4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4115]

Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment." This draft guidance provides clarification to industry and FDA staff of the Federal regulations that relate to diagnostic x-ray systems and their major components. These regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of "electronic products," as defined in FDA regulations. This draft guidance, when finalized, will supersede FDA's guidance entitled "Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment." This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-4115 for "Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4276, Silver Spring, MD 20993-0002, 301-796-5889.

SUPPLEMENTARY INFORMATION:

I. Background

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. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines diagnostic x-ray systems as both a medical device, under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), and an electronic product,

under section 531 of the FD&C Act (21 U.S.C. 360hh). As such, these devices are subject to the provisions of the FD&C Act that apply to medical devices (e.g., sections 510 and 520 of the FD&C Act (21 U.S.C. 360 and 360j)), and their implementing regulations as well as the provisions of the FD&C Act (sections 531 through 542 of the FD&C Act (21 U.S.C. 360hh through 360ss)) that apply to electronic products, known as the Electronic Product Radiation Control (EPRC) and their implementing regulations. These regulations pertain to the recordkeeping, reporting, manufacturing, importing, and installation of "electronic products" as defined under 21 CFR 1000.3(j). 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).

This draft guidance 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 draft guidance does not address requirements that may apply to such equipment as medical devices under provisions of the FD&C Act and its implementing regulations.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment." 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This guidance document is also available at https://www.regulations.gov. Persons unable to download an electronic copy of "Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X-Ray Equipment" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500029 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
1002, 1005, 1010, 1020, 1030, 1040, and 1050	Reporting and Recordkeeping for Electronic Products--General Requirements	0910-0025

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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