

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

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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 ACMUI 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

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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.

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

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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:

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~~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.

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~~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:

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- ~~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.

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~~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.

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~~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.

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2. FULL COMMITTEE MEETING AGENDA

~~2.1~~ The agenda for regularly scheduled ACMUI Full Committee meetings will be prepared by the ChairNMSS 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 ChairChairperson, 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.

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Before the Full committee meeting, the ChairChairperson 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.

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~~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:

1.3.1 The scheduling and conduct of ACMUI Full Committee meetings will be held in full compliance 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.

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

- 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.

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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.
- 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.
- 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.
- ~~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.~~

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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.

36. APPOINTMENT OF MEMBERS

- 36.1** 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.

36.2 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.

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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.

3.37.2 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.

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48. 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.

4.28.1 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

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.

4.38.5 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.

9.56 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.

9.76 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.

9.87 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.

512. ADOPTION AND AMENDMENTS

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~~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 NMSSNRC staff may propose an amendment to these bylaws. The proposed amendment will be sent to the ACMUI Chairperson. The ACMUI Chairperson will forward the proposed 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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~~5.312.2~~ The proposed amendment(s) may be voted on as early as the next ACMUI meeting after distribution to the members.

~~5.412.3~~ 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-NOVEMBER 10~~^{XX}, 2024~~19~~

ML24XXXXXXXX

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

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