7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0154]

Release of Patients Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG-8057, "Release of Patients Administered Radioactive Material." This proposed guide, Revision 1, provides licensees with more detailed instructions to provide to patients before and after they have been administered radioactive material than was in Revision 0. In addition, the guide includes a new section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations," as well as requirements for recordkeeping. Also, Table 3, "Dosages of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," has been revised to provide information for the recommended duration of interruption of breastfeeding to ensure that the dose to an infant or child meets the NRC's regulatory requirements.

DATES: Submit comments by **[INSERT DATE 30 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 ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with the regulatory guides (RGs) currently being developed or improvements in all published RGs are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal rulemaking Web site:** Go to https://www.regulations.gov/ and search for Docket ID **NRC-2019-0154**. Address questions about docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.BorgesRoman@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- **Mail comments to:** Office of Administration, Mail Stop: TWFN-7A06, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

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: Vered Shaffer, telephone: 630-829-9862, e-mail: Vered.Shaffer@nrc.gov, and Harriet Karagiannis, telephone: 301-415-2493, e-mail: Harriet.Karagiannis@nrc.gov. Both are staff members of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2019-0154** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document, by any of the following methods:

- **Federal Rulemaking Web Site:** Go to https://www.regulations.gov/ and search for Docket ID **NRC-2019-0154**.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://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 DG-8057 is available in ADAMS under Accession No. ML19108A463.

- **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-2019-0154** in your comment submission. 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 posts all comment submissions at https://www.regulations.gov/ as well as entering 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 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. Additional Information

The NRC is issuing for public comment a DG in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The DG, entitled, "Release of Patients Administered Radioactive Material," is temporarily identified by its task number, DG-8057. The DG-8057 is proposed Revision 1 to RG 8.39

This revision of the guide (Revision 1) provides licensees with more detailed instructions to provide to patients before and after they have been administered radioactive material than was in Revision 0. In addition, the guide includes a new section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations," as well as additional guidance for requirements for recordkeeping.

Also, Table 3, "Dosages of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," has been revised to provide information for the recommended duration of interruption of breastfeeding to ensure that the dose to an infant or child meet the NRC regulatory requirements.

III. Backfitting and Issue Finality

As discussed in the Implementation section of DG-8057, the NRC does not intend or approve any imposition of the guidance in this draft regulatory guide. Backfitting and issue finality considerations do not apply to licensees or applicants when

performing activities under part 35 of title 10 of the *Code of Federal Regulations* (CFR). Therefore, the NRC has determined that its backfitting and issue finality regulations would not apply to this draft regulatory guide, if ultimately issued as Revision 1 to RG 8.39, because the draft regulatory guide does not include any provisions within the scope of matters covered by the backfitting provisions in 10 CFR parts 50, 70, 72, or 76 or the issue finality provisions of 10 CFR part 52.

Dated at Rockville, Maryland, this 22nd day of July, 2019.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,
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