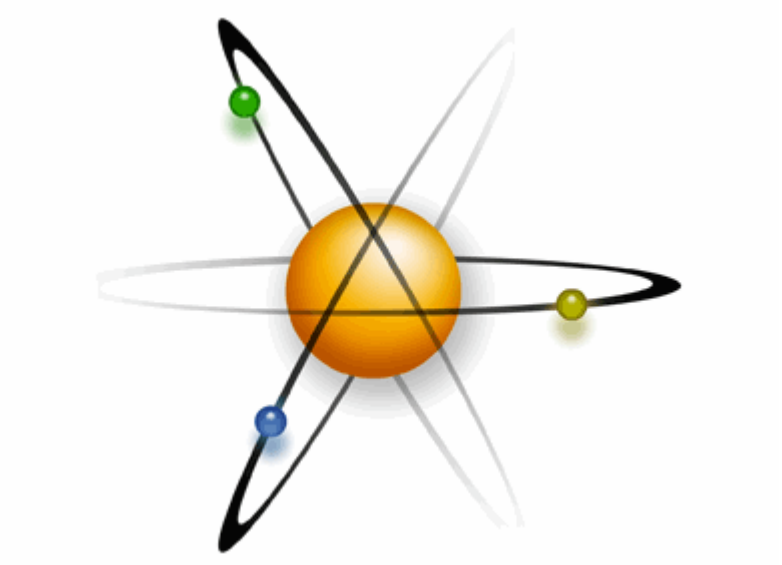
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

FALL 2024 MEETING
NOVEMBER 4 - 5, 2024

Meeting Handout



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MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
November 4 – 5, 2024
One White Flint North Building, 11555 Rockville Pike
Commissioner's Hearing Room
North Bethesda, Maryland 20852

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552b to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Monday, November 4, 2024 OPEN SESSION		
OPEN SESSION		
10:00 – 10:15	**1. Opening Remarks** Mr. Einberg will formally open the meeting and Mrs. Silberfeld will provide opening comments.	**C. Einberg, NRC** **D. Silberfeld, NRC**
10:15 – 10:30	**2. Old Business** Ms. Armstead/Ms. Roszkowski will review past ACMUI recommendations and provide NRC responses.	**L. Armstead, NRC** **T. Roszkowski, NRC**
10:30 – 10:45	**3. Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI, NRC**
10:45 – 11:00	**BREAK**	
11:00 – 11:45	**4. ACMUI Bylaws Subcommittee** Ms. Allen will provide an update to the ACMUI Bylaws.	**R. Allen, ACMUI**
11:45 – 12:15	**5. Y-90 Microspheres Medical Events** Ms. Spence will provide an overview of the NRC follow-up to the ACMUI recommendations on medical events related to the use of Y-90 microspheres.	**S. Spence, NRC**
12:15 – 1:30	**LUNCH**	
1:30 – 1:50	**6. Advance Act** The NRC staff will provide an overview of the Advance Act.	**M. King, NRC**
1:50 – 2:30	**7. Medical Team Updates** Dr. Tapp will provide an update on the Medical Radiation Safety Team's activities	**K. Tapp, NRC**
2:30 – 3:15	**8. NRC Evaluation of Current Patient Waste Guidance and Regulations** Mr. DiMarco will provide an overview of the current patient waste guidance and regulations.	**D. DiMarco, NRC**
3:15 – 3:30	**BREAK**	
3:30 – 4:00	**9. Status of Patient Release Guidance Revision** Dr. Tapp will provide a status update to the revision of RG 8.39, "Release of Patients Administered Radioactive Material."	**K. Tapp, NRC**
4:00 – 4:20	**10. Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI, NRC**
4:20 – 4:35	**11. Administrative Closing** Ms. Armstead/Ms. Roszkowski will provide a meeting summary and propose dates for the spring 2025 meeting.	**L. Armstead, NRC** **T. Roszkowski, NRC**
	BREAK	

Tuesday, November 5, 2024 CLOSED SESSION		
9:30 – 10:30	**12. Ethics Training**	**B. Klukan, NRC**
10:30 – 11:00	**13. Allegations Training**	**S. Hawkins, NRC**
11:00 – 11:30	**14. INFOSEC Training**	**M. MacDonald, NRC**
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2020 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date
11	As part of the Non-Medical Events report, the ACMUI recommended to the NRC staff and/or NMP to evaluate the issue of detection of short-lived medical isotopes in municipal waste (waste from nuclear medicine patients that might be triggering the landfill alarms) and provide some level of guidance, best practices, or additional instructions.	9/21/2020	*Accepted*	Propose to close	Fall 2024

2021 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date
10	The ACMUI endorsed the Radionuclide Generator Knowledge and Practice Requirements Subcommittee Report, and the recommendations provided therein.	10/04/2021	*Accepted*	Open	March 2026

2022 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date
4	The ACMUI endorsed the Y-90 microsphere ME Subcommittee report and the recommendations therein.	12/5/2022	*Accepted*	Propose to close	Fall 2024
6	The ACMUI established two subcommittees: one to create generic process checklists to be used during medical administrations and one to review the DFA draft proposed rule. The ACMUI also reestablished the Nursing Mothers guidelines to update the 2019 guidelines.	12/5/2022	*Accepted*	Open	Spring 2025

2024 ACMUI Recommendations and Action Items

	ITEM	DATE	STATUS		Target Completion Date
1	The ACMUI tentatively scheduled the fall 2024 meeting for November 4 - 5, 2024.	4/8/2024	*Accepted*	Propose to close	Fall 2024
2	The ACMUI formed a subcommittee to reassess including an interventional radiologist in ACMUI membership	4/8/2024	*Accepted*	Open	Spring 2025
3	The ACMUI formed a subcommittee to update the regulations in 10 CFR 30.35 that deal with financial assurance for Category 1 and Category 2 material.	4/8/2024	*Accepted*	Propose to close	Fall 2024
4	The ACMUI formed a subcommittee to review the Committee's bylaws regarding disclosures related to conflicts of interest	4/8/2024	*Accepted*	Propose to close	Fall 2024

OPEN FORUM

(No Handout)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

ACMUI Subcommittee on ACMUI ByLaws

Subcommittee Report

Rebecca Allen, MS, Chair
ACMUI Healthcare Administrator
November 4, 2024

Recommendations to revise the ACMUI Bylaws

Subcommittee Members

Rebecca Allen, MS (Chair)

Richard L. Green, BS Pharm

Michael O'Hara, MD

Zoubir Ouhib, MS

Harvey B. Wolkov, MD

NRC Staff Resource: Ms. Cindy Flannery

Charge to Bylaws Subcommittee

- To provide recommendations to revise the ACMUI bylaws considering the OIG's special inquiry with regards to appearance of conflict of interest of members.
- The subcommittee should also ensure that any of the changes in the FACA final rule effective May 20, 2024, are incorporated into the bylaws as appropriate.
- Staff recommends this as an opportunity to update the bylaws to ensure they contain sufficient information regarding conduct of meeting for ACMUI public meetings

Regulatory Concerns & Background of Report

- OIG Special Inquiry I2200187 concluded two ACMUI members had appearance of conflict of interest and suggested the NRC should consider strengthening procedures and revising the ethic section of the ACMUI bylaws for all ACMUI Members.
- ACMUI bylaws should also be updated due to the new FACA final rule effective May 20, 2024.
- Last revisions were in June 2019

Updates for Section 1: Scheduling, Agenda, and Conduct of Meetings

- Split this section into 3 separate sections
  - **Section 1: Scheduling Full Committee Meetings**
    - Clarified definition of Active participation in full committee meetings
    - Added requirement of Designated Federal Officer (DFO) must be present
  - **Section 2: Full Meeting Agenda**
    - Added prioritization of agenda items
  - **Section 3: Conduct of Meetings**
    - Added remote technology information
    - Added procedure for meeting
    - Clarified quorum
    - Added Chairperson expectations

Updates for Section Re: Transcripts

- New Section: Titled Transcripts/Meeting Summary
  - Clarified expectations on timelines and certifying transcripts or meeting summary.

Updates Section Re: Appointment of Members/Reappointment of Members

- Added new FACA language: membership to be fairly balanced to include those with relevant lived experience, and persons with demonstrated professional or personal qualifications.
- Added Reappoint of Members language: in accordance with September 26, 1996, Staff Requirements Memorandum, COMSECY-96-042, “Procedures for Reappointment of Advisory Committee Members”

Updates Section Re: Conduct of Members

- Conflict of interest: moved to separate section
- Added process for interacting with Director, MSST
- Added language about members not attempting to interpret ACMUI reports
- Added language about Special Government Employees conforming to NRC rules and regulations and expected to meet highest professional standards.

Updates Section Re: Adoption and Amendments

- Clarification on how to propose amendment
- Added language on voting requirements

Added New Section Re: Subcommittees

- Definition of Quorum
- Clarified Subcommittee Chairperson responsibilities
- Added language Subcommittee deliverables must be voted on and approved by Full Committee before sending to NRC.
- Per new FACA requirement: added language of DFO must be present on all subcommittee meetings.

Added New Section Re: Appointment of Officers

- Separated out from Appointment of Members
- Added “input from the MSST Director, MSEB Chief, and ACMUI Coordinator” to match ACMUI policy and procedure manual
- Added language to exclude FDA representative from being an officer to match ACMUI policy and procedure manual

Added New Section Re: Conflict of Interest

- Created separate section on COI
- Added language on expectations of ACMUI Members for divulging possible COI
- Added procedure to follow on Conflict of Interest and recusal
- Added procedure to follow during presentations
- Added procedure to follow for preparing ACMUI reports
- Added language for Chairperson responsibility
- Added language for DFO responsibility

Added New Section Re: Consultants

- Separate Section created
- Added service year language

Added New Section Re: ACMUI Reports

- Added language on process and expectations

Summary

- The subcommittee recommendations for updates to the ACMUI Bylaws should suffice the overall charge of the subcommittee.
- The old bylaws were 9 pages, and new proposed bylaws are 25 pages.
- Attached to the Subcommittee report is also a Track Changes version of the draft Bylaws for ACMUI members to review.

Subcommittee Comments

General Comments:

1. The general opinion of the subcommittee: we recommend the full committee approve the new proposed bylaws.
2. Subcommittee recommends establishing a five-year periodic review of the bylaws or when a revision of a significant item is needed due to unexpected or updated changes to other requirements.

Abbreviations and Acronyms

- ACMUI Advisory Committee on the Medical Uses of Isotopes
- COI Conflict of Interest
- COMSECY Communications Security
- DFO Designated Federal Officer
- FACA Federal Advisory Committee Act
- FDA Food and Drug Administration
- MSEB Medical Safety and Events Assessment Branch
- MSST Division of Materials safety, Security, State, and Tribal Programs
- NMSS Office of Nuclear Material Safety and Safeguards
- NRC Nuclear Regulatory Commission
- OIG Office Inspector General

U.S. Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee Review and Recommendations on

ACMUI Bylaws

Draft Report

Submitted: October 4th, 2024

Subcommittee Members

Rebecca Allen, MS (Chair)

Richard L. Green, BS Pharm

Michael O'Hara, MD

Zoubir Ouhib, MS

Harvey B. Wolkov, MD

NRC Staff Resource: Cindy Flannery

Charge

On April 8, 2024, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Chair created a subcommittee to provide recommendations to revise the AMCUI Bylaws in light of the Office of the Inspector General's (OIG) special inquiry with regards to the appearance of conflict of interest by members. The subcommittee should also ensure that any changes in the FACA rule, effective May 20, 2024, are incorporated into the bylaws as appropriate. Staff also recommended this is an opportunity to update the bylaws to ensure they contain sufficient information regarding conduct of meetings for ACMUI public meetings.

Background

The NRC's OIG issued a report on March 26, 2024, regarding a Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the ACMUI (OIG Case No. 12200187). As noted in the OIG report, advisory committees, such as ACMUI, are made up of experts who provide independent advice that supports agency decision-making processes. As experts in respective medical fields, affiliations with professional organizations are expected for members of the ACMUI. Based on findings of the OIG's special inquiry of appearances of conflict of interest for ACMUI members' active roles in such organizations, the NRC staff conducted a thorough review of its policies to identify program enhancements to ensure continued avoidance of current and future conflicts of interest and the appearance of conflicts of interest for ACMUI members. One such enhancement is to update the ACMUI bylaws to include additional information regarding the scope of federal conflict of interest requirements and the

responsibilities of members with respect to disclosing potential conflicts of interest or appearances of conflicts of interest to ACMUI leadership and the NRC.

Also, the Federal Advisory Committee Act (FACA) was updated May 2024 and the ACMUI bylaws should reflect the updates, as appropriate.

General Comments:

1. The general opinion of the subcommittee members was that we recommend the full committee approve the new proposed bylaws.
2. The subcommittee recommends establishing a five-year periodic review of the bylaws.
3. Attached to this report is a Track changes version of the draft revised bylaws for ease of comparison to original.

Specific Comments on the ACMUI Bylaws:

1. Section 1: Added requirement of Designated Federal Officer (DFO) must be present
2. Section 2: Added prioritization of agenda items
3. Section 3: Added remote technology information, added procedure for meetings, clarified quorum and added Chairperson expectations.
4. New Section: Titled Transcripts/Meeting Summary: Clarified expectations on timelines and certifying transcripts or meeting summary.
5. Updates for Section: Appointment of Members: added new FACA language: membership to be fairly balanced to include those with relevant lived experience, and persons with demonstrated professional or personal qualifications. Also added Reappointment language in accordance with COMSECY-96-042.
6. Added new section Subcommittees: added definition of quorum, clarified Subcommittee Chairperson responsibilities, added language on Subcommittee deliverables must be voted on and approved by Full Committee before sending to NRC, and add new FACA requirement of DFO must be present on all subcommittee meetings.
7. Add new section: Conflict of Interest: added language on expectations, added procedure to follow on COI and recusal, during presentations, preparing ACMUI reports, added Chairperson and DFO responsibilities.

Respectfully submitted on October 4th, 2024,
Subcommittee on Review and Recommendations on ACMUI Bylaws
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)

Attachment- Track Changes

~~ACMUI~~

~~JULY 10, 2019~~

~~U.S.~~ UNITED STATES NUCLEAR REGULATORY COMMISSION

~~OFFICE~~ OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

BYLAWS

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Advisory Committee on Medical Uses of Isotopes

Revised October XXX 2024

DRAFT ONLY

CONTENTS

PREAMBLE

These ~~bylaws~~Bylaws describe (1) the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and (2) the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, the current edition of Robert's Rules of Order will be followed. Certain issues that come before the ACMUI may involve legal issues and may require input from the U.S. Nuclear Regulatory Commission's (NRC's) Office of General Counsel for their ultimate resolution.

These ~~bylaws~~Bylaws have as their purpose fulfillment of the ACMUI's responsibility to provide objective and independent advice to the Commission through the NRC staff in the Division of Materials Safety, Security, State, and Tribal Programs (MSST), Office of Nuclear Material Safety and Safeguards (NMSS), with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the ACMUI members and the affected parties have an adequate opportunity to express their opinions, and that the resulting reports represent, to the extent possible, the best of which the ACMUI is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

~~BYLAWS ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES~~

1. SCHEDULING ~~and Conduct of~~FULL COMMITTEE MEETINGS

The ~~scheduling and conduct of~~Scheduling of ACMUI Full Committee meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulations as appropriate.

~~1.1 Scheduling of Meetings:~~

1.1~~.1~~ ACMUI meetings must be approved or called by the Designated Federal Officer (DFO). At least two regular meetings of the ACMUI will be scheduled each year, one in the spring and one in the fall. Scheduling conflicts may sometimes require deviations from this schedule and such changes must be approved by majority of the members of the Committee. Additionally, the ACMUI will meet with the Commission annually, unless the ~~Chair~~Chairperson or designated ~~Chair~~Chairperson of the ACMUI declines or the Commission declines such a meeting.

~~1.~~1.2 ACMUI Full Committee meetings will be open to the public, except for meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes. Active participation in the meeting is normally defined to:

- ~~1.~~Members of the Committee.
- NMSS/ACMUI staff, as needed.
- ACMUI consultants, or others assisting the Committee, as needed.;
- NRC staff and its consultants and contractors, as needed.;
- Members of the public and other stakeholders in accordance with FACA, or as needed.

1.3 All ACMUI meetings, open or closed, will be transcribed. During portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted to the extent that it does not interfere with ACMUI business or with the rights of the attending public.

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~~1.~~1.4~~—~~ Portions of ACMUI meetings that are open to the public should be broadcast or otherwise electronically disseminated (e.g. webcast) whenever possible, with closed captioning in accordance with the Americans with Disabilities Act.

~~1.~~1.5 All available meeting handouts should be electronically transmitted to the ACMUI members no later than two weeks prior to the meeting.

~~1.~~1.6~~—~~ All publicly available meeting handouts should be posted on the ACMUI public website no later than three business days prior to the meeting.

~~1.2 Meeting Agenda:~~

1.7 The Chairperson, or in the Chairperson's absence the Vice Chairperson, shall preside over the meeting. The Chairperson can delegate the responsibility to preside over the meeting to another member.

1.8 A Designed Federal Officer (DFO) must be present at all Full Committee meetings.

2. FULL COMMITTEE MEETING AGENDA

2.1 The agenda for regularly scheduled ACMUI Full Committee meetings will be prepared by the ~~Chair~~NMSS staff ~~of the ACMUI (referred to below as "the Chair") in~~ in consultation with the ~~NMSS staff.~~Chairperson of the ACMUI. ~~-~~The DFO must approve the agenda.~~-~~ The ~~Chair~~Chairperson, with the NMSS staff's assistance, will query ACMUI members, NRC staff, the Commission or individual Commissioners for agenda items prior to agenda preparation. A draft agenda should be provided to ACMUI members no later than 30 days prior to a scheduled meeting. The final agenda should be provided to members no later than 7 days prior to a scheduled meeting.

Before the Full committee meeting, the ~~Chair~~Chairperson and the DFO will review the findings of the Office of the General Counsel regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict. Refer to Section 9 for complete information on Conflict of Interest.

2.2 Items that require Full Committee review and comments, and Commission requests will receive high priority on the agenda. To the extent feasible, all review items that require a Committee report should be scheduled early in the

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Full Committee meeting as to allow adequate time for the Subcommittee Chairperson or member to prepare and/or revise a proposed ACMUI report. Information items, and items of general interest, may be placed on the agenda subject to the availability of time.

2.3 Except in unusual and pressing circumstances, the Full Committee will not review matters brought by the NRC staff unless documentation adequate to support a responsible review is provided to the members in a timely fashion.

2.4 Issues may come to the attention of the Committee through a variety of mechanisms, including self-generation. Whatever the source, review may be through any appropriate mechanism, including but not limited to, placement on a meeting agenda, or referral to a subcommittee.

~~1.~~3~~.~~ CONDUCT OF THE MEETING~~:~~

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~~1.~~3.1 ~~All~~The scheduling and conduct of ACMUI Full Committee meetings will be ~~held~~ in ~~full compliance~~accordance with ~~the~~ FACA~~.~~, as amended, implementing NRC rules and regulations and other relevant Federal regulations. The Committee has a responsibility to make available to the public, consistent with the requirements of FACA and the Freedom of Information Act, the information on which its final decisions and reports are based. Full committee meetings may be held, at the direction of the Chairperson, using remote technology by which all persons participating can be identified and hear each other at the same time. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

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~~1.~~3.2 The ~~Chair~~Chairperson will preside over the meeting. The Vice ~~Chair~~Chairperson will preside if the ~~Chair~~Chairperson is absent or if the ~~Chair~~Chairperson is recused from participating in the discussion. The DFO will preside when both the ~~Chair~~Chairperson and the Vice ~~Chair~~Chairperson are absent and/or recused from the discussion or when directed to do so by the Commission.

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- ~~1.~~The meeting will be called to order by the Chairperson and state the date, time, type of meeting and the Committee. At this time, also confirm there is a quorum.
- Chairperson to ask Committee members if there are any conflicts of interest to disclose and remind members about the recusal policy.
- Review of previous summary.

3.3 A majority (greater than one half) of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI

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meeting. Due to the collaborative nature of the committee's business, it is ideal that members meet in person, however, under special circumstances the Chairperson may authorize remote participation through remote technology shall constitute presence for the purpose of establishing a quorum.

~~1.~~3.4 The ~~Chair~~Chairperson has both the authority and the responsibility to maintain order and decorum and may, at his or her option, recess the meeting, if these are threatened. The DFO will adjourn a meeting when adjournment is in the public interest.

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~~1.~~3.5 Decisions shall be made by a majority vote of the current ACMUI membership. Should one or more members be unavailable for compelling reasons (such as extended incapacity or recusal), the current membership shall be regarded as reduced accordingly.

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~~1.~~3.6 ~~———~~The ~~Chair~~Chairperson may take part in the discussion of any subject before the ACMUI and may vote. The ~~Chair~~Chairperson should not use the power of the Chair to bias or otherwise limit the discussion~~.~~ but should use that power to keep the meeting focused and approximately on schedule. If the Chairperson is a strong advocate of one side of a controversial item, the Vice Chairperson should preside over that part of the meeting. Any dispute over the ~~Chair's~~Chairperson's level of advocacy shall be resolved by a vote on the ~~Chair's~~Chairperson's continued participation in the discussion of the subject. In matters where the ACMUI ~~Chair's~~Chairperson's unique experience and knowledge would be especially informative, the ~~Chair~~Chairperson may serve on relevant subcommittees. The ~~Chair~~Chairperson will serve at the discretion of the subcommittee members. However, the ACMUI ~~Chair~~Chairperson will not chair the subcommittee.

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~~1.~~3.7 When a consensus appears to have developed on a matter under consideration, the ~~Chair~~Chairperson will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI ~~position~~recommendation will be final until it has been formally adopted by consensus or formal vote and the transcript written and certified.

3.8 In the absence of any provision in the Bylaws, all meetings of the ACMUI shall be governed by the parliamentary rules and usages contained in the current edition of Robert's Rule of Order.

~~24~~. TRANSCRIPTS/MEETING SUMMARY

~~24~~.1 Transcripts of each Full committee meeting will be prepared by the ~~ACMUI Chair with assistance from the NMSS staff in accordance with the requirements in 10 CFR Part 7.~~ Court Reporter and sent to the ACMUI Coordinator and then sent to the ACMUI Chairperson or in absence of Chairperson, Vice Chairperson for certification. The Commission staff will prepare transcripts of ACMUI meetings with the Commission.

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~~24~~.2 In accordance with 10 CFR section 7.13(c), the ACMUI ~~Chair~~Chairperson, or other individual who presided over the meeting in place of the ACMUI ~~Chair~~Chairperson, will certify the transcripts~~.~~ no later than 90 days after the meeting, subject to receiving the working copy meeting summary within 30 working days after the meeting. By certifying the meeting summary, the Chairperson attests to the best of his or her knowledge to the completeness and technical accuracy of the meeting summary.

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~~24~~.3 Copies of the certified transcripts will be made available to the ACMUI members and to the public no later than 90 days after the meeting.

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~~2.4 NMSS staff will prepare a meeting summary, which will be made available to ACMUI members and to the public no later than 30 business days after the meeting.~~

5. ACMUI SUBCOMMITTEES

5.1 The Committee is organized around a number of topical subcommittees whose purpose is to obtain, analyze, and organize information for the consideration of the Full Committee. Initiation of a subcommittee may be requested by either NRC staff or ACMUI members. A subcommittee may also recommend a particular course of action to the Full Committee.

5.2 Changes to subcommittee membership and tasks are the responsibility of the ACMUI Chairperson. The ACMUI Chairperson should take into consideration member expertise/professional or personal qualifications, current subcommittee assignments, any possible conflict of interests, and relevant lived experience in determining subcommittee members. If ACMUI member has been assigned to be on a subcommittee and they do not feel they have the expertise, the member should discuss with the ACMUI Chairperson as soon as possible.

5.3 Subcommittee meetings are exempt from being public; however, subcommittee meetings will be conducted in accordance with FACA requirements whenever possible.

5.4 Any two members of the Subcommittee will constitute a quorum for any subcommittee meeting. No single member shall function as a subcommittee, although individual members may often collect information on behalf of either a subcommittee or the Full Committee.

5.5 The Subcommittee Chairperson has both the authority and the responsibility to maintain order and decorum and may recess the meeting until a later time if these are threatened. The Chairperson may also request the ejection of any person who ignores warnings and continues to address subjects not under discussion by the Subcommittee, or who otherwise interferes with the orderly conduct of the Subcommittee business.

5.6 Subcommittee meetings may be held, at the direction of the Subcommittee Chairperson, using remote technology by which all persons participating in the meeting can be identified and hear each other at the same time.

5.7 When Subcommittee has deliverables, those deliverables should be sent to the NRC staff before vote and approval by the Full Committee.

5.8 At the conclusion of the Subcommittee meetings, the Subcommittee Chairperson, with input from members present, will prepare a report and presentation for full committee consideration, as applicable.

5.9 A Designed Federal Officer (DFO) must be present at all Subcommittee meetings.

~~3~~6. APPOINTMENT OF MEMBERS

~~3~~6.1 ACMUI members are appointed by the Director, NMSS, after consultation with the Commission. The Commission determines the size of the ACMUI. The NRC will solicit nominations by notice in the *Federal Register* and by such other means, as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Director, NMSS. The committee membership should be fairly balanced to include those with relevant lived experience, and persons with demonstrated professional or personal qualifications. The term of an appointment to the ACMUI is 4 years, and the Commission has determined that no member may serve more than two consecutive terms (8 consecutive years), unless directed otherwise by the Commission.

~~3~~6.2 Reappoint of Members

In accordance with the September 26, 1996, Staff Requirements Memorandum, COMSECY-96-042, "Procedures for Reappointment of Advisory Committee Members," states that staff should consider a member's contribution to the committee before recommending reappointment. Staff may consider the member's participation on subcommittees and input provided during regular public meetings. The ~~Chair~~NRC staff may also use the ACMUI evaluation report to assist in making this determination.

7. APPOINTMENT OF OFFICERS

7.1 The Chairperson will be appointed by the Director, NMSS, with input from the MSST Director, MSEB Chief, and ACMUI Coordinator from the membership of the ACMUI~~. The Chair~~ except the FDA representative. The Chairperson will serve at the discretion of the Director, NMSS.

~~3.3~~7.2 The Vice ~~Chair~~Chairperson will be appointed by the Director, NMSS, with input from the MSST Director, MSEB Chief, and ACMUI Coordinator from the membership of the ACMUI~~.~~ except the FDA representative. The Vice ~~Chair~~Chairperson will serve at the discretion of the Director, NMSS.

~~4~~8. CONDUCT OF MEMBERS

~~4.1 All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest, as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest, unless they receive a waiver or prior authorization from the appropriate NRC official.~~

~~4.2~~8.1 The Advisory Committee on the Medical Use of Isotopes (ACMUI) functions to advise the Nuclear Regulatory Commission (NRC) on the medical use isotopic materials. The ACMUI is composed of members with a wide variety of radiation backgrounds and differing expertise. The committee examines medical issues of importance to the NRC and formulates an agreed upon ACMUI opinion. For this

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reason, it is inappropriate for an individual member to attempt to interpret ACMUI reports, recommendations, or actions, except as authorized by the ACMUI.

Individual members are always free, as individuals, to interact and communicate with the Director, Division of Materials Safety, Security, State and Tribal Programs. This channel will normally, but not always, be opened by the Director, Division of Materials Safety, Security, State and Tribal Programs and it should always be clear that the member is not representing the ACMUI but is functioning as an independent expert. Substantive contacts should be noted to the Chairperson of the ACMUI.

It is inappropriate for a member to use the latitude provided in the previous paragraph to undermine a declared ACMUI position.

8.2 Requests from outside parties should normally be honored by referral to the Director, Division of Materials Safety, Security, State and Tribal Programs. If an individual member is asked for an opinion, the member should respond, but with emphasis on the fact that individual members do not speak for the ACMUI. Potential requests from the media require more circumspection. The guiding principle is that a member should not undermine or reinterpret an ACMUI position but is under no obligation to profess agreement with the ACMUI majority.

8.3 ACMUI members performing contractual work for organizations other than the NRC shall not use the information developed by or for the NRC that is not in the public domain. Members should seek clarification when unsure about the information.

8.4 ACMUI members should submit their hours of work, as they relate to official ACMUI business, on the Thursday prior to the close of the pay period, unless noted otherwise. The hours shall be transmitted via the appropriate reporting method established by the DFO.

~~4.3~~8.5 For meetings requiring travel, ACMUI members should submit travel authorizations by the travel reporting procedure as directed by NMSS staff. ACMUI members should submit vouchers for reimbursement by the travel procedure as directed by NMSS staff no later than 5 business days after the meeting.

~~4.4 Upon completing their tenure on the~~ 8.6 ACMUI~~,~~ members ~~will return any privileged documents and accountable equipment ((~~who are appointed as ~~so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.~~

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~~4.5. ACMUI members should to~~ Special Government Employees) are expected to conform to all Federal regulations applicable thereto, as well as to the relevant NRC rules and regulations and are expected to attend meetings ~~regularly~~ and perform all assigned duties.

8.7 Members are expected to meet the highest professional standards of competence, integrity, objectivity, and collegial respect in upholding the reputation of the Committee.

9. CONFLICT OF INTEREST

9.1 All members of the ACMUI are required to comply with Federal ethics and conflict of interest laws, including but not limited to Title 5 of the Code of Federal Regulations (5 CFR), Part 2635, Standards of Ethical Conduct for Employees of the Executive Branch. All ACMUI members receive annual training on these requirements.

If a member believes that he or she may have a conflict of interest, as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed at an ACMUI full committee or Subcommittee meeting, this member should divulge it in advance to the Chairperson and the DFO, by oral, written, or electronic notification as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest unless they receive a written waiver or prior authorization from the appropriate NRC official.

It should be noted that prior work on a subject under review, even when undertaken for another agency or organization, does not represent a conflict of interest per se, but should be revealed to the Committee, on the record. The degree to which this earlier work compromises the member's impartiality will be determined by the Committee on a case-by-case basis. On the rare occasions in which the Committee's proposed action implies a judgment of the quality of that earlier work, it is a matter of professional ethics that the member does not vote.

If a member is uncertain if there is a potential conflict of interest with the subject of discussion, the member should discuss the issue of concern with the DFO and the Chairperson prior to discussing the topic and not use personal judgement.

9.2 When a member has a potential conflict on matters being considered by the ACMUI committee or subcommittee, the following procedure should be followed during the discussion of such matters at the Subcommittee or Full Committee

meetings and during the preparation of the ACMUI reports. These procedures are designed to ensure conflict of interest requirements are understood and followed, and to provide guidance for dealing with conflict-of-interest situations consistently by all members. The principles being implemented are that:

9.2-1 Members cannot participate in the Committee's review of their own work.

9.2-2 Members cannot personally and substantially participate in the review of any particular matter (including general matters such as rulemaking) that could directly and predictably affect their personal financial interests or financial interests of

- their spouse or minor child,
- their general partner or organization in which they serve as an officer, director, trustee, general partner, or employee,
- an organization with which they are negotiating or have an arrangement for prospective appointment

9.2-3 Members cannot personally and substantially participate in the review of any particular matter involving parties, such as license guidance that could directly and predictably affect the financial interests of the following:

- members of their household,
- anyone with whom they have a financial relationship, or
- relatives with whom they have a close personal relationship; or
- anyone that served during the previous year as an employee, officer, director, trustee, general partner, agent, consultant, contractor or attorney.

9.34 Based on the specific facts, the ACMUI Chairperson can grant a member a written waiver from these restrictions after consulting with the appropriate NRC official, Office of the General Counsel or the Ethics Department of the NRC.

9.45 ACMUI Meetings

During presentation or discussions at the Subcommittee or Full Committee meetings, the member who has a conflict with the particular matter being considered:

- Can ask questions to obtain clarifications or factual information.
- Can provide information to correct misinterpretations of facts by other members, or technical insights which may help the members better understand the issues under consideration.

- Should not engage in discussions which may be perceived by a reasonable person to be a criticism or endorsement of the appropriateness of the scope, direction, or quality of the work, or the adequacy of the methods or processes used to perform the work on the matter in which the member has a conflict of interest.

9.5~~6~~ Preparation of ACMUI Reports

The report preparation part of the ACMUI meetings is the most significant part of the meetings where both actual and perceived conflicts of interest should be avoided. Government ethics rules and procedures must be observed to protect the integrity of the committee process, in addition to avoiding violation of ethics regulations. The Committee process should not be perceived as being "biased" as a result of a member's organizational affiliation or contractual arrangements.

During preparation of ACMUI reports, the member who has conflict with the particular matter being considered:

9.5-1 Should not participate in the Committee's deliberations other than providing clarifications, technical insights, or factual information to other members.

9.5-2 Should not express opinions that would influence the Committee's position on the matter.

9.5-3 Should not provide input to the Committee report that relates to the matter.

9.5-4 Should not try to influence the Committee directly or indirectly or suggest changes to the reports that reflect the member's views on the matter.

9.5-5 Should not make, participate, or vote on the "motions" to make changes to the reports on the matter.

9.5-6 Should not participate in the voting process for approving the report.

9.~~7~~6 When the ACMUI is preparing a report that involves matters for which a member has a conflict of interest, these matters may be intertwined with all of the subjects being discussed. The member will then not be able to participate in any of the discussions related to the report. However, in some instances it may be possible for the member to participate in some of the discussions. Guidance will be given to members on a case-by-case basis.

The other members should be informed/cognizant of a particular member's conflict and should not ask the member to provide views on matters for which the member has conflict.

9.~~8~~7 During Subcommittee or Full Committee meetings, the respective Chairperson is responsible for ensuring that the above procedures are implemented properly. The Designated Federal Officer (DFO) for these meetings should remind the Chairperson if these procedures are not complied with properly. If the DFOs believes that their reminders were ignored, they should promptly inform NRC management.

10. CONSULTANTS

10.1 The ACMUI may augment its expertise with disciplines not currently on the ACMUI.

10.2 Consultants to the ACMUI are temporary appointments that may not exceed one year. The service year is from October 1 to September 30. All consultants must be reappointed at the beginning of each service year. Reappointment of a consultant is based on the contributions made by the consultant to the ACMUI activities and its continued needs.

11. ACMUI REPORTS

11.1 ACMUI reports shall be solely the product of the Committee members.

11.2 Unless matters coming under FACA exemptions are involved, Committee reports will be deliberated and concluded in public session.

11.3 Preparation of proposed ACMUI reports should be a function of the applicable subcommittee. The Subcommittee Chairperson or member should, if possible, distribute the proposed report and incorporate or note comments for deliberation by the Full Committee.

Proposed reports do not represent a Committee position. Their distribution shall be to ACMUI members, ACMUI consultants, and the ACMUI staff prior to their consideration by the Full Committee in public session. At the request of the Subcommittee Chairperson, ACMUI staff shall request the NRC staff and/or applicant/licensee to perform a proprietary review of draft reports. This review is strictly to identify potentially proprietary or sensitive information and not

intended to seek feedback or input on the substance of the draft report from the NRC staff or applicant/licensee.

11.4 Once a report is approved final by the Committee, it shall be issued as expeditiously as possible, after the following actions:

- The NRC staff shall review the report for technical accuracy, grammatical correctness, clarity, and propose changes, as appropriate, without altering the intent of the Committee. The author(s) and the Committee Chairperson will review the appropriateness of the changes proposed by the NRC staff and approve or disapprove them, as warranted. In the event of a disagreement between the author(s) and the NRC staff on a particular change, the Committee Chairperson's ruling will prevail.

- The author(s) should also review the report for clarity and grammatical correctness but should not make changes that alter the intent of the Committee. If the author(s) has/have doubts regarding a proposed change, the Committee Chairperson should be consulted before making the change.

- If, in the judgment of any member, a report contains a serious misstatement or factual error, and that possible error was not addressed by the Committee before final approval, the member can propose that the Chairperson recommend deferral of the matter until the next meeting. The Chairperson can also recommend deferral of a report if there are concerns that it contains ambiguity regarding an ACMUI position and needs clarification. The NRC staff will then conduct a poll of as many as possible of the members who participated in the preparation of the report, explaining the issue as fairly as they can. If a majority of those participants agree, the report shall be so deferred.

- In cases of time urgency, a rewording may be accomplished through collegial interaction, for example, through virtual platforms.

11.5 The final report should note any Committee member recused from participation in a matter.

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~~5~~12. ADOPTION AND AMENDMENTS

~~5~~

12.1 ~~Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director, NMSS.~~

~~5.2~~ Any member of the ACMUI or ~~NMSS~~NRC staff may propose an amendment to these bylaws. The proposed amendment will be sent to the ACMUI Chairperson. The ACMUI Chairperson will forward the prosed amendment to the Director, Division of Materials Safety, Security, State and Tribal Programs or designee for review and comment. The proposed amendment will be distributed to the members and scheduled for discussion at the next regular full ACMUI meeting.

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~~5.3~~12.2 The proposed amendment(s) may be voted on as early as the next ACMUI meeting after distribution to the members.

~~5.4~~12.3 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

12.4 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director, NMSS.

ABBREVIATIONS AND ACRONYMS

ACMUI	Advisory Committee on the Medical Uses of Isotopes
DFO	Designated Federal Officer
FACA	Federal Advisory Committee Act
MSST	Division of Materials Safety, Security, State, and Tribal Programs
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission

SUBJECT: ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES BYLAWS.

DATED ~~JULY~~ NOVEMER ~~10~~XX, 202~~419~~

ML24XXXXXXX

OFC	MSST/MSEB	ACMUI	OGC	NMSS/MSST	NMSS
NAME	CFlannery	ACMUI Membership		KWilliams	JLubinski
DATE					

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Protecting People and the Environment

Follow-up to Recommendations from the ACMUI Subcommittee on Y-90 Medical Events

Sarah Spence, MS, CHP
Health Physicist, NRC

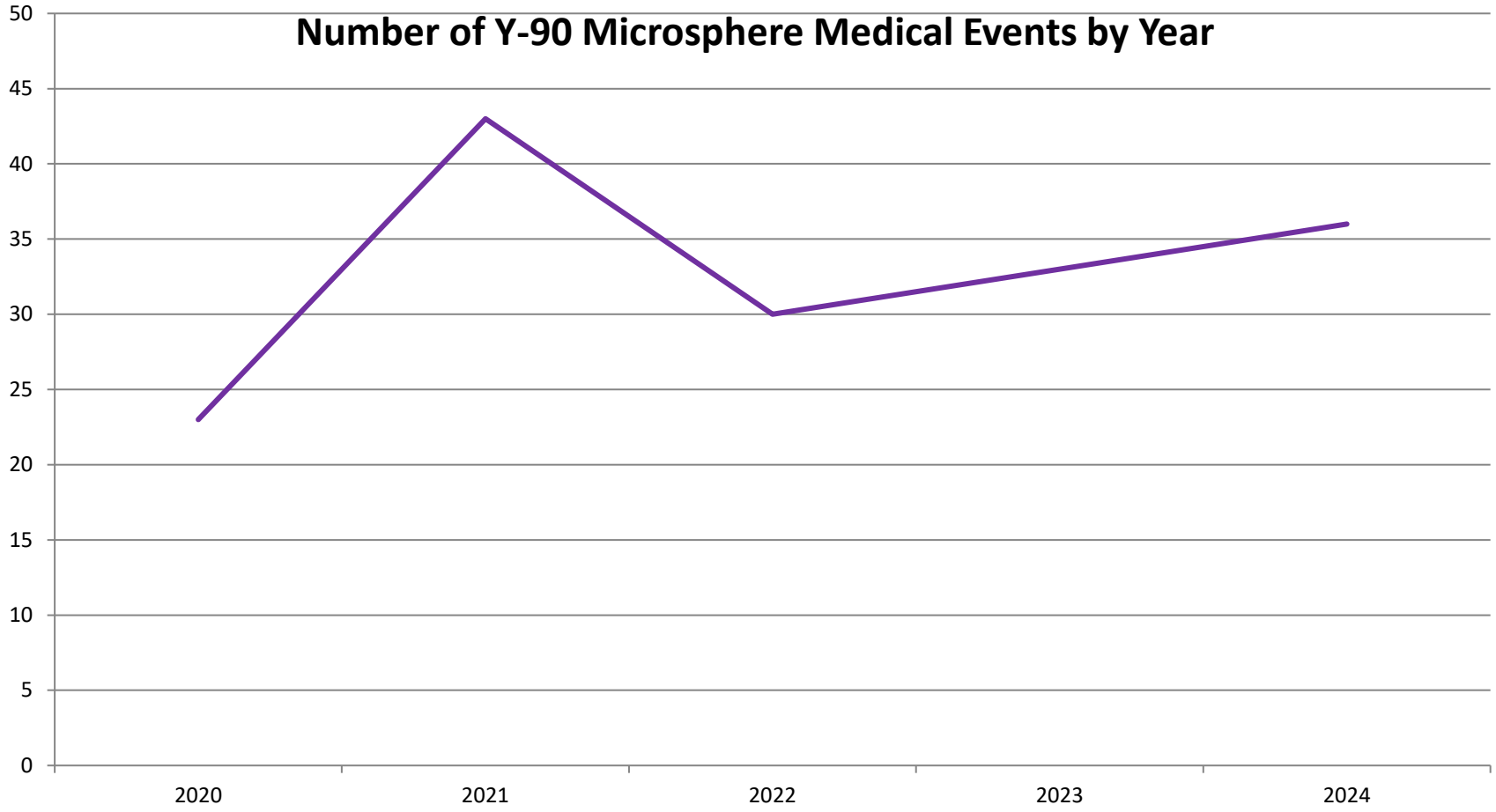
Agenda

- Y-90 Medical Event Subcommittee Recommendations
- Two-year event review
- Events Involving Vendor Tools
- Events of Note
- Conclusions

ACMUI Recommendations

- The NRC should evaluate the utility of the software programs and checklists provided by the microsphere vendors.
- The NRC should issue information notices to alert licensees of MEs and, where possible, make recommendations and suggest measures licensees can take to prevent similar events in the future.

Event Review



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Event Review

- NRC staff reviewed all Y-90 microsphere medical events from FY2023 and FY2024.

- Statistics at a glance:
  - Total events:
    - FY2023: 33
    - FY2024: 36
  - Events of Interest:
    - Vendor Tools: 0*
    - GI Shunting: 4

*See next slide for further discussion

- Types of Events:
  - Underdose:
    - FY2023: 26
    - FY2024: 29
  - Overdose:
    - FY2023: 1
    - FY2024: 2
  - Wrong Treatment Site:
    - FY2023: 6
    - FY2024: 5 (including GI shunting)

Events Involving Vendor Tools

- No events reported in FY2023 and FY2024 indicated that problems with vendor tools played a role in the cause of the event.
- Three events involved improper use of written directives; however human error was listed as the root cause of the medical event.
  - One event was due to a typographical error regarding treatment site.
  - One event was due to inconsistent use of units and a licensee-produced written directive spreadsheet.
  - One event resulted from administrative errors in ordering, followed by a failure to verify the activity prior to administration.

Abnormal Shunting Events

- In 2024, NRC staff noted an increase in reporting of shunting to the GI system.
- Four events reported between May and September, indicating the presence of microspheres in the stomach, intestine, and bowel as the reason for reporting.
- NRC staff is currently investigating these events with the assistance of Regional and Agreement State counterparts.

Abnormal Shunting Events (cont'd)

- Should these events be reported?
- Current regulations and guidance do not require reporting of Y-90 microsphere shunting as medical events if:
  - The licensee is using Revision 8 (February 2016) or newer of the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, or any revision of the Eye90 microspheres® Licensing Guidance.
  - Evaluation for shunting was performed as per manufacturer's recommendations. For example:
    - Pre-treatment Tc-99m MAA mapping was performed.
    - Angiography performed during catheter placement.
- NRC staff is still assessing whether these events met this exclusion criteria.

Conclusion

- There is no indication that vendor tools are contributing to the prevalence of Y-90 microsphere medical events.
- The NRC did not identify a new trend to issue new generic communications at this time.
- However, NRC staff is investigating an uptick in reporting of GI shunting of Y-90 microspheres to determine if generic communication is warranted.

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- FY – Fiscal year
- GI – Gastro-intestinal
- MAA – Macro-aggregated albumin
- ME – Medical Events
- NRC – Nuclear Regulatory Commission
- Tc-99m – Technetium-99m
- Y-90 – Yttrium-90

Questions?

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Protecting People and the Environment

NRC's Implementation of the ADVANCE Act

Mike King
Special Assistant for ADVANCE Act Implementation

November 4, 2024

The Core Team

Mike King
Special Assistant

Jessica Bielecki
Assistant General Counsel

John Lubinski
Director, NMSS

Owen Barwell
Chief Financial Officer

Jack Giessner
Administrator, Region 3

The Support Team

Shilp Vasavada
Project Management

Luis Betancourt
Project Management

Aaron McCraw
Communications

The Landscape Has Changed

Global decarbonization goals

Growing energy demands

Improved public perception

Unprecedented Bipartisan Support

House Vote
393-13

Senate Vote
88-2

Overview of the Act

- Update mission statement
- Enhance initiatives to achieve efficient, timely, and predictable license application reviews
- Establish an expedited procedure for reviewing qualifying new reactor license applications
- Implement changes to how the agency recovers fees from licensees, including establishing a lower hourly rate for advanced reactor applicants and pre-applicants

Overview of the Act

- Develop a regulatory framework for fusion technology
- Assess the licensing review process for new nuclear facilities at former fossil-fuel power plant sites and brownfield sites
- Develop strategies and guidance for microreactors
- Remove certain limitations on foreign ownership of some types of licensed facilities

Overview of the Act

Continue to support international coordination on nuclear technologies and licensing activities

Implement new requirements relating to nuclear fuel

Establish a nuclear energy traineeship subprogram to meet critical mission and nuclear workforce needs

Implement additional pay and hiring authorities

By the Numbers

16 Number of actions with Congressional deliverables to respond to the ADVANCE Act

19 Number of actions derived from the Act without Congressional deliverables

20 Number of interoffice project teams formed to address actions

Advance Act Project Key Milestones

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SECTION	PROJECT/POC	FY2024 Q4	FY2025 Q1	FY2025 Q2	FY2025 Q3	FY2025 Q4	FY2026 Q1	FY2026 Q2	FY2026 Q3	FY2026 Q4	FY2027 Q1	FY2027 Q2	FY2027 Q3	FY2027 Q4
101. International nuclear export and innovation activities.	**International Nuclear Export and Innovation** Jennifer Holzman, OIP			Feb 2025										
103. Export license notification.	**International Nuclear Export and Innovation** Jennifer Holzman, OIP			Feb 2025										
201./204. Fees for advanced nuclear reactor application review.	**Reduced Hourly Rate and Exclusion of Additional Activities** Anthony Rossi, OCFO		Dec 2024							Oct 2025**				
203. Licensing considerations relating to use of nuclear energy for nonelectric applications.	**Non-Electric Uses of Nuclear Energy** William Reckley, NRR		Dec 2024		Mar 2025	Apr 2025								
205. Fusion energy regulation.	**Fusion Licensing Framework Report** Kevin Williams, NMSS		Oct 2024	Jan 2025	Feb 2025	Jun 2025				Jul 2025				
206. Regulatory issues for nuclear facilities at brownfield sites.	**Brownfield Site Facilities** Assess potential regulatory modifications Submit report on modifications Develop/implement strategies Submit report on Implementation Sarah Lopas, NMSS		Nov 2024			Jul 2025				Aug 2025		Sept 2025		
									Jul 2026					Jun 2027 Jul 2027

Public Meeting*
Due to Commission*
Internal Deliverable*
Due to Congress

* Dates subject to change

** Effective date of revised fee rule, if approved

Advance Act Project Key Milestones

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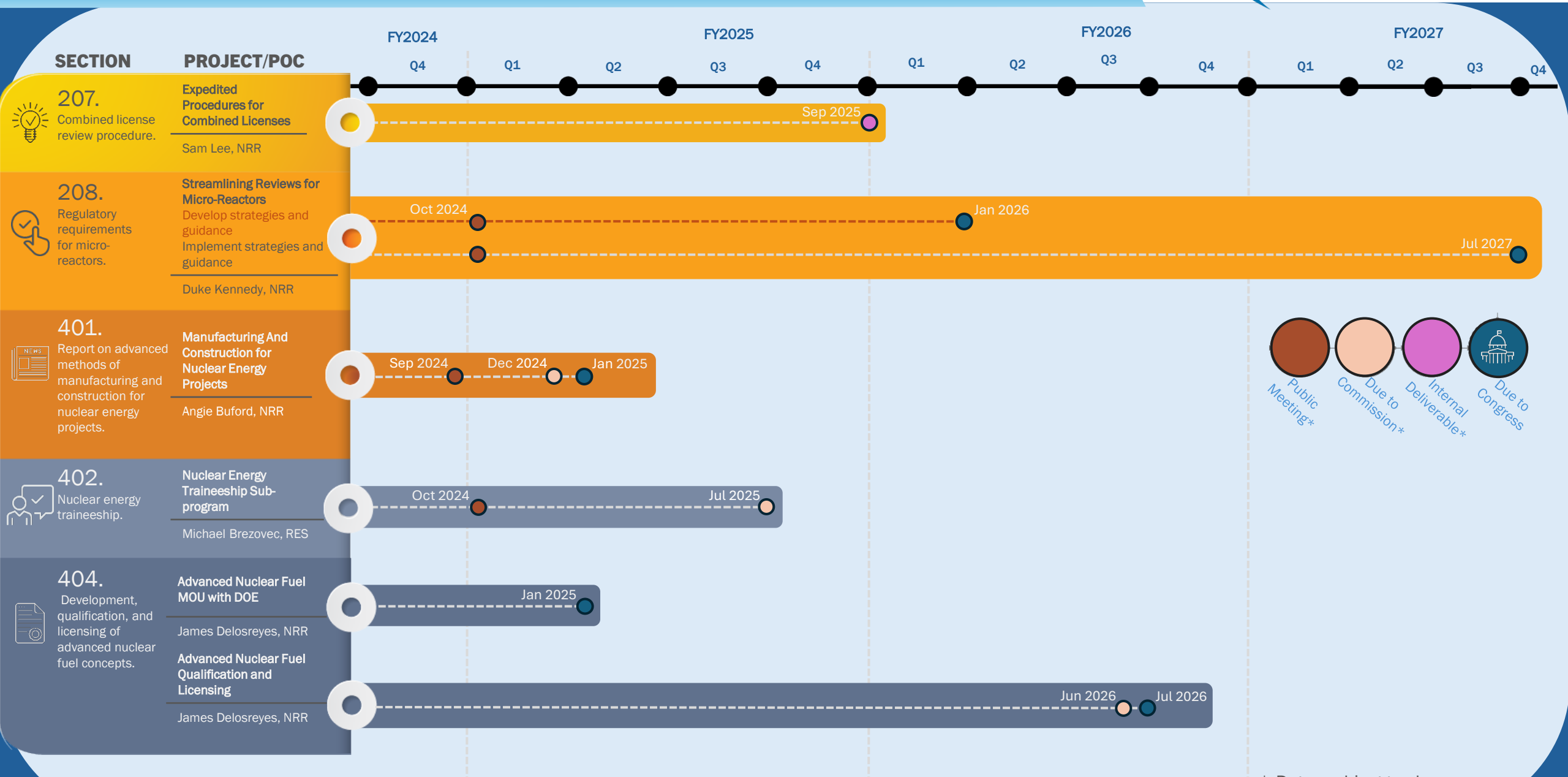

* Dates subject to change

Advance Act Project Key Milestones

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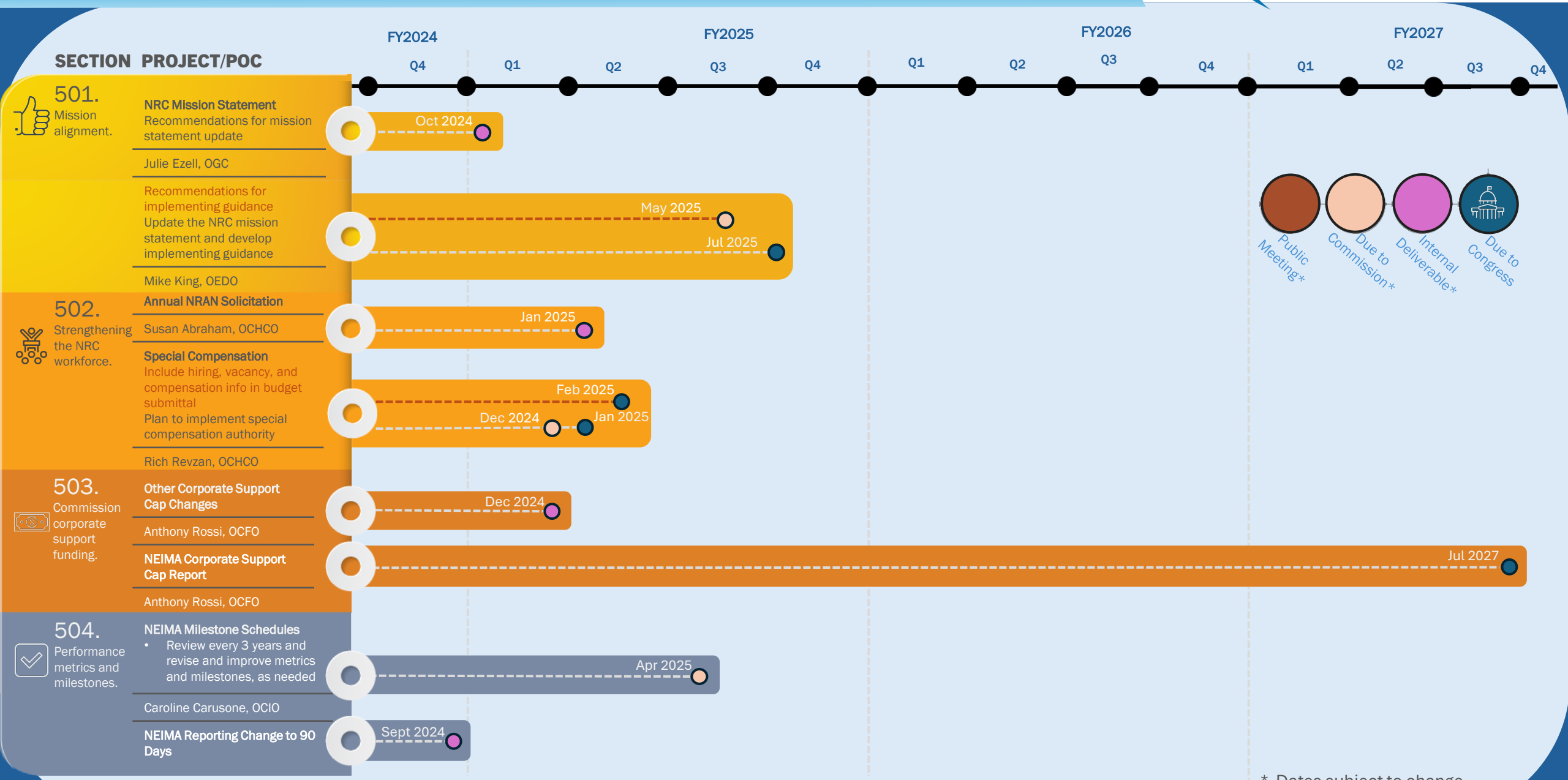

* Dates subject to change

Advance Act Project Key Milestones

#ADVANCENRC

SECTION	PROJECT/POC	FY2024 Q4	FY2025 Q1	FY2025 Q2	FY2025 Q3	FY2025 Q4	FY2026 Q1	FY2026 Q2	FY2026 Q3	FY2026 Q4	FY2027 Q1	FY2027 Q2	FY2027 Q3	FY2027 Q4
505. Nuclear licensing efficiency.	**Techniques and Guidance for Nuclear Reactor License Application Reviews** Jamie Pelton, NRR					July 2025								
506. Modernization of nuclear reactor environmental reviews.	**Nuclear Reactor Environmental Reviews** Ted Smith, NMSS			Sep 2024	Dec 2024	Jan 2025								
507. Improving oversight and inspection programs.	**Oversight and Inspection Programs** Phil McKenna, NRR Jane Marshall, NMSS								Jun 2025	Jul 2025				
601. Technical correction.	**NPUF Criteria** Revised rulemaking plan for Non-Power and Utilization Facilities (NPUF) Withdrawal of Rulemaking Plan for Non-Power and Utilization Facilities Holly Cruz, NRR			Oct 2024					Mar 2025					
602. Report on engagement with the Government of Canada with respect to nuclear waste issues in the Great Lakes Basin.	**Great Lakes Basin Nuclear Waste Issues** Shawn Smith, NMSS								Jun 2025	Jul 2025				

Public Meeting*
Due to Commission*
Internal Deliverable*
Due to Congress

* Dates subject to change

Contact Us

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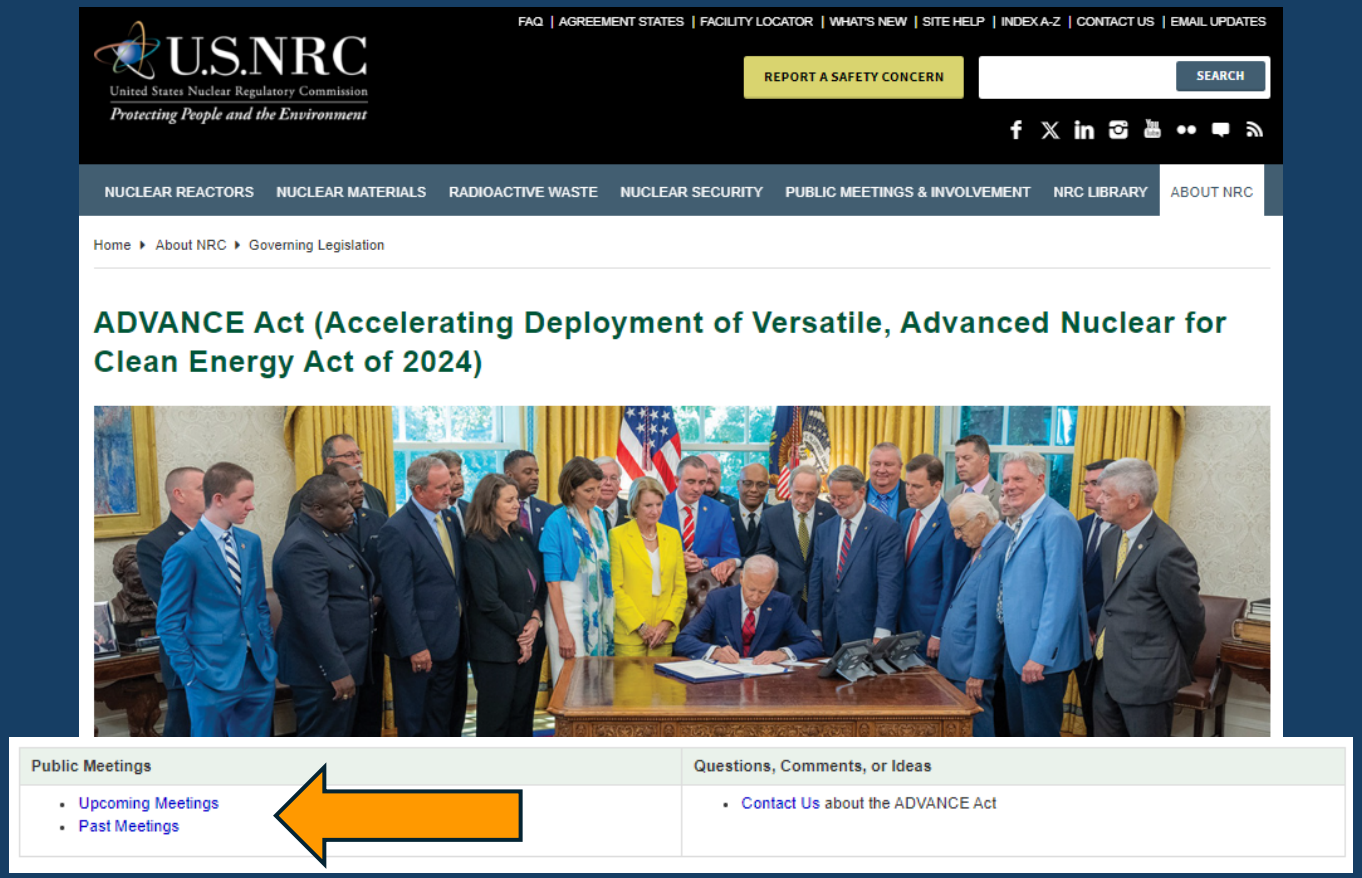
Luis Betancourt	Support Team	Luis.Betancourt@nrc.gov
Shilp Vasavada	Support Team	Shilp.Vasavada@nrc.gov

Section	Project	Lead	Email Address
101/103	International Nuclear Export and Innovation	Jennifer Holzman, OIP	Jennifer.Holzman@nrc.gov
201/204	Reduced Hourly Rate and Exclusion of Additional Activities	Anthony Rossi, OCFO	Anthony.Rossi@nrc.gov
203	Non-Electric Uses of Nuclear Energy	William Reckley, NRR	William.Reckley@nrc.gov
205	Fusion Licensing Framework Report	Kevin Williams, NMSS	Kevin.Williams@nrc.gov
206	Brownfield Site Facilities	Sarah Lopas, NMSS	Sarah.Lopas@nrc.gov
207	Expedited Procedures for Combined Licenses	Samuel Lee, NRR	Samuel.Lee@nrc.gov
208	Streamlining Reviews for Micro-Reactors	Duke Kennedy, NRR	William.Kennedy@nrc.gov
401	Manufacturing And Construction for Nuclear Energy Projects	Angie Buford, NRR	Angela.Buford@nrc.gov
402	Nuclear Energy Traineeship Sub-program	Michael Brezovec, RES	Michael.Brezovec@nrc.gov
404	Advanced Nuclear Fuel	James Delosreyes, NRR	James.Delosreyes@nrc.gov
501	Mission Statement Update	Julie Ezell, OGC	Julie.Ezell@nrc.gov
502	Annual NRAN Solicitation	Susan Abraham, OCHCO	Susan.Abraham@nrc.gov
502	Special Hiring and Compensation Authority	Rich Revzan, OCHCO	Richard.Revzan@nrc.gov
503	Corporate Support Funding	Anthony Rossi, OCFO	Anthony.Rossi@nrc.gov
504	Performance Metrics and Milestones	Caroline Carusone, OCIO	Caroline.Carusone@nrc.gov
505	Nuclear Licensing Efficiencies	Jamie Pelton, NRR	Jamie.Heisserer@nrc.gov
506	Environmental Reviews	Ted Smith, NMSS	Theodore.Smith@nrc.gov
507	Oversight and Inspection Programs	Phil McKenna, NRR Jane Marshall, NMSS	Philip.McKenna@nrc.gov Jane.Marshall@nrc.gov
601	NPUF Rulemaking	Holly Cruz, NRR	Holly.Cruz@nrc.gov
602	Great Lakes Basin Coordination	Shawn Smith, NMSS	Shawn.Smith@nrc.gov

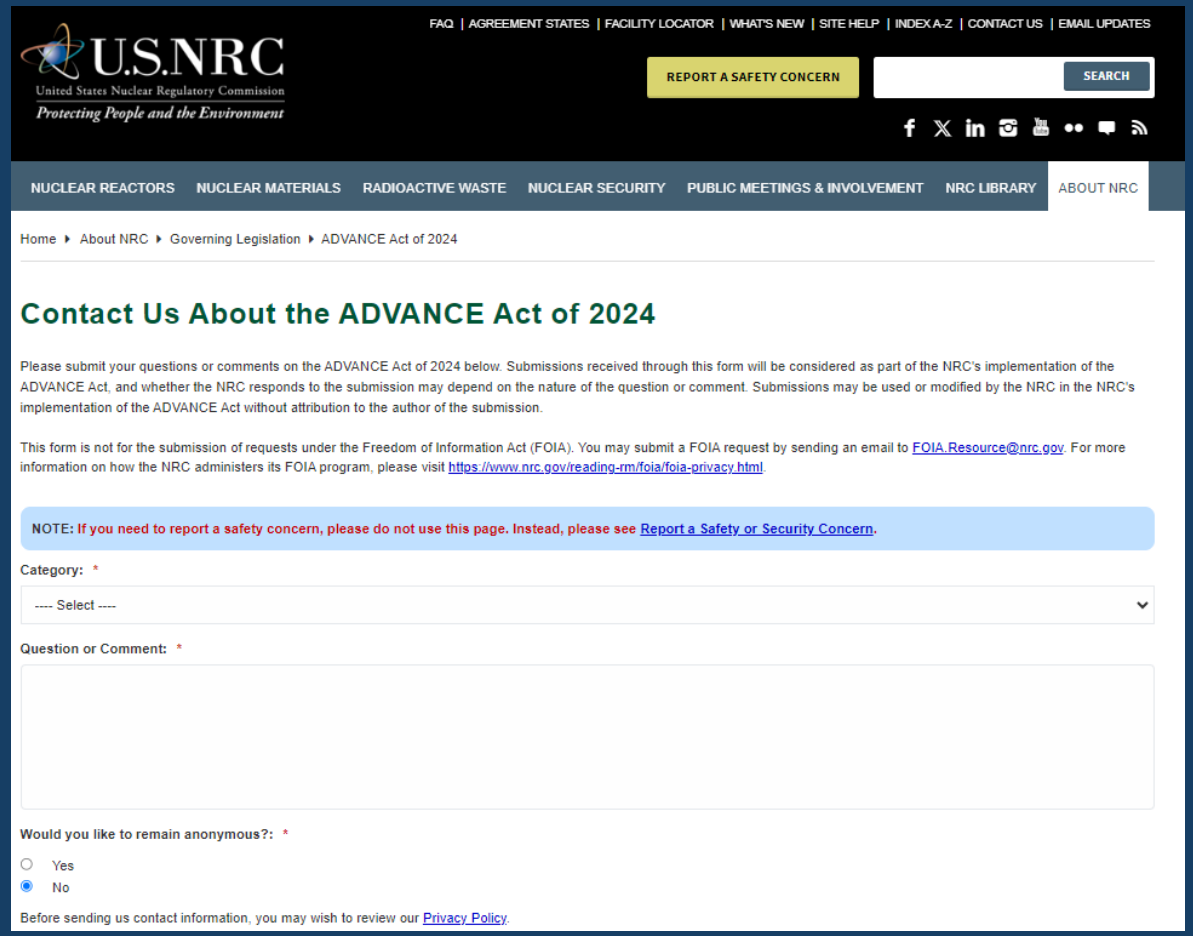
To Stay Updated

For NRC's public information site for ADVANCE Act updates



For Your Questions and Ideas

Contact us with ADVANCE Act questions, comments and ideas



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U.S.NRC
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Protecting People and the Environment

NRC MEDICAL TEAM UPDATES

Katie Tapp, PhD
Medical Team Leader
November 4, 2024

Outline

01 RULEMAKING

02 GUIDANCE

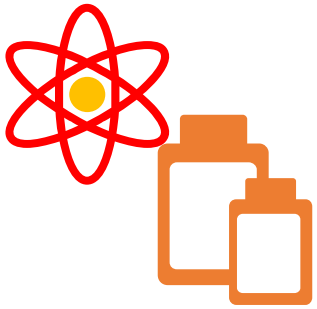
03 OTHER EFFORTS

MEDICAL RULEMAKINGS

Medical Rulemakings

EXTRAVASATIONS

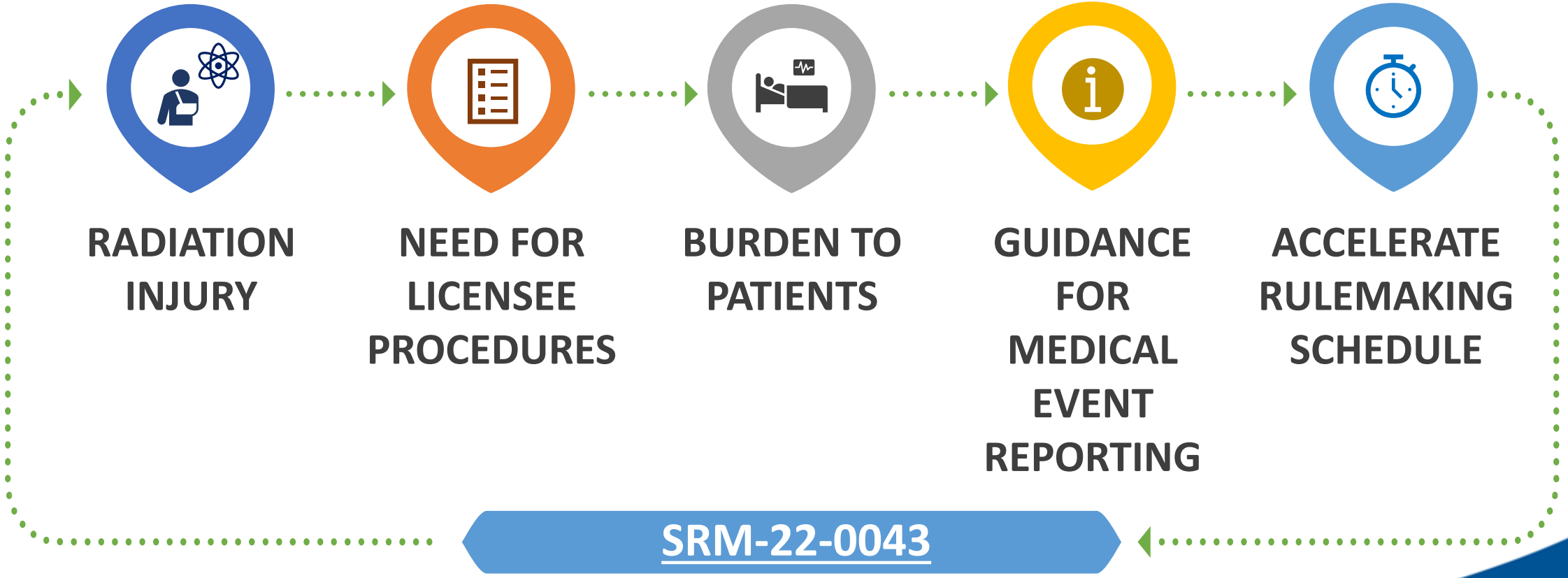
Ongoing rulemaking to amend 10 CFR Part 35 to require reporting of certain nuclear medicine extravasations.



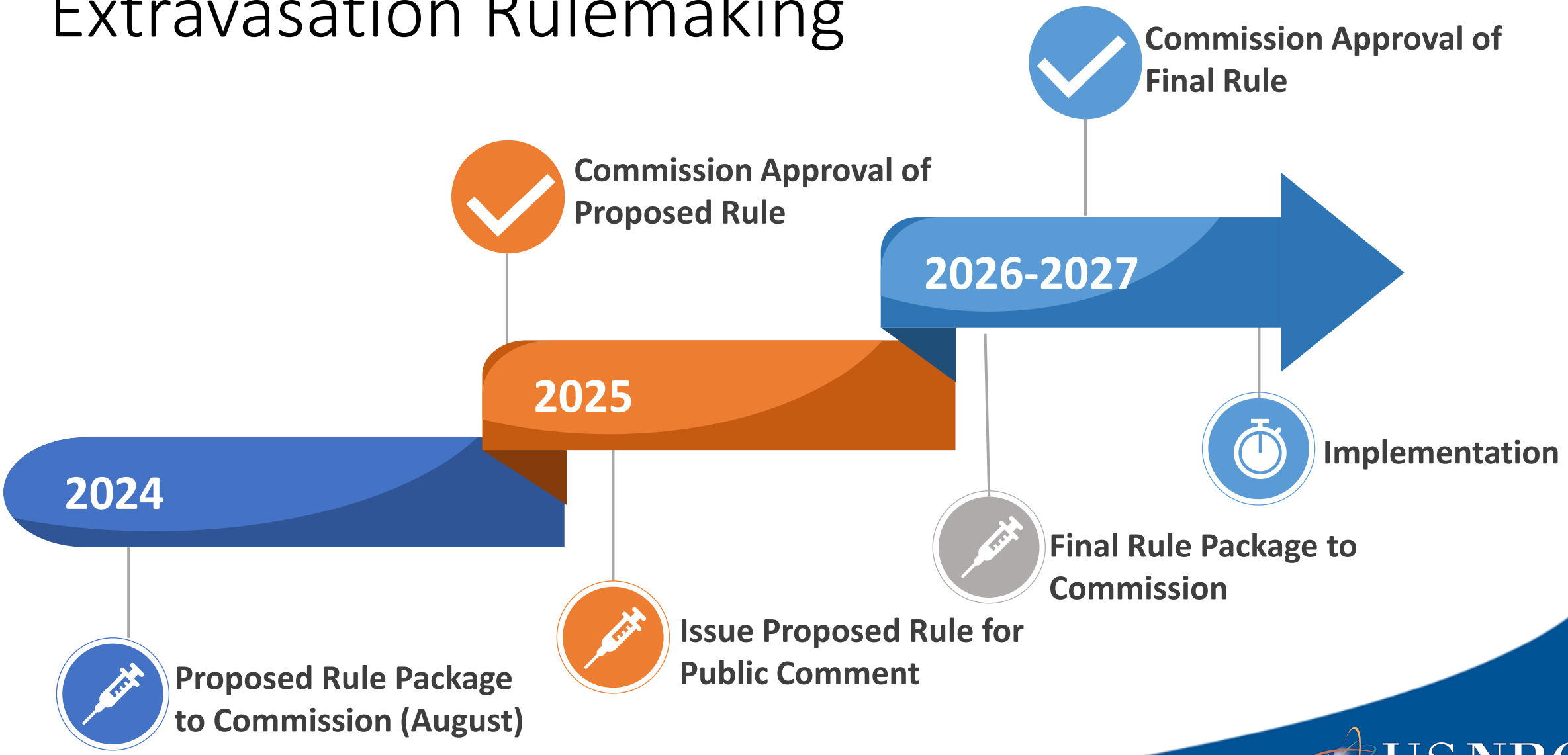
EMT/RB-82 GENERATORS

Ongoing rulemaking to establish requirements for Rb-82 generators and well-established EMTs currently regulated under 10 CFR 35.1000 and establish flexibility for future EMTs.

Extravasations Rulemaking



Extravasation Rulemaking



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EMT/Rb-82 Generator Rulemaking

RB-82 GENERATORS

Address challenges with Rb-82 generators that have been historically addressed through enforcement discretion

WELL-ESTABLISHED EMTS

Address requirements for microspheres, GSRs, intravascular brachytherapy, eye applicators, and other NRC-evaluated EMTs

FUTURE EMTS

Consider updating regulations to accommodate future new uses of byproduct material or radiation from byproduct material in medicine

TRAINING AND EXPERIENCE

Re-evaluate T&E requirements for EMTs and propose potential changes

OTHER CHANGES

Supervision, Radiation Safety Committees, Multi-dose protocols

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EMT/Rb-82 Generator Rulemaking Timeline

July 2023

Issued regulatory basis for public comment

August 2023

Held public meeting to facilitate comments on the reg basis

Winter 2026

Issue proposed rule and draft implementation guidance to Commission

Winter 2027

Issue final rule and implementation guidance to Commission

Veterinary Release

1 Rekindle veterinary release rulemaking effort

2 Enhancing existing codes to include animal phantom models to calculate exposures from common geometries

3 Develop a regulatory guide providing criteria for common procedures and considerations for release

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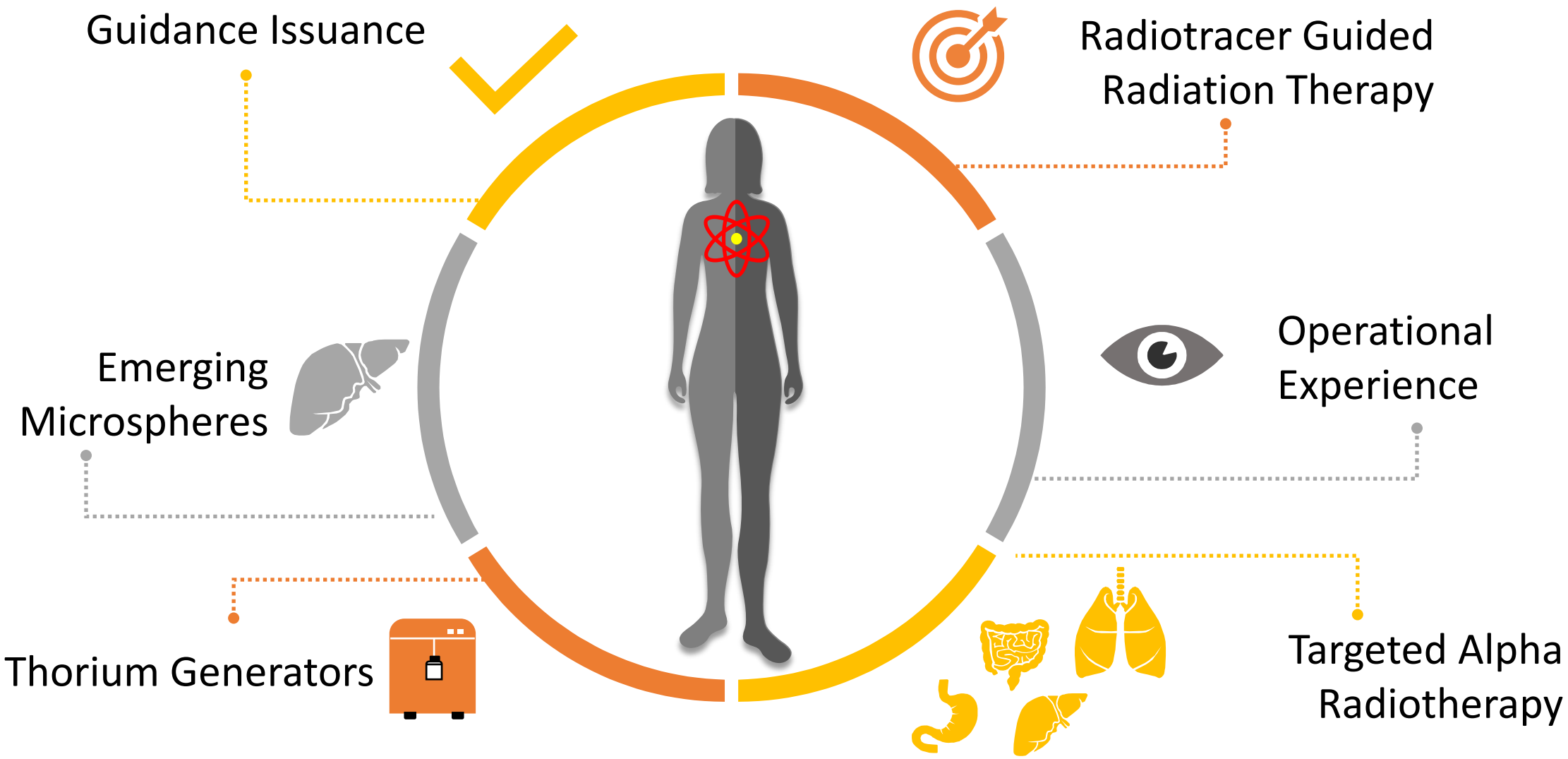
Guidance Development and Updates

EMERGING MEDICAL TECHNOLOGIES



NRC Medical Toolkit | EMTs: https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html

Training and Experience Guidance

- Interim Staff Guidance clarifies roles and responsibilities of authorized users.
- Consolidated guidance.
- No new requirements.
- Public Comment Period Closes today.

Regulatory Guide for Reporting and Evaluating Medical Events

Regulations

- Medical Event Reporting
- Dose to embryo/fetus
- Written directives
- Procedures

Generic Communications

- Information Notices
- Regulatory Issue Summaries

References

- Guidance
- SRMs
- Policy Statements
- International Standards

Examples

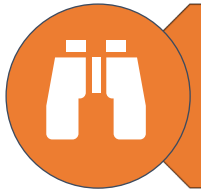
- For most commonly reported medical events
- For most common medical procedures

OTHER EFFORTS

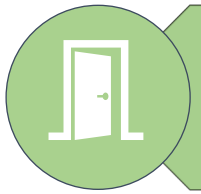
ACMUI Procedures Update

- Enhanced Policy and Procedure
- Bylaws Revision
- New Member Guidance Update
- Additional Ethics Training
- Updated Hiring Practices

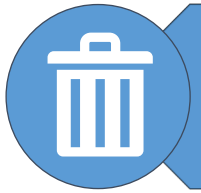
Additional Activities



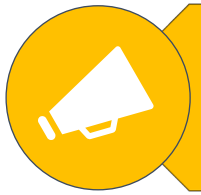
Inspection Procedures Update



Patient Release Revision



Develop Waste Guidance



Continued Operational Experience Communications

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AMP – Authorized medical physicist
- AU – Authorized User
- EMT – Emerging medical technology(ies)
- GSR – Gamma stereotactic radiosurgery
- IN – Information Notice
- NRC – Nuclear Regulatory Commission
- RSO – Radiation Safety Officer
- Rb – Rubidium
- SRM – Staff requirements memorandum
- T&E – Training and experience

Contact Us!

Katherine.Tapp@nrc.gov

medicalquestions.resource@nrc.gov

Medical Uses Licensee Toolkit | NRC Public Website

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Radioactive Material in Patient Waste

Daniel DiMarco
Health Physicist

Outline

- Background
- Patient Release
- Separated Licensed Material
- NRC Communications
- Additional Considerations
- Conclusion

Background

- Fall 2020 ACMUI meeting recommended that the National Material Program evaluate nuclear medicine patient waste found in municipal landfills
- Additional stakeholder communication requested consistent guidance managing patient waste following patient release

Background

- 10 CFR 2003(4)(b) allows for disposal of excreta containing licensed radioactive material into the sanitary sewer
- 10 CFR 35.92 allows for material to be held for decay-in-storage if the half-life is less than 120 days
  - Otherwise the material must be disposed of as low level waste

Patient Release

- 10 CFR 35.75, “Release of individuals containing unsealed byproduct material of implant containing byproduct material” allows licensees to authorize release from control of any individual administered byproduct material if exposure to any other individual is not likely to exceed 5 mSv (0.5 rem)
  - Requires patient instruction if dose to other individuals is likely to exceed 1 mSv (0.1 rem)

Patient Release

- Regulatory Guide 8.39 provide guidance for acceptable methods to release patients
  - Dose calculations are based on external exposure
  - Primarily based on administration of therapeutic I-131 and does not include recently approved radiopharmaceuticals
- Also provides guidance on instruction content since the patient is no longer under the licensee's control once released
- The RG recommends the healthcare provider discuss a plan for management of biologic waste, including discarding trash separately and holding for decay

Separated Licensed Material

- Exposure to the public may be through direct contact or through exposure to byproduct material separated from the patient, such as material put into waste
- Past literature reviews found dose from material separated from patients is expected to be small relative to the external exposure from direct contact.
- However, detectable amount of byproduct material has ended up in unauthorized waste streams from released patients.

NRC Communication

- NRC has issued multiple Information Notices on managing patient waste
  - IN 91-03; IN 99-3; IN 2017-02
- Guidance focused on waste coming from licensee facilities and best practices for patient instructions
- No guidance for waste produced after the patient is released

NRC Communication

- Following the 2020 ACMUI recommendation, the NRC staff surveyed the Agreement States to find if they had programs in place to manage this waste and if new guidance would be beneficial

NRC Communication

- Staff received responses from 11 States
  - Most states responded that they currently had no guidance, while some had minimal guidance for I-131 patients with no guidance for newer radiopharmaceuticals
  - Some states indicated that issuing guidance would reduce risks and costs associated with these types of events
  - States also noted that radiological exposure is fairly low, especially considering other risks present at a municipal landfill

Additional Considerations

- Theranostics is a field that is growing extremely quickly in both size and complexity
- New Lu drugs are being tested on bigger patient populations
- Recent clinical successes with theranostic drugs has prompted R&D for many large drug companies
- Novel isotopes are being explored for medical use

Additional Considerations

- Lu-177 has a potential impurity (Lu-117m) that has a half life of 161 days
- Ac-225 has a potential impurity (Ac-227) that has a half life of 21.7 years
- These impurities are longer than the decay-in-storage limit of 120 days, and, if detectable, must be disposed of as low level waste.

Additional Considerations

- The number of clinical trials of new radiotherapeutics is rapidly increasing
- Some outpatient trials are collecting patient excreta for analysis and transporting back to the clinic for analysis
- There is not guidance for how this activity can be performed

Conclusions

- Public dose limits are well-defined in regulations
- However, there is a lack of guidance regarding waste following patient release
- There are increasing use leading to more waste, new questions, and stakeholder interest to provide guidance in this matter

Next Steps

- Staff proposes to create clear guidance regarding waste following patient release
- This guidance would be sent to the ACMUI for review and include a public comment period during development.

Next Steps

- ACMUI Presentation on Waste – November 4
- Development of draft guidance – Early 2025
- ACMUI review – Spring Meeting 2025
- Publish draft guidance for public comment – 2025

Acronyms

- Ac-225 – Actinium 225
- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- CFR – Code of Federal Regulations
- I-131 – Iodine 131
- IN- Information Notice
- Lu-177 – Lutetium 177
- NMP – Nuclear Materials Program
- RG – Regulatory Guide

Questions?

NRC Update to Patient Release Guidance

Katie Tapp, PhD
Medical Team Leader
November 4, 2024

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AGENDA

- Patient Release Regulations
- Current Guidance
- Guidance Revision
- Examples
- Discussion

Patient Release Regulations

Patient Release Regulations

A licensee may authorize release of a patient if the total radiation dose to any other individual from exposure to the released patient is not likely to exceed 5 mSv (500 mrem)

A licensee must provide written instructions to the patient to maintain doses ALARA if the exposure to any other individual is likely to exceed 1 mSv (100 mrem)

A record of the basis for authorizing the release is required if exposure is calculated using retained activity, occupancy factor less than 0.25 at 1 meter, biological or effective half life, or considering shielding.

Evaluation of Patient Release

2011: Identify gaps in patient release data

2012: Revisit release calculations

2014: Revise Regulatory Guide 8.39

2018: Completed staff evaluation of patient release program

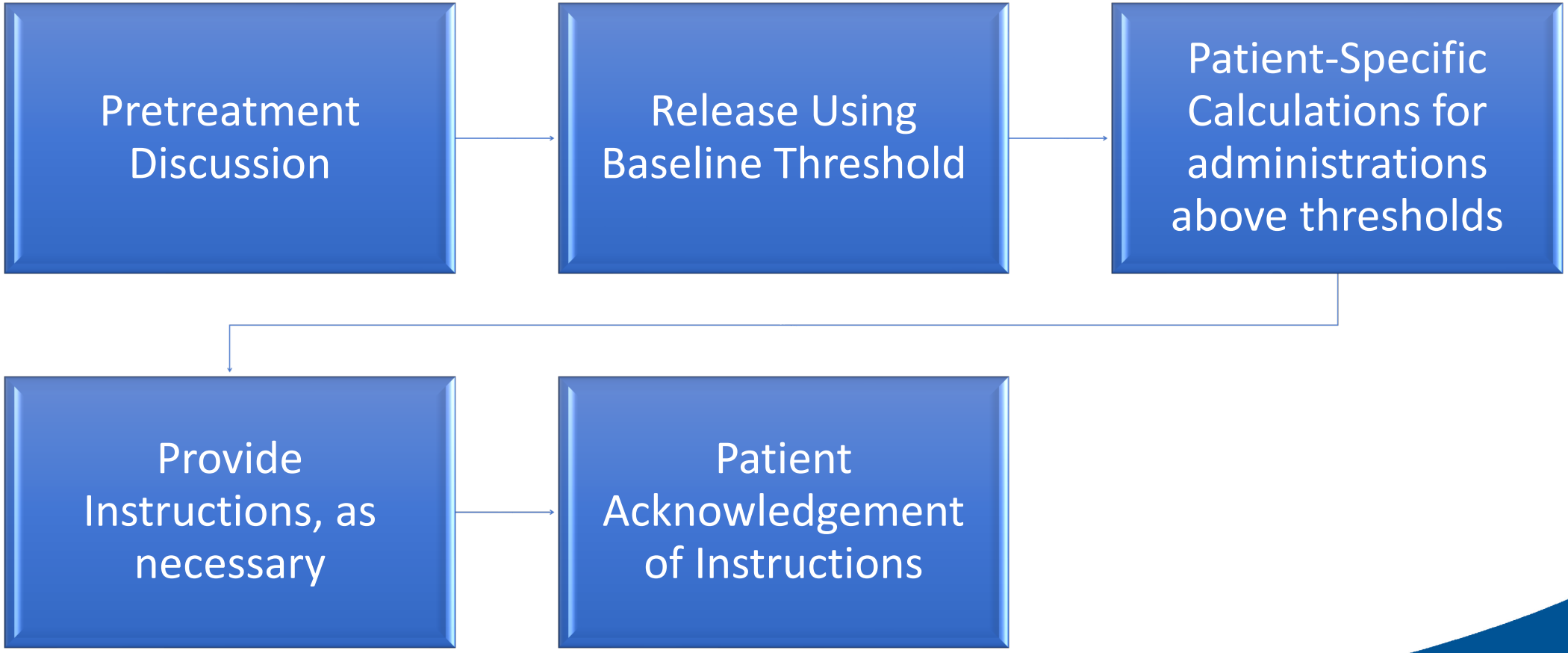
Findings of the Patient Release Evaluation

Regulations adequately protect the public and rulemaking is not warranted as of 2018.

Update to guidance is warranted as the methodology provides in the guidance can **UNDERESTIMATE** exposure to the public in some situations such as public transportation.

Current Guidance

CURRENT PATIENT RELEASE WORKFLOW GUIDANCE



CURRENT GUIDANCE FOR PATIENT-SPECIFIC CALCULATIONS

Guidance on using patient specific occupancy factors when patients are given instructions.

Provides guidance for use of biological half life for I-131.

No guidance provided for patients who cannot follow instructions or exposure occurs at distances different than 1 m.

Current Instructions for Patient Specific Occupancy Factor of 0.25 at 1 m

- Maintain distance for at least 2 days
- Sleep alone for at least 1 night
- Do not use public transportation for 1 day
- No prolonged automobile trip for at least 2 days
- Sole use of the bathroom for at least 2 days
- Drink plenty of fluids for at least 2 days

Guidance Revision

PROPOSED CHANGES IN DRAFT REVISION 2

Increased conservatism in threshold assumptions to ensure *ALL* patients released are not likely to cause exposure over limits.

Provided consistent method to modify threshold values.

Included beta emitters and other emerging radioisotopes.

MULTI-TIER APPROACH

1. Baseline Thresholds – No patient specific information needed.
2. Screening Criteria based on instructions – Multiple examples being developed for currently approved administrations.
3. Patient Specific Calculations – Flexible for unique needs.
4. Hold Time Calculations – Based on needs and available for planning purposes.

Regulatory Guide 8.39, Release of Patients Administered Radioactive Material

Comment Resolution

Simplifying Methodology

Cost-Benefit Analysis

WHAT IS NEXT

Revised draft will be provided to ACMUI for review and comment

Revised draft issued for additional public comment

Final Issuance

Discussion

OPEN FORUM

(No Handout)

April 2025

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1 **AAPM** **AMCP**	2 **AMCP**	3 **AMCP**	4	5
6	7 **Tentative ACMUI Date**	8 **Tentative ACMUI Date**	9 **Tentative ACMUI Date**	10 **Tentative ACMUI Date**	11	12 **Passover**
13 **Passover**	14 **Passover**	15 **Passover**	16 **Passover**	17 **Passover**	18 **Passover**	19 **Passover**
20 **Passover** **Easter**	21	22	23	24	25	26
27	28 **Tentative ACMUI Date**	29 **Tentative ACMUI Date**	30			

May 2025

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11 **Mother's Day**	12 **Tentative ACMUI Date** **Second Passover**	13 **Tentative ACMUI Date**	14 **Tentative ACMUI Date**	15 **Tentative ACMUI Date** **Lag B' Omer**	16 **Lag B'Omer**	17
18	19 **CRCPD**	20 **CRCPD**	21 **CRCPD**	22 **CRCPD**	23	24
25	26 **Memorial Day**	27	28	29	30	31