



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 "RELEASE 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
TELEPHONE: 301-415-6360

E-MAIL: said.daibes@nrc.gov

/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

NATIONAL SCIENCE FOUNDATION**Agency Information Collection Activities: Comment Request****AGENCY:** National Science Foundation.**ACTION:** Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: <http://www.reginfo.gov/public/do/PRAMain>.

DATES: Comments regarding this information collection are best assured of having their full effect if received by August 26, 2019.

FOR FURTHER INFORMATION CONTACT: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street NW, Room 10235, Washington, DC 20503, and Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission may be obtained by calling 703-292-7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the

information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

Title of Collection: Grantee Reporting Requirements for Partnerships for Research and Education in Materials (PREM).

OMB Number: 3145-0232.

Type of Request: Intent to seek approval to renew an information collection.

Overview of this Information Collection: The Partnerships for Research and Education in Materials (PREM) aims to enhance diversity in materials research and education by stimulating the development of formal, long-term, collaborative research and education relationships between minority-serving colleges and universities and centers, institutes and facilities supported by the NSF Division of Materials Research (DMR). With this collaborative model PREMs build intellectual and physical infrastructure within and between disciplines, weaving together knowledge creation, knowledge integration, and knowledge transfer. PREMs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. New knowledge thus created is meaningfully linked to society, with an emphasis on enhancing diversity.

PREMs enable and foster excellent education, integrate research and education, and create bonds between learning and inquiry so that discovery and creativity more fully support the learning process. PREMs capitalize on diversity through participation and collaboration in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

PREMs will be required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. To support this review and the management of the award PREMs will be required to develop a set of management and performance indicators for submission annually to NSF via the Research Performance Project Reporting module in *Research.gov*. These indicators are both

quantitative and descriptive and may include, for example, the characteristics of personnel and students; sources of financial support and in-kind support; expenditures by operational component; research activities; education activities; patents, licenses; publications; degrees granted to students involved in PREM activities; descriptions of significant advances and other outcomes of the PREM effort.

Each PREM's annual report will include the following categories of activities: (1) Research, (2) education (3) outreach, (4) partnerships, (5) diversity, (6) management, and (7) budget issues.

For each of the categories the report will describe overall objectives for the year, problems the PREM has encountered in making progress towards goals, anticipated problems in the following year, and specific outputs and outcomes.

PREMs are required to file a final report through the RPPR and external technical assistance contractor. Final reports contain similar information and metrics as annual reports but are retrospective.

Use of the Information: NSF will use the information to continue funding of PREMs, and to evaluate the progress of the program.

Estimate of Burden: 50 hours per PREM for 15 PREMs for a total of 750 hours.

Respondents: Non-profit institutions.

Estimated Number of Responses per Report: One from each of the fifteen PREMs.

Dated: July 23, 2019.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019-15947 Filed 7-25-19; 8:45 am]

BILLING CODE 7555-01-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 August 26, 2019. 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 Website:* 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; email: 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, email: Vered.Shaffer@nrc.gov, and Harriet Karagiannis, telephone: 301–415–2493, email: 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 Website:* 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 email 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,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2019–15868 Filed 7–25–19; 8:45 am]

BILLING CODE 7590–01–P