4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. FDA-2015-N-0828]

Performance Standards for Ionizing Radiation Emitting Products; Fluoroscopic Equipment; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend a Federal performance standard for ionizing radiation to correct a drafting error regarding fluoroscopic equipment measurement. We are taking this action to ensure clarity and improve the accuracy of the regulations.

DATES: Submit electronic or written comments on this proposed rule or its companion direct final rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-0828 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Gonzalez, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4641, Silver Spring, MD 20993-0002, 301-796-5889.

SUPPLEMENTARY INFORMATION:

I. What is the Background of This Proposed Rule?

FDA is proposing to correct a drafting error regarding fluoroscopic equipment measurement (see § 1020.32 (21 CFR 1020.32)). Specifically, this proposed amendment would change the words "any linear dimension" in the current regulation to read "every linear dimension" (see 21 CFR 1020.32(b)(4)(ii)(A)). The alternative performance standard,

§ 1020.32(b)(4)(ii)(B), currently contains the same phrase but would remain unchanged. We are proposing to amend the language to make the performance standards mutually exclusive. This will ensure clarity and improve the accuracy of the regulations.

FDA first proposed the performance standards in the Federal Register of December 10, 2002 (67 FR 76056), to account for technological changes in fluoroscopic equipment. That proposed rule did not specify which measurement of the visible area of an image receptor determined the applicable performance standard (67 FR 76056 at 76092). When we addressed comments to that proposed rule in the Federal Register of June 10, 2005, we agreed with one comment that adding the words "any linear dimension" would clarify the determination of the performance standard (70 FR 33998 at 34007).

FDA ultimately incorporated the phrase in two places, potentially reducing the clarity of the rule (70 FR 33998 at 34040). Section 1020.32(b)(4)(ii) sets performance standards based on a threshold, so the language for each standard should be mutually exclusive. That is, only one standard, and not the other, should apply to the image receptor in question. However, some image receptors may have linear dimensions that are both greater than and less than 34 cm, for example, receptors with a hexagonal shape. In such cases, the performance standards may not be mutually exclusive, so both standards may appear to apply. This proposed rule would amend § 1020.32(b)(4)(ii)(A) to read "every linear dimension" to ensure the standards are mutually exclusive. The amendment will improve the clarity and accuracy of the regulations.

II. Why Is FDA Publishing This Companion Proposed Rule?

This proposed rule is a companion to a direct final rule that corrects a drafting error regarding fluoroscopic equipment measurement. The direct final rule is published in the final rules section of this issue of the Federal Register. The direct final rule and this companion

proposed rule are substantively identical. This companion proposed rule will provide the procedural framework to finalize a new rule in the event we withdraw the direct final rule because we receive significant adverse comment. We are publishing the direct final rule because we believe it is noncontroversial, and we do not anticipate any significant adverse comments. If we do not receive any significant adverse comments in response to the direct final rule, we will not take any further action on this proposed rule. Instead, within 30 days after the comment period ends, we intend to publish a notice that confirms the effective date of the direct final rule.

If FDA receives any significant adverse comments regarding the direct final rule, we will withdraw it within 30 days after the comment period ends. We will then proceed to respond to the comments under this companion proposed rule using our usual notice-and-comment rulemaking procedures under the Administrative Procedure Act (APA) (5 U.S.C. 552a, et seq.). The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. We will consider any comments that we receive in response to this companion proposed rule to be comments also regarding the direct final rule and vice versa. We will not provide additional opportunity for comment.

A significant adverse comment is one that explains why the rule would be inappropriate (including challenges to the rule's underlying premise or approach), ineffective, or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, we consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the APA (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse

comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

You can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures," announced in the Federal Register of November 21, 1997 (62 FR 62466).

III. What Is the Legal Authority for This Proposed Rule?

This proposed rule, if finalized, would amend § 1020.32. FDA's authority to modify § 1020.32 arises from the same authority under which FDA initially issued this regulation, the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e-360j, 360hh-360ss, 371, and 381).

IV. What Is the Environmental Impact of This Proposed Rule?

FDA has determined under 21 CFR 25.30(h) and 25.34(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. What Is the Economic Analysis of Impact of This Proposed Rule?

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts;

and equity). The Agency believes that this proposed rule would not be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule does not add any additional regulatory burdens, the Agency has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in a 1-year expenditure that meets or exceeds this amount.

The purpose of this proposed rule is to correct a drafting error regarding fluoroscopic equipment measurement in a performance standard for ionizing radiation. The amendment will improve the clarity and accuracy of the regulations. Because this proposed rule is a technical correction and would impose no additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

VI. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. What Are the Federalism Implications of This Rule?

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

List of Subjects in 21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1020 is proposed to be amended as follows:

PART 1020--PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. The authority citation for 21 CFR part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e-360j, 360hh-360ss, 371, 381.

2. Revise § 1020.32(b)(4)(ii)(A) to read as follows:

§ 1020.32 Fluoroscopic equipment.

(b) * * *

(4) * * *

(ii) * * *

(A) When every linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image.

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Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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