[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2016-0190]

Program-Specific Guidance About Commercial Radiopharmacy 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 commercial nuclear pharmacy use of byproduct material. The NRC is requesting public comment on draft NUREG-1556, Volume 13, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy 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 **March 24, 2017**. 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 comments 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-2016-0190**. 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: Said Daibes, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6863; e-mail: Said.Daibes@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2016-0190** 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-2016-0190**.

- **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 13, Revision 2, is available in ADAMS under Accession No. ML16356A040.

- **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 13, Revision 2, is also available on the NRC's public Web site on the: 1) "Consolidated Guidance About Materials Licenses (NUREG-1556)" page at https://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-2016-0190** 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

NUREG-1556, Volume 13, Revision 2 provides program-specific guidance to assist applicants and licensees in preparing applications for materials licenses for commercial radiopharmacies. In particular, it describes the types of information needed to complete NRC Form 313, "Application for Materials License." It 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 13, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." These comments will be considered in the final version or subsequent revisions.

This draft NUREG-1556, Volume 13, Revision 2 does not include any revisions associated with the proposed rule "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments." That proposed rule would amend the following requirements in parts 30, 32, and 35 of title 10 of the *Code of Federal* Regulations related to commercial nuclear pharmacies:

- removal of the requirement for the board certified nuclear pharmacist to have an attestation statement in addition to the board certificate;
- measuring molybdenum contamination and reporting of failed technetium generators;
- labeling requirements for radioactive drugs; and

- clarifying other revisions to the regulations.

This draft NUREG-1556, Volume 13, Revision 2 does not include any guidance for the proposed rule revisions because that rule is not final at this time.

The proposed rule, "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments," and proposed changes to NUREG-1556 commercial radiopharmacy licenses associated with the proposed rule were published for public comment in the *Federal Register* (79 FR 42409 and 79 FR 42224) on July 21, 2014. Comments received on those changes in the proposed rule and guidance are being considered by the NRC staff separately. If the proposed rule becomes final, the proposed revisions to NUREG-1556, Volume 13 addressing the implementation of the proposed rule will be incorporated into NUREG-1556, Volume 13, Revision 2 before its final publication.

Dated at Rockville, Maryland, this 13th day of January, 2017.

For the U.S. Nuclear Regulatory Commission

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

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