[7950-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 40 and 70

[NRC-2012-0074]

RIN 3150-AH91

Implementation of Requirements for Distribution of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim guidance; request for comment.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. The rulemaking also redefines some categories of devices to be used under exemption from licensing requirements, adds explicit provisions regarding the sealed source and device registration process, and adds flexibility to the licensing of users of sealed sources and devices. This action was primarily intended to make licensing processes more efficient and effective. These changes will affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license. The NRC has prepared interim guidance to address implementation of the final regulations. This document announces the availability of the implementation guidance document for public comment.

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

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and is publicly available, by searching on http://www.regulations.gov under Docket ID NRC-2012-0074. You may submit comments by any of the following methods:

- **Federal rulemaking Web site:** Go to http://www.regulations.gov and search for Docket ID NRC-2012-0074. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.
- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- **Fax comments to:** RADB at 301-492-3446.

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

FOR FURTHER INFORMATION CONTACT: Shirley Xu, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-7640, e-mail: *Shirley.Xu@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2012-0074 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2012-0074. Documents related to the rulemaking can be found by searching on Docket ID NRC-2008-0338.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library 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 interim guidance is available in ADAMS under Accession No. ML112150558. NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance about Materials Licenses Applications for Sealed Source and Device Evaluation and Registration Final Report" is available in ADAMS under Accession No. ML041340618; NUREG-1556, Vol. 8, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution Licenses" is available in ADAMS under Accession No. ML010370065; and NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees" is available in ADAMS under Accession No. ML010120151.

- **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.

B. Submitting Comments

Please include Docket ID NRC-2012-0074 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 to be 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. 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. Discussion

The NRC published a proposed rule in the *Federal Register* on June 24, 2010 (75 FR 36212), to amend its regulations in parts 30, 31, 32, 40 and 70 of Title 10 of the *Code of Federal Regulations* (10 CFR) to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. In that notice, the NRC also proposed to redefine categories of devices to be used under exemptions, add explicit provisions regarding

the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. The public comment period on the proposed rule closed on September 7, 2010. The NRC received 10 comments on the proposed rule.

The NRC considered these comments in developing a final rule [RIN 3150-AH91; Docket ID NRC-2008-0338], which is being published in the Rules and Regulations Section of this issue of the *Federal Register*. The final rule will affect manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and under exemptions from licensing.

In conjunction with the final rule, the NRC has developed interim guidance. The interim guidance document provides guidance to a licensee or applicant for implementation of 10 CFR parts 30, 31, 32, 40 and 70, "Requirements for Distribution of Byproduct Material." It is intended for use by applicants, licensees, Agreement States, and the NRC staff. The interim guidance describes methods acceptable to the NRC staff for implementing the revised regulations. The approaches and methods described in the guidance document are provided for information and use in implementing the revised regulations. Methods and solutions different from those described in the interim guidance are acceptable if they meet the requirements in 10 CFR parts 30, 31, 32, 40, and 70.

At this time, the NRC is announcing the availability for use of "Interim Guidance for Implementation of the Final Rule, Requirements for Distribution of Byproduct Material in 10 CFR Parts 30, 31, 32, 40, and 70." The document provides guidance on implementing the revised provisions of 10 CFR parts 30, 31, 32, 40, and 70. The NRC is also requesting public comment on this interim guidance. Guidance on the revised regulations will be included in the next revision of the relevant volumes in NUREG-1556, "Consolidated Guidance about Materials

Licenses." Comments received on this interim guidance will be considered in the updating of those volumes of NUREG-1556.

Dated at Rockville, Maryland, this **25th** day of **June** 2012.

For the Nuclear Regulatory Commission.

/RA/

Mark A. Satorius, Director
Office of Federal and State Materials
and Environmental Management Programs.

Licenses." Comments received on this interim guidance will be considered in the updating of those volumes of NUREG-1556.

Dated at Rockville, Maryland, this **25th** day of **June** 2012.

For the Nuclear Regulatory Commission.

/RA/

Mark A. Satorius, Director
Office of Federal and State Materials
and Environmental Management Programs

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