

Dated: August 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21236 Filed 8–29–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0920]

Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems.” FDA has developed this guidance to inform the coronary and peripheral stent industry about selected updates to FDA’s thinking regarding certain non-clinical testing for these devices. While FDA is considering more substantial updates to the “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” guidance (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071863.htm>), we are issuing this update on select sections in order to notify the industry in a timely manner of our revised recommendations. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 30, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for

Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Lindsay Pack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1270, Silver Spring, MD 20993–0002, 301–796–5214; or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3226, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop entitled “Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching” on March 8 and 9, 2012, that provided information on current practices for performing these tests (see <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm287535.htm>). A group of participants from industry, test facilities, and academia provided comments on practices for corrosion testing and nickel ion release testing. Based on the discussion at the workshop, this draft guidance updates a key aspect of sample conditioning for pitting corrosion testing that is less burdensome, and includes additional information on when galvanic corrosion testing may be omitted with justification, based on information gained from the workshop. This guidance provides updates only for the following topics:

- Pitting corrosion potential;
- Galvanic corrosion;
- Surface characterization; and
- Nickel ion release.

This draft guidance provides cross-references and updates to the related sections of the existing “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and

Associated Delivery Systems” guidance. Following the close of the comment period on this guidance, FDA intends to consider the comments received, revise this draft guidance as appropriate, and publish it in final. Simultaneously, FDA will issue an update to the existing guidance to add cross-references where this selected updates guidance supersedes the existing recommendations. Subsequently, FDA will incorporate the elements of the final select updates guidance into an anticipated revision of the entire “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” guidance.

This draft guidance also lists the relevant product codes for stents addressed in the guidance. Of note is that the product code NXP (Stent, Tibial), which is not currently listed in the existing “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” guidance, has been added. This product code was not created until after the current guidance was published, however, the recommendations in this draft guidance are applicable to tibial stents. Further, FDA will include this product code in the anticipated revision of the entire “Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems” guidance.

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 Agency’s current thinking on certain non-clinical testing for coronary and peripheral stents. 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 requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

To receive “Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems,” you may either send

an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1826 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

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>.

Dated: August 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-21191 Filed 8-29-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2013-0019; OMB No. 1660-0026]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the

information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before September 30, 2013.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to oir.submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598-3005, facsimile number (202) 646-3347, or email address FEMA-Information-Collections-Management@dhs.gov.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: State Administrative Plan for the Hazard Mitigation Grant Program.

Type of information collection:

Extension, without change, of a currently approved information collection.

Form Titles and Numbers: None.

Abstract: The State Administrative Plan is a procedural guide that details how the State will administer the HMGP. The State must have a current administrative plan approved by the appropriate FEMA Regional Administrator before receiving HMGP funds. The administrative plan may take any form including a chapter within a comprehensive State mitigation program strategy.

Affected Public: State, local or Tribal government.

Estimated Number of Respondents: 32.

Estimated Total Annual Burden Hours: 512.

Estimated Cost: There are no recordkeeping, capital, start-up or maintenance costs associated with this information collection.

Dated: August 22, 2013.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2013-21244 Filed 8-29-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2013-0040]

Guide for the Evaluation of Alert and Notification Systems for Nuclear Power Plants, FEMA-REP-10, Rev. 1

AGENCY: Federal Emergency Management Agency; DHS.

ACTION: Notice of availability of proposed policy; request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) requests public comments on the Guide for the Evaluation of Alert and Notification Systems for Nuclear Power Plants, FEMA-REP-10, Rev. 1.

DATES: Comments must be received by October 29, 2013.

ADDRESSES: You may submit comments, identified by Docket ID FEMA-2013-0040, by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov> Follow the instructions for submitting comments. Please note that this proposed policy is not a rulemaking and the Federal Rulemaking Portal is being utilized only as a mechanism for receiving comments.

Mail/Hand Delivery/Courier:

Regulatory Affairs Division, Office of Chief Counsel, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: John Schafer, Engineer, Professional Services Branch, Technological Hazards Division, Protection and National Preparedness Directorate, John.Schafer@fema.dhs.gov. (202) 341-4896.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Instructions: All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice, which can be viewed by clicking on the "Privacy Notice" link on the homepage of www.regulations.gov.

You may submit your comments and material by methods specified in the **ADDRESSES** section. Please submit your comments and any supporting material by only one means to avoid the receipt and review of duplicate submissions.