[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0154]

Release of Patients Administered Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 1 to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Material." This RG (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, "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," has been revised.

DATES: Revision 1 to RG 8.39 is available on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: 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, using the following methods:

- **Federal rulemaking Web site:** Go to https://www.regulations.gov and search for Docket ID **NRC-2019-0154**. Address questions about NRC docket IDs in Regulations.gov to Jennifer Borges, telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Document collection at https://www.nrc.gov/reading-rm/adams.html**.** To begin the search, 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 ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 1 to RG 8.39 may be found in ADAMS under Accession No. ML19232A081.
- **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.

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FOR FURTHER INFORMATION CONTACT: Vered Shaffer, Office of Nuclear Regulatory Research, telephone: 630-829-9862, e-mail: Vered.Shaffer@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

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

RG 8.39 described methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations. Specifically, the RG provides licensees with instructions for patients before and after they receive medical procedures involving the administration of radioactive material, as well as requirements for recordkeeping. The RG also lists activities and dose rates that may be used by licensees for the release of patients in order to meet NRC regulatory requirements.

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, "Activities 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.

II. Additional Information

Proposed revision 1 of RG 8.39 was issued with a temporary identification of Draft Regulatory Guide, (DG) -8057. The NRC published a notice of the availability of DG-8057 in the *Federal Register* on July 29, 2019 (84 FR 36127) for a 30-day public comment period. The public comment period was extended for another 30 days (84 FR 39383; August 9, 2019). The public comment period closed on September 26, 2019. Public comments on DG-8057 and the staff responses to the public comments are available under ADAMS under Accession No. ML19353B203.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Revision 1 of RG 8.39 does not constitute backfitting as defined in title 10 of the *Code of Federal Regulations* (10 CFR) section 50.109, "Backfitting" and as described in NRC Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (ADAMS Accession No. ML18093B087); affect the issue finality of any approval issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" or constitute forward fitting as that term is defined and described in MD 8.4. 10 CFR Part 35, "Medical Use of Byproduct Material," does not include backfitting or issue finality provisions and the forward fitting policy in MD 8.4 does not apply to these licensees. In addition, licensees will not be required to comply with the positions set forth in this RG.

Dated: April 2, 2020.

For the Nuclear Regulatory Commission.

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