

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4130]

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Certifier	Monica Oliver

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Medical Devices; Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA." This guidance document is intended to provide guidance to the industry about meeting requirements for disclosure to assemblers, and to others upon request, of certain types of information at a cost not to exceed the cost of publication and distribution to ensure that x-ray systems will meet Federal performance standards.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Thomas M. Jakub, Center for Devices and Radiological Health (HFZ-322), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4591.

SUPPLEMENTARY INFORMATION:

I. Background

This final Level 1 guidance document entitled "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA" is intended to provide guidance to diagnostic x-ray system manufacturers, users, assemblers, and others concerning the requirement to disclose information about the assembly, installation, adjustment, and testing (AIAT) of x-ray components for diagnostic x-ray systems. (See § 1020.30(g) (21 CFR 1020.30(g))). With the advancement of technology and the use of computers with corresponding software, manufacturers need clarification about what information must be disclosed to satisfy the requirements of AIAT disclosure. This final Level 1 guidance document supersedes the corresponding draft guidance entitled "Draft Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems," which was announced in the **Federal Register** on October 8, 1999 (64 FR 54901). The comment period closed on January 6, 2000. The agency received several comments and recommendations concerning the draft guidance. A number of comments received by the agency addressed issues that do not fall within the scope of the guidance and § 1020.30(g). The final guidance contains only minor changes from the draft guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on information disclosure by manufacturers to assemblers for diagnostic x-ray systems, as required by § 1020.30(g). It does not create or confer any rights for or on any person

and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

III. Electronic Access

In order to receive "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (2619) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA" is also available at <http://www.fda.gov/cdrh/comp/2619.html>. Guidance documents are also available on the Dockets Management Branch website at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted,

except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/26/01
March 26, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

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