



Office of Nuclear Material Safety and Safeguards Procedure Approval

Standing Committee for Reviewing Emerging Medical Technologies

Interim State Agreements (SA) Procedure SA-802

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NOTE

***Any changes to the procedure will be the responsibility of the NMSS Procedure Contact.
Copies of NMSS procedures are available through the NRC Web site at
<https://scp.nrc.gov>***

I. INTRODUCTION

This document describes guidance for the implementation of the Standing Committee for Reviewing Emerging Medical Technologies (SCREMT). Integrating early legal, Agreement State, and NRC staff feedback into the licensing decisions pertaining to emerging medical technologies should ensure that the regulation of these technologies is thorough, prompt, and provides for the safe use of the technology.

II. OBJECTIVES

The standing committee should:

- A. Provide guidance and oversight to the Office of Nuclear Material Safety and Safeguards (NMSS) staff during development of the licensing guidance.
- B. Review the basis for the decision to proceed with developing 35.1000 licensing guidance.
- C. Review and comment on the draft licensing guidance prior to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) review.
- D. Re-review the draft licensing guidance if significant changes were made to the licensing guidance as part of the ACMUI, Agreement State, and NRC staff review period.

III. BACKGROUND

The NRC amended Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," on April 24, 2002 (67 FR 20249) to add Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material," and amended Section 35.12, "Application for license, amendment, or renewal." The regulations were amended to codify regulatory requirements for the use of new medical uses of byproduct material or radiation from byproduct material (i.e., an emerging technology) that is not specifically addressed in 10 CFR Part 35 Subparts D through H. By adding these requirements to the regulations, it enables applicants to seek authorization for a medical use technology that did not fit the categories created by NRC's regulatory requirements (i.e., 10 CFR Part 35 Subparts D, E, F, G, and H).

Under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," each application for an emerging technology is evaluated on a case-by-case basis. The NRC evaluates each application in conjunction with the ACMUI, the medical community, and developers of the new technology, as appropriate, to determine the (1) risks associated with the technology, and (2) the appropriate regulatory requirements, including the training and experience requirements for use of the technology.

In the past, a joint NRC/Agreement State working group was formed to develop and issue licensing guidance for each medical use approved under 10 CFR 35.1000. The working group was created after the NMSS staff determined that the medical use technology was not specifically addressed in 10 CFR Part 35 Subparts D through H.

Under this process, licensing guidance for emerging technologies took approximately 14 months year or more to complete. The time it took to form these working groups contributed to the lengthy review times. In some situations, inconsistencies in the National Materials Program occurred when some Agreement States issued a license prior to the completion of the NRC's 35.1000 licensing guidance. These weaknesses and mishaps demonstrated the need for and importance of an established process with structure, organization, and a focus on collaboration. The revised SCREMT should result in increased awareness of new technologies and developing licensing guidance 4-6 months ahead of the previous schedule.

IV. ROLES AND RESPONSIBILITIES

- A. Director, NMSS / Division of Materials Safety, Security, State, and Tribal Programs (MSST)
 - 1. Approves the SCREMT charter;
 - 2. Proposes a path forward when briefed on any major dissenting opinion in which the SCREMT is unable to resolve;
 - 3. Approves a term extension for the Agreement State representative or the NRC regional designee, if sought; and
- B. Chief, NMSS/MSST / Medical Safety and Events Assessment Branch (MSEB)
 - 1. Assigns Medical Radiation Safety Team (MRST) staff to emerging medical technology reviews;
 - 2. Serves as the NRC Co-Chair to the SCREMT or delegates the responsibility;
 - 3. Assigns or requests staff support for the SCREMT Coordinator position;
 - 4. Manages the alternation of regions (RI, RIII, and RIV) when seeking qualified personnel to serve on the SCREMT. Coordinates with the Director, Division of Nuclear Materials Safety (DNMS) or Division of Radiological Safety and Security (DRSS) of the NRC regional office identified to obtain new standing committee members to support the SCREMT;
 - 5. Concurs and issues licensing guidance documents; and
 - 6. Briefs the MSST Director prior to issuance of licensing guidance.
- C. NRC Co-Chair
 - 1. Co-chairs and convenes the SCREMT meetings;
 - 2. Has knowledge of the licensing process, emerging medical technologies, and is the NMSS/MSST/MSEB Chief or designee.
 - 3. Collaborates with the Agreement State co-chair and receives briefings from the MRST staff to determine if adequate workload exists to warrant a

standing committee meeting;

4. Provides feedback to the MRST staff, both verbal and written, as a member of the SCREMT; and
5. Seeks collaboration with the other SCREMT members and tries to maximize agreement on key points.

D. MRST staff, NMSS/MSST/MSEB

1. Coordinates with the industry regarding upcoming medical technologies;
2. Collaborates with the NRC FDA Liaison on the FDA status of emerging technologies and monitors two FDA websites; "Device Approvals, Denials, and Clearances" and "Drugs@FDA: FDA-Approved Drugs."
3. Coordinates with the SCREMT co-chairs to clearly communicate the anticipated review schedules and when the SCREMT feedback will be needed;
4. Performs the initial screening of the 35.1000 Checklist and presents the results to the SCREMT;
5. Acts as the point-of-contact for the 35.1000 licensing guidance. This process should include working with the ACMUI, the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology and any additional regulatory requirements for the medical use of the technology;
6. Presents licensing challenges and issues to the SCREMT and incorporates or addresses the feedback;
7. Receives feedback from the SCREMT on their review of the licensing documents and incorporates or addresses the feedback prior to submitting the licensing documents to the ACMUI for review;
8. Ensures that the licensing documents and support materials are added to the Agencywide Document Access and Management System (ADAMS);
9. Maintains the list on the NRC public website titled "Status of NRC Review of Emerging Technologies;" and
10. Includes the licensing conditions resulting from the 35.1000 licensing guidance in the Web-Based Licensing (WBL) system.

E. SCREMT Coordinator, NMSS/MSST

1. Participates in the SCREMT meeting as a non-voting member;
2. Schedules SCREMT meetings, including audiovisual support for long-distance collaboration;

3. Takes and issues minutes of SCREMT meetings;
 4. Ensures that the meeting minutes are placed in ADAMS as non-public;
 5. Maintains the “Emerging Medical Technologies” SharePoint site, which is an NRC-only working space;
 6. Develops methodology of sharing documents with SCREMT members (NRC BOX Enterprise and File Synchronization System, secure zip, etc.) to appropriately handle the distribution of non-public, Official Use Only documents to the Agreement State members;
 7. Tracks the term of the NRC regional representative and alternate. Notifies the MSEB Chief prior to the end of the term to enable outreach to the NRC regions to obtain new SCREMT members; and
 8. Designates an alternate or assigns responsibilities to SCREMT members when unable to attend.
- F. Representative, Office of General Counsel (OGC) / Rulemaking, Agreement States & Fee Policy (RAF)
1. Participates in the SCREMT;
 2. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents;
 3. Coordinates with their management, if unable to attend or participate, to ensure that OGC representation is available;
 4. Ensures legal sufficiency and consistency with current laws, regulations, and agency policy; and
 5. Concurs on licensing guidance documents.
- G. Representative, OGC / Materials, Fuel Cycle & Waste Programs (MFW)
1. Supports the MRST development of licensing guidance;
 2. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents;
 3. Ensures legal sufficiency and consistency with current laws, regulations, and agency policy; and
 4. Provides a no legal objection on licensing guidance documents.
- H. Director, DRSS in Region I, III, and IV
1. Assigns two qualified staff members to the SCREMT, the regional

representative and the alternate, when contacted by the MSEB Chief.

- I. Regional Designee, DRSS
 1. Participates in the SCREMT for a 3-year term;
 2. Either is a fully qualified license reviewer or inspector, or has experience in medical licensing reviews, inspection, or management thereof and has knowledge or experience with emerging medical technologies;
 3. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents;
 4. Coordinates the participation of the Alternate regional Designee when unable to participate; and
 5. Contacts the SCREMT Coordinator 6 months prior to the expiration of the 3-year SCREMT term; and
 6. Provides adequate turnover to the next assigned regional designee.
- J. Alternate Regional Designee, DRSS
 1. Participates in the SCREMT when assigned;
 2. Has experience in medical licensing reviews, inspection, or management thereof and has knowledge or experience with emerging medical technologies; and
 3. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents when assigned.
- K. Chair, Organization of Agreement States (OAS) Executive Board:
 1. Approves the SCREMT charter after collaborating with the OAS Executive Board; and
 2. Approves recommendations for Agreement State Representative participation on the SCREMT, after collaborating with the OAS Executive Board, and after the Agreement State Representative(s) has received their management's approval to participate on the SCREMT.
- L. Director of Emerging Issues and Advocacy, OAS Executive Board
 1. Serves as the Agreement State Co-chair to the SCREMT or delegates the responsibility.
- M. Agreement State Co-chair
 1. Co-chairs and convenes the SCREMT meetings;

2. Has knowledge of the licensing process, emerging medical technologies, inspections, and is the Director of Emerging Issues and Advocacy on the OAS Executive Board or designee.
 3. Collaborates with the NRC Co-Chair and receives briefings from the MRST staff to determine if adequate workload exists to warrant a SCREMT meeting. Helps to establish meeting schedules, agendas, and appropriate due dates;
 4. Provides feedback to the MRST staff as an active member of the SCREMT;
 5. Seeks collaboration with the other SCREMT members and tries to maximize agreement on key points;
 6. Briefs the OAS Executive Board on any relevant issues or items of interest. Uses discretion on whether the OAS Executive Board should review the 35.1000 licensing determination, licensing guidance documents, or specific sections of the document, during the SCREMT licensing review period. (The official comment period for Agreement State input will occur after the SCREMT feedback is incorporated.)
 7. Addresses any issues or concerns raised by the OAS Executive Board with the NRC Co-Chair or MRST staff, as appropriate;
 8. Provides an objective perspective on any topic discussed by the SCREMT, based on experience gained from working for an Agreement State;
 9. Manages the recruitment of the Agreement State Representative and Alternate;
 - a) Compiles a list of interested Agreement State staff who meet the criteria to serve as a representative or alternate on the SCREMT.
 - b) Determines the timing of recruitment to correspond with the 3-year term limit of the current OAS Designee.
 - c) Assigns one of its members as the Agreement State Representative to be responsible for participating in a 3-year term on the SCREMT and assigns a members to serve as alternates.
 10. Assigns a delegate if unable to attend meetings; and
 11. Signs outgoing correspondence resulting from SCREMT proceedings.
- N. Representative, Agreement State
1. Participates on the SCREMT;
 2. Either is a fully qualified license reviewer or inspector, has experience in medical licensing reviews, inspection, or management thereof, and has knowledge or experience with emerging medical technologies;

3. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents;
 4. Communicates with the Agreement State Co-chair on any issues or concerns pertaining to the 35.1000 licensing determination or licensing guidance document that, in his/her opinion, should be elevated to the OAS Executive Board;
 5. Coordinates the participation of the Alternate Agreement State Representative(s) when unable to participate; and
 6. Contacts the Agreement State Co-chair 6 months prior to the expiration of their 3-year term and provides adequate turnover to the next assigned Agreement State representative.
- O. Alternate Representative(s), Agreement State
1. Participates in the SCREMT meetings to remain current on topics of discussion and serves as a resource to the group;
 2. Has experience in medical licensing reviews, inspection, or management thereof and has knowledge or experience with emerging medical technologies;
 3. Reviews and provides feedback on the 35.1000 licensing determination and guidance documents when assigned; and
 4. Contacts the Agreement State Co-chair 6 months prior to the expiration of their 3-year term and provides adequate turnover to the next assigned Agreement State alternate representative.

V. GUIDANCE

A. Meeting Schedule

SCREMT meetings should be held periodically; however, the schedule should be flexible to the workload.

If the anticipated workload for is expected to be high due to multiple technology reviews, the co-chairs should create a meeting schedule to strike a balance between the SCREMT members' normal commitments while ensuring that prompt attention is given to the licensing reviews and the corresponding deadlines.

B. Membership

The SCREMT should operate as an NRC/Agreement State steering committee as described in MD 5.3. The SCREMT should comprise of six members representing NMSS, OGC, OAS, and one NRC region. The SCREMT should be co-chaired by an NRC and an OAS representative.

The Agreement State and NRC regional members would have set term limits (i.e., 3 years) which would end at different times. The regional representative will rotate between Region I, III, and IV and will change at the end of each term limit.

1. SCREMT Co-Chairs

- a) The NRC Co-Chair should be assigned to the MSEB Chief or designee.
- b) The Agreement State Co-Chair should be assigned to the Director of Emerging Issues and Advocacy on the OAS Executive Board or designee.

2. SCREMT Coordinator

- a) The SCREMT Coordinator participates as a non-voting member.

3. SCREMT Members

- a) OGC representative
- b) NRC regional representative
- c) Agreement State representative

4. SCREMT Alternate Members

The NRC region and OAS should designate qualified persons to serve as the SCREMT members' alternates. Alternate members may be from a different regional Office or Agreement State than the Regional Designee or the Agreement State Representative. In the instance that a SCREMT member would be absent at a meeting, the SCREMT member should contact the SCREMT alternate members to arrange for their participation and provide any key points that should be represented.

The SCREMT alternate members may be selected as the SCREMT members if the SCREMT members leaves the SCREMT prematurely.

5. Subject Matter Experts

The SCREMT may seek additional expertise on an as-needed basis. The SCREMT may request additional Agreement State or NRC representatives or consultants to participate in the SCREMT meetings as a subject matter expert to address concerns relative to a specific aspect of the emerging medical technology. The subject matter expert is not a voting member of the SCREMT.

6. Observers

Staff from NMSS, OGC, OAS, and the NRC regions may attend the SCREMT meetings in a training capacity but are not voting members.

C. Meeting Category

SCREMT meetings are non-public as the content is pre-decisional.

D. Meeting Protocols

1. The co-chairs, MRST staff, or SCREMT Coordinator should provide any relevant documentation to the SCREMT in advance of the meeting.
2. To convene a SCREMT meeting, a quorum must be present. A quorum is established if four SCREMT members are present, so long as one co-chair and one Agreement State personnel is present. (The presence of the Agreement State co-chair and three other standing committee members is sufficient.) Designees or alternates count toward reaching a quorum.
3. The co-chairs should lead the meeting.
4. The SCREMT Coordinator should keep or delegate the keeping of the meeting minutes.
5. The co-chairs should consult with other SCREMT members to reach a collaborative agreement on any points of contention and instructions on how the MRST staff should move forward.

If the co-chairs are unable to identify a collaborative agreement on an important issue, then the co-chairs would bring the issues to the attention of the NRC office management, the OAS Executive Board, and OGC, as applicable.

E. Meeting Types and Feedback

The SCREMT feedback sought by the MRST staff will depend on the type of meeting held.

1. Status Updates

Objective: The co-chairs or the MRST staff should provide a status briefing of emerging medical technologies, associated licensing guidance documents, and relevant deadlines.

Feedback: No feedback or recommendations are required by the SCREMT.

2. Emerging Medical Technology Briefings

Objective: The MRST staff should provide general and background information on the emerging medical technology.

Feedback: No feedback or recommendations are required by the SCREMT. SCREMT members may provide insights on different elements of the

emerging medical technology and how it should be regulated.

3. Confirmation of 35.1000 Licensing Determination Checklist

Objective: The MRST staff should present the basis of why the licensing of the emerging medical technology belongs in 35.1000, including a summary of the checklist and any areas of uncertainty.

Feedback:

- a) After the MRST staff presentation, the co-chairs should lead an open and frank discussion on the appropriateness of 35.1000 for this emerging medical technology. The co-chairs should determine whether the MRST staff's responses are sufficient enough to bring the MRST staff's recommendation to a vote.
- b) The SCREMT should vote to confirm the MRST staff's recommendation.

The three options are: 1) confirmation of the MRST staff's recommendation to license under 35.1000; 2) recommendation to license under a different section of 10 CFR Part 35; or 3) MRST staff needs to go back and develop its recommendation further.

A vote of 75 percent is required for the MRST staff to move forward with developing 35.1000 licensing guidance.

4. Licensing Guidance Document Briefing

Objective: The MRST staff should present the draft licensing guidance documents to the SCREMT, including highlighting any sections in the licensing guidance documents that are controversial or in-depth.

Feedback: The SCREMT members should record comments, feedback, or revisions on the document electronically and submit the file to the MRST staff. The SCREMT members should submit the feedback to the MRST staff by the agreed upon due date.

F. Meeting Methods

The meetings should be conducted via telephone or web conferencing technology to ensure the full participation of offsite SCREMT members. All available technology should be used to facilitate interaction with the SCREMT members (e.g., conference calls, email, NRC BOX Enterprise and File Synchronization System, Microsoft Teams, WebEx services).

G. Meeting Minutes

1. Meeting minutes should summarize major discussions topics and any dissenting SCREMT member opinions and alternative recommendations, especially the collaborative agreement. The meeting minutes are not meant

to be a verbatim account of the proceedings.

2. Meeting minutes are not required if the standing committee was gathered as a status update meeting or a technology briefing meeting.
3. Meeting minutes should be added to ADAMS as non-public, pre-decisional. The meeting minutes should be provided to the SCREMT members for their review prior to them being finalized.

H. Agreement State Representative Participation in the SCREMT

1. The Agreement State Co-Chair and Representative may attend in person or remotely using available technology. Remote means of participation will be used whenever possible. On rare occasions, the Agreement State Co-Chair and Representative may be requested to attend the meeting in person. For these occasions, NMSS should cover the expenses associated with the travel in accordance with Federal Travel Regulations.
2. On the rare occasion that the Agreement State Representative is unable to participate in the meeting because of a conflict, one of the designated alternates should be contacted.
3. In the instance that the Agreement State Representative (or the NRC regional designee) should seek to extend the SCREMT term beyond 3 years, approval from the MSST director is required.
4. There is regulatory significance of the SCREMT, especially the participation of standing committee members from the Agreement States. This ensures that collaboration between the NRC and the Agreement States occurs. Section 274(g) of the Atomic Energy Act of 1954, as amended states that “the Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.”

VI. REFERENCES

NMSS SA Procedures available at <https://scp.nrc.gov/procedures.html>.

Title 10 of the *Code of Federal Regulations* Part 35, “Medical Use of Byproduct Material,” Subpart K, “Other Medical Uses of Byproduct Material or Radiation from Byproduct Material.” ([10 CFR 35.1000](#))

NRC Management Directive 5.3, Agreement State Participation in Working Groups. [ADAMS Accession No. ML18073A142](#).

Memorandum of Understanding Between the U.S. Nuclear Regulatory Commission and the U.S. Department of Health and Human Services Food and Drug Administration, December 4, 2002. [ADAMS Accession No. ML023520399](#).

U.S. FDA website, "[Recently Approved Devices.](#)"

U.S. FDA website, "[Device Approvals, Denials, and Clearances.](#)"

U.S. FDA website, "[Drugs at FDA: FDA-Approved Drugs.](#)"

U.S. NRC public website; "[Status of NRC Review of Emerging Technologies.](#)"

Atomic Energy Act of 1954, as amended; <https://www.nrc.gov/about-nrc/governing-laws.html#atomic>

VII. REVISIONS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into the ADAMS are listed below.

No.	Date	Document Title/Description	ADAMS Accession Number
0	10/04/2022	SA-802: Standing Committee for Reviewing Emerging Medical Technologies	ML22269A546