

**WORKING GROUP CHARTER**  
**Rulemaking on Reporting Nuclear Medicine Injection Extravasations as Medical Events**  
**(Extravasations Rulemaking)**  
**Docket ID No. NRC-2022-0218; RIN 3150-AK91**

**PURPOSE**

The purpose of this working group (WG) is to develop proposed and final rules that would amend the U.S. Nuclear Regulatory Commission's (NRC's) regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material" to include requirements for medical event reporting of extravasations that require medical attention for a suspected radiation injury (Extravasations Rulemaking). The information obtained from the medical event reporting of these extravasations would enhance the tracking and trending of these events and promote sharing information on their occurrence, detection, mitigation, and possible preventive strategies. This rulemaking would affect medical licensees who administer intravenous radiopharmaceuticals for diagnostic and therapeutic purposes. The working group would also develop related guidance. This charter describes the WG's composition and updated scope of rulemaking activities and provides an estimated schedule for developing the proposed rule.

**BACKGROUND**

In May 2020, the NRC received a petition for rulemaking requesting the NRC to amend [10 CFR Part 35](#) to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 Sieverts). In accordance with 10 CFR 2.803, the NRC docketed the petition as PRM-35-22 and reviewed the petition under 10 CFR 2.803(b)(1). The NRC reviewed the petitioner's request and conducted an independent evaluation of whether radiopharmaceutical extravasations should be reported as medical events, considering input from the Advisory Committee on the Medical Uses of Isotopes (ACMUI), Agreement States, external stakeholders, and available published literature on extravasations. In May 2022, the NRC staff proposed a rulemaking plan to the Commission under SECY-22-0043 that recommended amending 10 CFR Part 35 to include the reporting of certain nuclear medicine injection extravasations as medical events. The staff's rulemaking plan is available in ADAMS under Accession No. [ML21268A005](#).

In the Staff's Requirement Memorandum (SRM) for SECY-22-0043, the Commission approved the staff's recommended option to initiate a rulemaking that would amend 10 CFR Part 35 to include certain nuclear medicine injection extravasations as reportable medical events. The Commission's SRM is available in ADAMS under Accession No. [ML22346A115](#).

**MEMBERSHIP**

Direct WG support is expected from the Division of Materials Safety, Security, State, and Tribal Programs (MSST) and the Division of Rulemaking, Environmental, and Financial Support (REFS), both within the Office of Nuclear Material Safety and Safeguards (NMSS); Organization of Agreement States, Inc. (OAS); and the Office of the General Counsel (OGC).

On January 16, 2019, NMSS issued NMSS Procedure State Agreement (SA)-801A, "Agreement State Participation in Rulemaking Working Groups" (ADAMS Accession No. ML18263A239). SA-801A details the procedure for NRC and Agreement State interactions during the entire

rulemaking process and complements other NRC directives and guidance for rulemaking activities. In accordance with SA-801A, this is an NRC/OAS WG as described under NRC Management Directive 5.3, “Agreement State Participation in Working Groups,” and chaired by an NRC staff member. The WG membership may change during execution of the project. The WG may seek additional expertise as needed. Membership and responsibilities are depicted in the following table:

Organization	Working Group Members
NRC/NMSS/REFS	Irene Wu, Chair and Rulemaking Project Manager (PM); Andrew Carrera*, Backup Rulemaking PM; Krupskaya Castellon and Tricia Lizama*, Regulations Specialist; and Dan Ruby, Cost Analyst
NRC/NMSS/MSST	Daniel DiMarco, Technical Lead; Katherine Tapp*, Guidance PM; and TBD*, Agreement State Liaison
OAS	Becki Harisis (Nebraska), Agreement State Representative
NRC/OCIO	Fajr Majeed*, Information Management Analyst
NRC/OE	Susan Woods*, Sr. Enforcement Specialist
NRC/RES	Brian Allen* and Rigel Flora*, Technical Support
NRC/Region I	Hiba Ahmed*, Regional Representative
NRC/OGC	Max Smith and Ian Irvin*, Attorney

\* These working group members are consulted for this rulemaking on an as-needed basis.

If the WG needs management support to resolve issues that are significant or have policy implications, then a Steering Committee would be convened for this effort. Alternatively, a Project Sponsor may be appointed for this effort in lieu of a Steering Committee.

## **SCHEDULE**

The high-level schedule below covers the proposed rule development process. The schedule is preliminary and may change. A more detailed schedule will be provided to WG members.

WG kickoff meeting	February 7, 2023
Explore basis for addressing new complex issues proposed in the SRM and develop streamlined information request <i>Federal Register</i> notice	February – April 2023
Publication of the information request FRN	April 19, 2023
Public meeting	May 24, 2023
Prepare draft proposed rule package and related guidance	May 2023 – January 2024
Regulations Specialist, Branch Chiefs, and Divisions concurrence	January – February 2024
Interoffice concurrence and QTE review	February – March 2024
ACMUI and Agreement States/Standing Committee on Compatibility review	February – June 2024
RASB QA review and OGC NLO review	June – July 2024

NMSS FO and OEDO concurrence	July – August 2024
Submit draft proposed rule package and related guidance to the Commission	August 12, 2024

### **LEVEL OF EFFORT EXPECTED OF WG MEMBERS**

To support the schedule and activities listed above, approximately 100 hours of effort is expected for WG members (excluding the WG members that are consulted for this rulemaking on an as-needed basis) with no authoring responsibility to:

1. Attend and participate in WG weekly meetings on the development of the draft proposed rule package and guidance, and review draft documents, from February 2023 – January 2024, approximately 1 hour each meeting, 48 hours total.
2. Support three management alignment briefings during the proposed rule development period, in July – August 2023, approximately 2 hours each meeting, 6 hours total.
3. Support two meetings with stakeholders, from May to July 2023, approximately 2 hours each meeting, 4 hours total.
4. Review the draft proposed rule package and guidance and provide comments to management (if requested by the division management or OAS Director of Rulemaking) during the Agreement State review and NRC interoffice review and concurrence period, approximately 20 hours total.
5. Attend and support monthly Steering Committee meetings or meetings with the Project Sponsor (if needed), from February 2023 – August 2024, approximately 1 hour each meeting, 19 hours total.

Management briefings will be held, as needed, during the development of the proposed rule package. Members of the WG are invited to attend and support these briefings. WG members should keep their management apprised of WG activities throughout the development of the proposed rule. WG meeting dates and locations will be coordinated by the project managers in consultation with the WG. All WG meetings and briefings will be teleconference supported. Maximum use will be made of available electronic communication options to facilitate interaction within the WG and among its members. Examples of these communications include teleconference calls, emails, and other options.

This working group operates as an NRC/OAS working group with the roles and responsibilities described in [Section IV of SA-801A](#) and [NRC Management Directive 5.3](#).

---

Christopher Regan, Director, NRC/NMSS/REFS	Date
--	------

---

Kevin Williams, Director, NRC/NMSS/MSST	Date
---	------

---

Steve Seeger, Chair, OAS	Date
--------------------------	------

SUBJECT: WORKING GROUP CHARTER Rulemaking on Reporting Nuclear Medicine  
Injection Extravasations as Medical Events (Extravasations Rulemaking)  
DATED:

**DISTRIBUTION:**

Public  
IWu, NMSS  
ACarrera, NMSS  
DBearde, NMSS  
JShepherd, NMSS  
DDimarco, NMSS  
CValentin-Rodriguez, NMSS  
CEinberg, NMSS  
TClark, NMSS  
KWilliams, NMSS  
DSilberfeld, NMSS  
CRegan, NMSS

**ADAMS Accession No.: ML23081A510**

<b>OFFICE</b>	NMSS/REFS/MRPB	NMSS/MSST/MSEB	NMSS/REFS/MSEB
<b>NAME</b>	IWu	DBearde	DDimarco
<b>DATE</b>	3/30/2023	3/30/2023	3/30/2023
<b>OFFICE</b>	NMSS/MSST/MRPB	NMSS/MSST/MSEB	NMSS/MSST/MSEB
<b>NAME</b>	JShepherd	CValentin-Rodriguez	CEinberg
<b>DATE</b>	4/12/2023	4/12/2023	4/18/2023
<b>OFFICE</b>	NMSS/MSST/SALB	NMSS/MSST	NMSS/REFS
<b>NAME</b>	RJohnson	KWilliams	CRegan
<b>DATE</b>	4/13/2023	4/20/2023	4/20/2023

**OFFICIAL RECORD COPY**