



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

June 21, 2023

ALL AGREEMENT STATES  
CONNECTICUT, INDIANA, WEST VIRGINIA

EXTENSION TO COMMENT PERIOD FOR U.S. NUCLEAR REGULATORY COMMISSION  
DRAFT REGULATORY GUIDE-8061 "RELEASE OF PATIENTS ADMINISTERED  
RADIOACTIVE MATERIAL" (STC-23-047)

**Purpose:** To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff published a *Federal Register* notice (FRN) on June 13, 2023 ([88 FR 38047](#)), extending the comment period for draft regulatory guide (DG). DG-8061, "Release of Patients Administered Radioactive Material" ([88 FR 24495](#)). This is a follow-up to [STC-23-042](#), issued on June 8, 2023, notifying Agreement States of the availability of DG-8061 for comment.

**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 the 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 revised RG 8.39 in April 2020 based on direction from the Commission to incorporate guidance previously provided in generic communications and example patient instructions. Since that revision, the NRC has been working on revising the guidance to update the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients.

**Discussion:** The DG-8061 provides updated guidance based on the available scientific information and data, which licensees can use for more accurate estimates of the timing, circumstances, and risks associated with patient release; public doses from the released patients; and when instructions or records are required.

This revision specifically 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 extended comment period closes on August 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>.

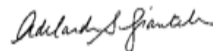
You may submit comments by any of the following methods. We encourage electronic comment submission through the Federal rulemaking website.

Federal rulemaking website: Go to <https://www.regulations.gov> and search for Docket ID NRC-2023-0086. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Stacy Schumann; telephone: 301-415-0624; email: [stacy.schumann@nrc.gov](mailto:stacy.schumann@nrc.gov).

Mail comments to: Office of Administration, Mail Stop: TWFN-7-A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

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Signed by Giantelli, Adelaide  
on 06/21/23

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