

Charter for the U.S. Nuclear Regulatory Commission/Agreement State Working Group to Develop the Rulemaking Plan on Updates for Emerging Medical Technologies

PURPOSE

The purpose of the Charter is to establish a Working Group (WG) to develop a rulemaking plan to request the Commission's approval to initiate a rulemaking to improve the efficiency and effectiveness of the U.S. Nuclear Regulatory Commission's (NRC's) National Materials Program. Specifically, the WG will evaluate incorporating the emerging medical technologies currently licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material," into more appropriate Subparts in 10 CFR Part 35.

OBJECTIVE

The WG will complete the streamlined rulemaking plan SECY paper to identify the emerging medical technologies that can be regulated under 10 CFR Part 35, Subparts D through H, and provide rulemaking options and recommendations to the Commission.

BACKGROUND

The NRC amended 10 CFR Part 35 on April 24, 2002 (67 FR 20249) to, among other things, add Subpart K, "Other Medical Uses of Byproduct Material or Radiation From Byproduct Material," and amend Section 35.12, "Application for license, amendment, or renewal." These regulations were amended to add generic requirements for new medical uses of byproduct material or radiation from byproduct material, i.e., an emerging medical technology, that is not specifically addressed in Subparts D through H. Applications for emerging medical technologies are reviewed and approved under Subpart K, Section 35.1000, "Other medical uses of byproduct material or radiation from byproduct material." Section 35.12(d) includes the specific information that a licensee or applicant needs to provide to the NRC for review.

Currently, each application for an emerging medical technology under 10 CFR 35.1000 is evaluated by the NRC on a case-by-case basis. The NRC evaluates each application in conjunction with the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), the medical community, and developers of the new technology, as appropriate. The purpose of the evaluation is to determine: 1) the risks associated with the technology, and 2) the appropriate regulatory requirements, including the training and experience, as well as the facilities and equipment, required for use of the new technology.

Currently, the NRC staff issues licensing guidance for review of medical uses approved under 10 CFR 35.1000. Licensing guidance does not need to be adopted by Agreement States for purposes of compatibility (Compatibility Category D). Rulemaking to move medical uses currently approved under 10 CFR 35.1000 into Subparts D through H of 10 CFR Part 35 will improve consistency in the National Materials Program for the NRC and the Agreement States given that Agreement States will need to adopt compatible regulations. The compatibility category will be determined during the proposed rulemaking development if the Commission approves rulemaking. Rulemaking would also allow current emerging technologies that are becoming prevalent (e.g., gamma stereotactic radiotherapy devices and micro-particles labeled with radioactive material) to be licensed without need for further development of 10 CFR 35.1000 licensing guidance. This would save time and resources for the NRC and the Agreement States, as well as for applicants.

Given the above, the NRC staff is forming an NRC/Organization of Agreement States, Inc. (OAS) WG to develop a rulemaking plan to request the Commission to initiate a rulemaking for the review and evaluation of emerging medical technologies.

MEMBERSHIP

The WG is sponsored by 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 Materials Safety and Safeguards (NMSS). Management sponsors for this activity are Christian Einberg, Branch Chief, NMSS/MSST, and June Cai, Branch Chief, NMSS/REFS.

On January 16, 2019, the NMSS issued NMSS Procedure SA-801A, “Agreement State Participation in Rulemaking Working Groups” (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 Management Directive 5.3, “Agreement State Participation in Working Groups,” and chaired by an NRC staff member. The WG membership and responsibilities are depicted in the following table:

Organization	Working Group Members
NRC/NMSS/MSST	Maryann Ayoade, Chair and Technical Lead Lisa Dimmick, Back Up and Technical Lead
OAS	Zubaida Gulshan, Agreement State Representative
OAS	Jayson Moak, Agreement State Representative
NRC/NMSS/REFS	Torre Taylor, Rulemaking Project Manager Thomas Young, Back Up Project Manager
NRC/NMSS/REFS/Regulatory Analysis and Support Branch (RASB)	Jill Shepherd, Team Leader, Regulations Specialist
NRC/NMSS/REFS/RASB	Antonio Gomez, Cost Analyst
NRC/Region	Penny Lanzisera, Regional Representative
NRC/Office of the General Counsel (OGC)	Maxine Segarnick, Legal Counsel

The WG may choose to designate a member on the ACMUI to serve as a WG member or advisor. The WG may seek additional expertise on an as-needed basis. If the WG needs management support to resolve issues that are more than minor, then a Steering Committee would be convened for this effort. The Steering Committee Chairperson would be the Director or Deputy Director of REFS, and the members would include REFS/RASB Branch Chief, the Director of MSST, the Director of the Division of Nuclear Materials Safety, Region I, the OGC Assistant General Counsel for Reactors and Materials Rulemaking, and the OAS Director of Rulemaking who is appointed by the OAS Executive Board/Director of Emerging Issues and Advocacy, or their designees.

ACTIVITIES AND SCHEDULE

The WG will begin meeting after both the OAS and NRC Co-Chairs accept this charter. The WG will aim to complete a draft rulemaking plan for submission to NRC and OAS management for review around April 2020. A more detailed schedule is being developed. Estimated major milestones are shown below:

WG kick off meeting	October 2019
Align Division, Office, and OEDO on the scope of the rulemaking plan	December 2019
WG completes draft rulemaking plan	January 2020
Interoffice concurrence package approved	January 2020
ACMUI courtesy review	February 2020
OGC Declaration of No Legal Objection (NLO)	March 2020
Division and Office level concurrence (MSST, REFS, OAS, and NMSS)	April 2020
EDO concurs and provides to SECY	June 2020

LEVEL OF EFFORT

WG members should expect to provide commitment to this activity until the objectives are completed. The expected level of effort is 6-10 hours per week, which includes two meetings per week. Periodic briefings with interested managers on the WG activities may be held to solicit feedback and comments. The level of effort would be 1 hour per briefing.

The NRC WG members should charge time associated with the activities identified in this charter to CAC 001126 and EPID U-2019-RU5-0003, “Rulemaking Plan for Updated Emerging Medical Technologies.”

MEETINGS

It is anticipated that all meetings 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 options include conference calls, e-mail, the NRC BOX Enterprise and File Synchronization System (EFSS, a cloud-based service that provides a secure mechanism for sharing files with external collaborators), Skype For Business, and WebEx services.

WORKING GROUP MEMBERS ROLES AND RESPONSIBILITIES

The responsibilities of the Agreement State representative are specified in Section IV.I of SA-801. Responsibilities of WG members from the NRC offices depend on their areas of programmatic responsibility and expertise. The following points reflect the duties and responsibilities listed in NMSS Policy and Procedures 6-10, Revision 3 (September 2018), “NMSS Procedures for Preparation and Review of Rulemaking Packages.” In general, WG members are responsible for:

1. Working with the WG Chairs to: assess the tasks needed to prepare the rulemaking plan package; review and comment on drafts; address comments; assist in estimating any information collection burden; assist in the development of cost estimates; assist in preparing briefing materials; and facilitate concurrence on the package.
2. Keeping their supervisors and managers apprised of the WG activities, obtaining comments and input on policy decisions from their supervisors and managers, and notifying their supervisors of potential problems or policy issues.

3. Ensuring that the views of their management are understood and presented to the WG.
4. Keeping their counterparts in the NRC regional offices and Agreement States apprised of the rulemaking plan, requesting input and considering replies.
5. Attending WG meetings and coming prepared to participate.
6. Providing timely input.
7. Providing correct technical information or legal advice.
8. Informing the WG Chairs of conflicting priorities, previously unanticipated problems, and other potential sources of delay.
9. Keeping their Steering Committee member informed, if one is established.
10. Facilitating the concurrence process by keeping their supervisor informed of significant issues of concern and helping to develop an appropriate resolution of those issues. Ideally, a WG member should have kept their management apprised and no new issues arise during the concurrence process.
11. Supporting any briefings.
12. Preparing and presenting material related to areas for which they may have a lead for ACMUI meetings.

<i>/RA Theresa Clark Acting for/</i>	November 27, 2019
John R. Tappert, Director, NRC/NMSS/REFS	Date

<i>/RA/</i>	November 26, 2019
Michael Layton, Director, NRC/NMSS/MSST	Date

<i>/RA/</i>	November 21, 2019
Terry Derstine, Chair, OAS	Date

SUBJECT: CHARTER FOR THE U.S. NUCLEAR REGULATORY
 COMMISSION/AGREEMENT STATE WORKING GROUP TO DEVELOP THE
 RULEMAKING PLAN ON UPDATES TO EMERGING MEDICAL TECHNOLOGIES
 (DOCKET ID NRC-2018-0297), DATE: November 27, 2019

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OFFICE	NMSS/MSST	NMSS/MSST	NMSS/REFS	NMSS/MSST	OAS	NMSS/REFS
NAME	MAyoade	CEinberg	JCai	MLayton Director	TDerstine	JTappert Director
DATE	10/23/2019	10/31/2019	10/25/2019	11/7/2019	11/21/2019	11/27/2019

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