

identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

### B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies](http://www.faa.gov/regulations_policies) or
3. Accessing the Government Printing Office's Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

Issued under authority provided by 49 U.S.C. 106(f), 40103(b), and 44701(a)(5), in Washington, DC, on March 31, 2015.

**Abigail Smith,**

*Director, Aeronautical Information Services.*

[FR Doc. 2015-08098 Filed 4-10-15; 8:45 am]

**BILLING CODE 4910-13-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 June 29, 2015.

**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.

\* \* \* \* \*

Dated: April 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–08361 Filed 4–10–15; 8:45 am]

**BILLING CODE 4164–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R09–OAR–2014–0832; FRL–9925–34–Region 9]

### Revisions to the California State Implementation Plan, Northern Sierra Air Quality Management District

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a revision to the Northern Sierra Air Quality Management District (NSAQMD) portion of the California State Implementation Plan (SIP). The submitted SIP revision contains the District’s demonstration regarding Reasonably Available Control Technology (RACT) requirements for the 1997 8-hour ozone National Ambient Air Quality Standards (NAAQS). The submitted SIP revision also contains negative declarations for volatile organic compound (VOC) source categories for the NSAQMD. We are proposing to approve the submitted SIP revision under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

**DATES:** Any comments on this proposal must arrive by May 13, 2015.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–OAR–2014–0832, by one of the following methods:

1. *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the on-line instructions.

2. *Email:* [steckel.andrew@epa.gov](mailto:steckel.andrew@epa.gov).

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

**Instructions:** All comments will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through [www.regulations.gov](http://www.regulations.gov) or email.

[www.regulations.gov](http://www.regulations.gov) is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** Generally, documents in the docket for this action are available electronically at [www.regulations.gov](http://www.regulations.gov) and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at [www.regulations.gov](http://www.regulations.gov), some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** James Shears, EPA Region IX, (213) 244–1810, [shears.james@epa.gov](mailto:shears.james@epa.gov).

**SUPPLEMENTARY INFORMATION:** This proposal addresses the revisions to the NSAQMD portion of the California SIP. In the rules and regulations section of the **Federal Register**, we are approving the SIP revision in a direct final action without prior proposal because we

believe this SIP revision is not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposal. Please note that if we receive adverse comment on a specific provision of this SIP revision and if that provision may be severed from the remainder of the SIP revision, we may adopt as final those provisions of the SIP revision that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: February 12, 2015.

**Alexis Strauss,**

*Acting Regional Administrator, Region IX.*

[FR Doc. 2015–08419 Filed 4–10–15; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R03–OAR–2015–0166; FRL–9926–16–Region 3]

### Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Adoption of Control Techniques Guidelines for Offset Lithographic Printing and Letterpress Printing; Flexible Package Printing; and Adhesives, Sealants, Primers, and Solvents

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve revisions to the Pennsylvania State Implementation Plan (SIP) submitted by the Commonwealth of Pennsylvania. These revisions pertain to control of volatile organic compound (VOC) emissions from offset lithographic printing and letterpress printing, flexible package printing, and adhesives, sealants, primers, and solvents. These revisions also meet the requirement to adopt Reasonably Available Control Technology (RACT) for sources covered by EPA’s Control Technique Guidelines (CTG) recommendations for the following categories: Offset lithographic printing and letterpress printing, flexible package printing, and adhesives, sealants, primers, and solvents. This