[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2016-0122]

Program-Specific Guidance about Medical Use Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is revising its licensing guidance for licenses authorizing medical use of byproduct material. The NRC is requesting public comment on draft NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." The document has been updated from the previous revision to include information on safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices. This document is intended for use by applicants, licensees, and the NRC staff.

DATES: Submit comments by **[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to assure consideration of comments received on or before this date.

ADDRESSES: You may submit comment by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2016-0122**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H8, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on accessing information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Katie Tapp, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0236; e-mail: Katherine.Tapp@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2016-0122** when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

- **Federal Rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2016-0122**.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection

at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The draft NUREG-1556, Volume 9, Revision 3, is available in ADAMS under Accession No. ML16328A214.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

The draft NUREG-1556, Volume 9, Revision 3, is also available on the NRC's public Web site on the: 1) "Consolidated Guidance About Materials Licenses (NUREG-1556)" page at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/; and the 2) "Draft NUREG-Series Publications for Comment" page at http://www.nrc.gov/public-involve/doc-comment.html#nuregs.

B. Submitting Comments

Please include Docket ID **NRC-2016-0122** in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the

NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Further Information

The NUREG provides guidance to existing medical use of byproduct material licensees and to an applicant that are preparing a medical use of byproduct material license application. The NUREG also provides the NRC with criteria for evaluating a license application. The purpose of this notice is to provide the public with an opportunity to review and provide comments on draft NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." These comments will be considered in the final version or subsequent revisions.

This draft of NUREG-1556, Volume 9, Revision 3 does not include any revisions associated with the proposed rule "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments." This proposed rule amends requirements in parts 30, 32, and 35 of title 10 of the *Code of Federal* Regulations for the following:

- reporting and notification of medical event for permanent implant brachytherapy; training and experience for authorized users, medical physicists, Radiation Safety Officers and nuclear pharmacists;
- measuring molybdenum contamination and reporting of failed technetium and rubidium generators;
- allowing Associate Radiation Safety Officers to be named on a medical use license;

and,

- clarifying other revisions to the regulations.

This draft of NUREG-1556, Volume 9, Revision 3 does not include any guidance for the proposed rule revisions as that rule is not final at this time.

The proposed rule and proposed changes to NUREG-1556, Volume 9, associated with the proposed rule were published for public comment in the *Federal Register* (79 FR 42409, 79 FR 42224) on July 21, 2014. Comments received on those changes are being considered by the NRC staff separately. If the proposed rule becomes final, the proposed revisions to NUREG-1556, Volume 9 addressing the implementation of the proposed rule will be incorporated into this NUREG-1556, Volume 9, Revision 3 before its final publication.

Dated at Rockville, Maryland, this 30th day of November, 2016.

For the U.S. Nuclear Regulatory Commission

Daniel S. Collins, Director
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

[FR Doc. 2016-29214 Filed: 12/5/2016 8:45 am; Publication Date: 12/6/2016]