

WORKING GROUP CHARTER
Petition for Rulemaking (PRM)-35-22, “Nuclear Medicine Injection Extravasations as Medical Events”

PURPOSE: The purpose of this working group (WG) is to review and provide a recommendation for closing the petition for rulemaking (PRM)-35-22, “Nuclear Medicine Injection Extravasations as Medical Events.” The U.S. Nuclear Regulatory Commission (NRC) received the petition for rulemaking from Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC, dated May 18, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20157A266), requesting that the NRC revise its regulations to require reporting of nuclear medicine injection extravasations as medical events. In addition, the Office of Nuclear Material Safety and Safeguards (NMSS) is conducting a pilot effort to evaluate how Agile Project Management concepts can be incorporated in the management of a rulemaking project to achieve improved outcomes as part of the rulemaking innovation effort. Specifically, this pilot effort applies Agile project management concepts as an alternative to the traditional PRM project management approach. The WG will evaluate the application of Agile concepts throughout the pilot, and course corrections will be made, as needed, in real time. This charter describes the WG’s composition, activities, and schedule.

MEMBERSHIP: This WG is sponsored by the NMSS Division of Rulemaking, Environmental, and Financial Support (REFS) and Division of Materials Safety, Security, and State and Tribal Programs (MSST). The project sponsor for this activity is Kevin Williams, Director, NMSS/MSST. The WG will consist of NRC staff members and a representative from the Organization of Agreement States, Inc. (OAS). The membership and roles are depicted in the table below. The WG may seek additional expertise on an as-needed basis.

Organization	Working Group Member
NRC/NMSS/REFS/Regulatory Analysis and Rulemaking Support Branch (RASB)	Pamela Noto, Project Manager
NRC/NMSS/REFS/Materials Rulemaking and Project Management Branch	Vanessa Cox, Rulemaking Project Manager
NRC/NMSS/MSST/Medical Safety and Events Assessment Branch	Daniel Dimarco, Technical Lead
NRC/Office of the General Counsel (OGC)	Ian Irvin, Legal Support
NRC/NMSS/REFS/RASB	Jill Shepherd, Regulations Specialist
OAS	Allyson Stout

A Petition Review Board (PRB) may be convened if it is determined that a formal PRB is needed during key decision points in the pilot process. If formed, the PRB would include the following members:

1. Director of MSST
2. Director of REFS
3. OGC Assistant General Counsel for Reactors and Materials Rulemaking

4. OAS Director of Rulemaking, who is appointed by the OAS Executive Board/Director of Emerging Issues and Advocacy, or their designees, and
5. REFS/RASB Branch Chief

OBJECTIVE: The WG has four objectives:

1. Under the project sponsor’s guidance, recommend closure path for PRM-35-22 (e.g., deny the PRM, incorporate the PRM to an existing rulemaking, or accept the PRM for rulemaking) with consideration of public comments.
2. Evaluate key decisions of the Agile pilot process:
 - Is a formal PRB needed, or are there any alternatives?
 - What type of concurrence is formally needed?
 - If the decision is made to accept the petition and begin development of a rulemaking plan for submission for the Commission, should an Agile approach continue to be used?
3. Develop a PRM closure package for Commission review and approval.
4. Evaluate the application of Agile concepts throughout the pilot and look for opportunities to communicate its progress and insights with interested parties during the development process. Complete a lessons-learned summary after completion of the pilot.

SCHEDULE: The high-level schedule below covers the petition review process up to the recommendation and determination of key decisions. A more detailed schedule will be provided to WG members.

Public comment period closed	November 2020
Conduct monthly sprints	January 2021 – April 2021
Evaluate and determine key decisions	May 2021

A schedule for the PRM closure package will be developed after key decisions are determined and will be shared with the WG members. The entire PRM process is estimated to take 18 months.

LEVEL OF EFFORT EXPECTED OF MEMBERS: To support the schedule and activities listed above through the recommendation and determination of key decisions, approximately 75 hours of effort is expected to:

1. Sprint planning and review meetings will occur monthly for four months (January through April), approximately 1 to 2 hours each.
2. The WG will meet biweekly from January through April for approximately 1 hour to work through the sprint backlog tasks for the current Sprint.
3. Develop a technical evaluation of each issue identified in the petition and provide a recommendation. The level of effort would be around 2 hours per week for the next 15 weeks.
4. Summarize and provide a response to public comments received. The level of effort would be around 2 hours per week for the next 15 weeks.

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Levels of effort for the PRM closure package will be provided closer to the development of the package.

Management briefings will be held as needed during the petition review process. WG members are invited to attend and support these briefings. 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 conference calls, e-mails, and other options.

This working group operates as an NRC/Agreement State working group with the roles and responsibilities described in Section IV of State Agreement 801A, "Agreement State Participation in Rulemaking Working Groups," and NRC Management Directive 5.3, "Agreement State Participation in Working Groups."

Kevin Williams, Director, NRC/NMSS/MSST


Kevin
Williams



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Williams
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Kevin Coyne, Director, NRC/NMSS/REFS

Kevin A.
Coyne



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David Crowley, Chair, OAS

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SUBJECT: CHARTER FOR AGREEMENT STATE MEMBER OF WORKING GROUP ON
PETITION FOR RULEMAKING (PRM)-35-22, "NUCLEAR MEDICINE
INJECTION EXTRAVASATIONS AS MEDICAL EVENTS"

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