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

June 8, 2023

ALL AGREEMENT STATES
CONNECTICUT, INDIANA, WEST VIRGINIA

ISSUANCE OF A *FEDERAL REGISTER* NOTICE REQUESTING COMMENTS ON DRAFT REGULATORY GUIDE-8061 "RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS" (STC-23-042)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff published a *Federal Register* notice (FRN) on April 21, 2023, requesting comments on draft regulatory guide (DG), DG-8061, "Release of Patients Administered Radioactive Material" (88 FRN 24495).

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.

Discussion: As described in STC-19-049, 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 in two phases. Phase 1 was completed in April 2020 when Revision 1 of the RG was issued which incorporated guidance currently provided in generic communications and patient instructions. This draft is part of Phase 2, which provides an update the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients.

This draft revision provides (1) information for the administered activity and measured dose rate thresholds to demonstrate compliance for commonly used radionuclides, (2) calculational methodologies to accommodate threshold modifications for patient-specific exposure situations with modifying factors for biokinetics, occupancy, geometry, and attenuation based on patient-specific information, (3) calculations assuming unity for the occupancy factor if patient-specific information is not known, to avoid underestimating exposure, (4) flexibility for emerging radiopharmaceuticals that could be used for diagnostic or therapeutic purposes, (5) radiopharmaceutical activity thresholds for patients who may continue breastfeeding an infant or child after administration of radioactive material, with recommendations for breastfeeding interruption times for many typical administered medical dosages, and (6) a new section on "Sources Separated from the Patient."

The comment period closes on June 20, 2023. You can access the FRN and the DG using the following link: https://www.federalregister.gov/documents/2023/04/21/2023-08418/draft-regulatory-guide-release-of-patients-administered-radioactive-material.

We encourage electronic comment submission through the Federal rulemaking website (https://www.regulations.gov). Please include Docket ID NRC–2023–0086 in your comment submission.

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Signed by Giantelli, Adelaide
on 06/08/23

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STC 23 0XX U.S. NRC Federal Register Notice Draft Regulatory Guide- 8061 "Release of Patients Administered Radioactive Materials" DATE June 8, 2023

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