**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
**WASHINGTON, D.C. 20555-0001**

August 9, 2019

ALL AGREEMENT STATES, VERMONT

U.S. NUCLEAR REGULATORY COMMISSION *FEDERAL REGISTER* NOTICE DRAFT REGULATORY GUIDE-8057 "RELASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS" (STC-19-049)

**Purpose:** To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff published a *Federal Register* notice (FRN) on July 26, 2019, requesting comments on draft regulatory guide (DG), DG-8057, "Release of Patients Administered Radioactive Material" (84 FR 36127). On August 9, 2019, the NRC staff issued a second FRN (84 FR39383) for DG-8057 extending the comment period to September 26, 2019.

**Background:** Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material" (RG 8.39) was issued in April 1997 and provides guidance on how a licensee can determine a release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material from a medical institution. RG 8.39 also provides information on when instructions to the patient are required, and when records are required to be generated and maintained. The NRC staff is currently updating RG 8.39 based on both direction from the Commission and the staff's evaluation of the program for regulating patient release. The staff committed to a phased approach to comprehensively update RG 8.39: Phase 1 would include incorporation of guidance currently provided in generic communications and patient instructions; and Phase 2 would update the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients.

**Discussion:** The DG-8057 is the Phase 1 part to update RG 8.39. This draft revision provides licensees with more detailed instructions to provide to patients before and after they have been administered radioactive material. In addition, DG-8057 includes a new section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations." 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 and provides updated information for the recommended durations of interruption of breastfeeding to ensure that the dose to an infant or child meets the NRC's regulatory requirements. The comment period closes on September 26, 2019. A copy of the FRN has been enclosed or you can access the document using, https://www.federalregister.gov/documents/2019/07/26/2019-15868/release-of-patients-administered-radioactive-material).

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-2019-0154. Address questions about NRC dockets to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.BorgesRoman@nrc.gov.

- 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.

POINT OF CONTACT: Said Daibes E-MAIL: said.daibes@nrc.gov
TELEPHONE: 301-415-6360

***/RA/***

Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs

Enclosure:
DG-8057, "Release of Patients Administered Radioactive Material *Federal Register* notice

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION *FEDERAL REGISTER* NOTICE DRAFT REGULATORY GUIDE-8057 "RELASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS" (STC-19-049) **DATE August 9, 2019**

DISTRIBUTION:
CRCPD
OAS

**ADAMS Accession No.: ML19221B530**

| OFFICE | MSST | MSST | MSST |
|---|---|---|---|
| NAME | LDimmick | PMichalak | CEinberg |
| DATE | 08/9/19 | 08/9/19 | 08/ 9/19 |

**OFFICIAL RECORD COPY**