



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL  
SAFETY AND SAFEGUARDS

# BYLAWS

Advisory Committee on the Medical Uses of Isotopes

Revision 1 - June 25, 2025

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## **PREAMBLE**

These 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 (OGC) for their ultimate resolution.

These 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, the ACMUI members and the affected parties have an adequate opportunity to express their opinions, and 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 COMMITTEE MEETINGS**

The scheduling of ACMUI 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 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 Chairperson or designated Chairperson of the ACMUI declines or the Commission declines such a meeting.
- 1.2 ACMUI 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. Attendees of ACMUI meetings, include:
  - 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;
  - 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.
- 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.
- 1.5 All available meeting handouts should be electronically transmitted to the ACMUI members no later than two weeks prior to the meeting.
- 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.
- 1.7 The Chairperson shall preside over the meeting. The Chairperson can delegate the responsibility to preside over the meeting to another member, such as the Vice Chairperson.
- 1.8 A DFO must be present at all committee meetings.

## **2. COMMITTEE MEETING AGENDA**

- 2.1 The agenda for regularly scheduled ACMUI committee meetings will be prepared by the NMSS staff in consultation with the ACMUI Chairperson. The DFO must approve the agenda. The 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 as soon as possible, but no later than 7 days prior to a scheduled meeting.

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

- 2.2 Agenda items that require 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 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 committee will not review matters brought by the NRC staff unless documentation adequate to support a responsible review is provided to the members with enough time for them to review and respond to the matter. .
- 2.4 Issues may come to the attention of the ACMUI 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.

## **3. CONDUCT OF THE MEETING**

- 3.1 The scheduling and conduct of ACMUI committee meetings will be in accordance with 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. 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 OGC.
- 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.

- 3.3 The meeting will be called to order by the presiding individual who will state the date, time, type of meeting, and confirmation of a quorum (a majority of the current membership of the ACMUI). The Chairperson will ask committee members to disclose any conflicts of interest and will remind members about the recusal policy.
- 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 meeting. Due to the collaborative nature of the committee's business, it is ideal that members meet in person for committee meetings. However, under special circumstances, the Chairperson or MSST Director may authorize remote participation through remote technology for the purpose of establishing a quorum.
- 3.4 The 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.
- 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.
- 3.6 The Chairperson may take part in the discussion of any subject before the ACMUI and may vote. The Chairperson should not use the power of the Chair position 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 Chairperson's level of advocacy should be resolved by a vote on the Chairperson's continued participation in the discussion of the subject. In matters where the ACMUI Chairperson's unique experience and knowledge would be especially informative, the Chairperson may serve on relevant subcommittees. The Chairperson will serve at the discretion of the subcommittee members. However, the ACMUI Chairperson may not chair the subcommittee.
- 3.7 When a consensus appears to have developed on a matter under consideration, the 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 recommendation will be final until it has been formally adopted by consensus or formal vote and the transcript written and certified.

## **4. TRANSCRIPTS/MEETING SUMMARY**

- 4.1 Meeting minutes, i.e., transcripts, of each committee meeting will be sent to the ACMUI Chairperson or the individual who presided over the meeting for certification in accordance with the requirements of 10 CFR Part 7. The Commission staff will prepare transcripts of ACMUI meetings with the Commission.
- 4.2 In accordance with 10 CFR Section 7.13(c), the ACMUI Chairperson, or other individual who presided over the meeting in place of the ACMUI Chairperson, will certify the meeting minutes, i.e., transcripts, which, among other things, shall include a copy of each report or other document received, issued, or approved by the committee. By certifying the transcripts, the Chairperson attests to the best of his or her knowledge to the completeness and technical accuracy of the transcript. The DFO must ensure that minutes are certified for accuracy by the chairperson within 90 calendar days of the meeting to which they relate. Agencies should post the meeting minutes on the agency advisory committee website not later than 14 calendar days after the meeting minutes have been certified. Copies of the certified transcripts will be made available to the ACMUI members and to the public.

## **5. ACMUI SUBCOMMITTEES**

- 5.1 The committee is organized around a number of topical subcommittees whose purpose is to prepare recommendations for the full committee consideration. Initiation of a subcommittee may be requested by either NRC staff or ACMUI members. A subcommittee may 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, and any possible conflicts-of-interests in determining subcommittee members. If an ACMUI member has been assigned to serve on a subcommittee and they do not feel they have the expertise, the member should discuss this matter with the ACMUI Chairperson as soon as possible.
- 5.3 Subcommittee meetings are preparatory meetings, as defined as, “meetings of two or more advisory committee or subcommittee members convened solely to gather information, conduct research, or analyze relevant issues and facts in preparation for deliberation by advisory committee members in a public meeting of the advisory committee, or deliberation by subcommittee members in a public meeting of the subcommittee (where applicable). These meetings to conduct preparatory work do not include deliberation among advisory committee or subcommittee members,” see FACA final rule, 89 Fed. Reg. 27673, 27687; Apr. 18, 2024.
- 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 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 a subcommittee has deliverables, those deliverables should be sent to the NRC staff to be posted on the NRC website prior to a full committee meeting for deliberation and vote.
- 5.8 At the conclusion of the subcommittee meetings, the subcommittee Chairperson, with input from members present, will prepare a report and presentation for committee consideration, as applicable.
- 5.9 Subcommittee work product may not be presented to the Commission before it is approved by the full committee. Any recommendations to the Commission must be made by the full committee.
- 5.10 A DFO must be present at all subcommittee meetings.

## **6. APPOINTMENT OF MEMBERS**

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



## **7. APPOINTMENT OF OFFICERS**

- 7.1 The ACMUI Chairperson and Vice Chairperson will be appointed by the Director, NMSS, with input from the MSST Director, Medical Safety and Events Assessment Branch (MSEB) Chief, Senior Health Physicist in MSEB, and ACMUI Coordinator. Any member of the ACMUI, except for the Food and Drug Administration representative, may serve as the Chairperson or Vice Chairperson. The Chairperson will serve at the discretion of the Director, NMSS.

## **8. CONDUCT OF MEMBERS**

- 8.1 The ACMUI functions to advise the NRC on the medical use of 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 and the presentation of individual views, that have not been approved by the full committee, is not authorized.

Individual members may, as individuals, interact and communicate with the MSST Director. In this instance, the member is not representing the ACMUI but is functioning as an independent expert. The MSST Director should note substantive contacts to the ACMUI Chairperson.

It is inappropriate for a member to individually undermine a declared ACMUI position.

- 8.2 Communications from outside parties should normally be referred to the MSST Director. If an individual member is asked for an opinion by a non-media source, the member can respond but must emphasize to his or her audience that he or she is not speaking 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.
- 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 five business days after the meeting.

- 8.6 ACMUI members (who are appointed as 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 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 the Standards of Ethical Conduct for Employees of the Executive Branch set forth in Title 5 of the Code of Federal Regulations (5 CFR), Part 2635 and Title 18, Chapter 11 of the United States Code (18 USC). 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 CFR Part 2635, with regard to an agenda item to be addressed at an ACMUI committee or subcommittee meeting, this member should divulge it in advance to 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 an NRC Ethics 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 participate in the committee's consideration and vote on that action.

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 prior to participating in discussions of the topic within ACMUI Committee or Subcommittee meetings and not use personal judgment.

- 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 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, or
- their general partner or organization in which they serve as an officer, director, trustee, general partner, or employee, or
- 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 specific parties, such as license guidance that could directly and predictably affect the financial interests of the following:

- members of their household; or
- 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.

9.3 Based on the specific facts, the NMSS director (or designee), in collaboration with the ACMUI Chairperson, can grant a member a written waiver from these restrictions after consulting with an NRC Ethics Official.

9.4 During presentations or discussions at the subcommittee or 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 The report preparation part of the ACMUI meetings is one 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 a conflict with the particular matter being considered should not:

- participate in the committee’s deliberations other than providing clarifications, technical insights, or factual information to other members;

- express opinions that would influence the committee's consideration and resolution of the matter;
- provide input to the committee report that relates to the matter;
- try to influence the committee directly or indirectly or suggest changes to the reports that reflect the member's views on the matter;
- make, participate, or vote on the "motions" to make changes to the reports on the matter; or
- participate in the voting process for approving the report.

9.6 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 a conflict.

9.7 During subcommittee or committee meetings, the respective Chairperson is responsible for ensuring that the above procedures are implemented properly. The DFO for these meetings should remind the Chairperson if these procedures are not complied with properly. If the DFO believes that their reminders were ignored, they should promptly inform NRC management.

## **10. CONSULTANTS**

- 10.1 Pursuant to Management Directive (MD) 10.6, "Use of Consultants and Experts," the NMSS Office Director, may augment the ACMUI's 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.

## **11. ACMUI REPORTS**

- 11.1 ACMUI reports shall be solely the product of the committee members acting as the full committee.
- 11.2 Unless matters coming under FACA exemptions are involved, committee reports will be deliberated and concluded in a 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 committee.

Proposed reports do not represent a committee position. Their distribution shall be to ACMUI members, ACMUI consultants, and the NRC staff providing administrative support to the ACMUI prior to their consideration by the committee in a public session. At the request of the subcommittee Chairperson, ACMUI members 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 full 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 ACMUI 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 ACMUI 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 members as possible 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 as well as any dissenting committee member views.

## **12. ADOPTION AND AMENDMENTS**

12.1 Any member of the ACMUI or 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 proposed amendment to the MSST Director, or designee,

for review and comment. The proposed amendment will be distributed to the members and scheduled for discussion at the next regular committee meeting.

- 12.2 The proposed amendment(s) may be voted on as early as the next ACMUI meeting after distribution to the members.
- 12.3 The ACMUI shall consult with OGC 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 NMSS Director.

## **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	U.S. Nuclear Regulatory Commission

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