 CFR §1020.31(b)(1)) A test method for determining compliance with this performance standard is identified in the regulations. (21 CFR §1020.31(b)(2)) A test of x-ray equipment should produce data to verify the proper operation or performance of the x-ray system or component. For example, information on how to test for radiation leakage or proper beam alignment is important when the assembler needs to use a special technique due to the special design of the component or when the beam alignment procedures are so complex that a computer program is needed.

The manufacturer's documentation or basic software programs provide critical information about testing for applicable federal performance standards that correspond to the manufacturer's AIAT specifications. However, the manufacturer may have additional enhanced software programs, with privileged access codes, that conduct the required tests more quickly to save time. The enhanced software programs may operate in conjunction with other proprietary accessories or functions, such as a daily test trend analysis that is relayed to the manufacturer in order to schedule advanced service calls. This helps the user avoid any interruption in the clinical use of the system. Such proprietary functions may increase the value of the system to the user, but the accessories and the

software programs used in conjunction with these functions do not fall within the scope of AIAT for purposes of meeting applicable federal performance standards, provided they are not required by the AIAT instructions.

Manufacturers should provide all informational materials needed for assembly, installation, adjustment, and testing, as described above, regardless of the format in which those materials exist. Manufacturers may provide assemblers and other members of the public hard copies of instructional software, as long as the package made generally available contains adequate, complete, and useable instructions for assembly, installation, adjustment, and testing.

Software

Some manufacturers bundle AIAT information 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 AIAT documentation or the AIAT software at cost. Manufacturers who bundle their AIAT software with other software may comply with 1020.30(g) by providing the entire bundle at the cost of the AIAT software. Alternatively, the manufacturer may, by parceling the software domains, provide only the AIAT software to assemblers and others. Manufacturers may also satisfy the performance standard by providing printed materials, or by any other means that result in the provision of adequate, complete, and useable instructional materials.

Cost

Manufacturers may recover from assemblers and others the "cost" of providing required instructional materials. Manufacturers should, in negotiation with purchasers, assemblers, and others, determine the dollar amount for any instructional package. Although private parties can and should set the exact price for materials provided under subsection (g), the performance standard establishes limits on what costs manufacturers may recover in determining that price.

The agency has explained that 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, or other costs associated with each package the manufacturer provides under the performance standard. This principle should govern the calculation of the costs for all information subject to disclosure, whether printed, encoded in software, or any other format. For software, recoverable charges equivalent to printed materials would include such factors as the cost of the technical labor of producing such additional package or unit, computer disks, and packaging materials used to produce each additional unit of software. Using a reasonable set of factors should govern the calculation of the costs for any materials that are provided.

Although the question concerning cost has arisen primarily in the context of disclosing AIAT information, the same principle should also apply to the cost of disclosure of safety and technical information to the user of diagnostic x-ray systems or computed tomography equipment. In any

scenario involving AIAT information disclosure, the factors that constitute a recoverable cost should not create a profit or loss for the manufacturer.

Closing Summary

The public health need to provide AIAT information to assemblers and users since the Radiation Control for Health and Safety Act was passed in 1968 has not changed. If the information is not available, the public may be exposed to unnecessary radiation hazards from electronic products. Without this information, FDA, manufacturers, assemblers, users, and consumers could not make reasonable determinations or decisions associated with the safe and effective use of diagnostic x-ray systems and computed tomography components and systems in their health care.

For further information regarding compliance with the information disclosure requirements for diagnostic x-ray systems and their major component systems, please contact Thomas M. Jakub at 301 594-4591.