

Serving on the Advisory Committee on the Medical Uses of Isotopes: A Member's Guide

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Serving on the Advisory Committee on the Medical Uses of Isotopes: A Member's Guide

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ABSTRACT

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides a valuable service to the U.S. Nuclear Regulatory Commission (NRC) through advice and recommendations. To be able to advise effectively, it is important that ACMUI members have a basic understanding of the committee's role and responsibilities. Likewise, it is also important that members have a basic understanding of NRC processes and requirements. Effective advice serves medical patients and the public by enabling the NRC Commission to make decisions based on the issues currently impacting the medical regulated community. The ACMUI should help the NRC staff to ensure that any regulations that are developed promote safety and are useful, realistic, practical, and not overly burdensome.

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ACMUI	Advisory Committee on the Medical Uses of Isotopes
CFR	<i>Code of Federal Regulations</i>
Commission	the five-member collegial body appointed by the President and confirmed by the Senate for staggered 5-year terms that heads the U.S. Nuclear Regulatory Commission
DFO	Designated Federal Official
eCFR	electronic <i>Code of Federal Regulations</i> public website
ETS2	E-Gov Travel System 2 (i.e., Concur)
HSPD-12	Homeland Security Presidential Directive-12
MD	management directive
MSEB	Medical Safety and Events Assessment Branch
MSST	Division of Materials Safety, Security, State, and Tribal Programs
NMED	Nuclear Material Events Database
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
OGE	U.S. Office of Government Ethics
SGE	Special Government Employee
U.S.C.	United States Code

1 BASICS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1.1 Establishment of the ACMUI

The U.S. Nuclear Regulatory Commission (NRC) established the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in 1958. The ACMUI was established under the authority of the Federal Advisory Committee Act and is executed under the provisions of Title 41 of the *Code of Federal Regulations* (CFR) Part 102-3, "Federal Advisory Committee Management," and regulations contained within 10 CFR Part 7, "Advisory Committees." The Commission-established advisory body consists of health care professionals in diverse specialties, representing diagnostic and therapeutic applications of medicine and medical administration. The ACMUI advises the NRC staff on the creation of medical regulations that are useful, realistic, practical, not overly burdensome, and not inappropriately intrusive in the practice of medicine.

1.2 Purpose of the ACMUI

The purpose of the ACMUI is to provide advice on policy and technical issues that arise in regulating the medical use of radioactive material for diagnosis and therapy. The ACMUI provides this advice as requested by the Director, Division of Materials Safety, Security, State, and Tribal Programs (MSST) in the Office of Nuclear Material Safety and Safeguards (NMSS). In addition, the ACMUI provides consulting services to staff, as requested by the Director, MSST. The ACMUI charter establishes the objective and scope of the committee.

1.3 Open-Session and Closed-Session Public Meetings

The ACMUI comprises health care professionals from all over the country who have full-time positions with their primary employers. Because the ACMUI provides its services on a part-time basis, the NRC limits the number of public meetings. During these meetings, the ACMUI may bring regulatory issues and their insights to the attention of the NRC staff.

The ACMUI must conduct its activities in an open forum that gives reasonable access to members of the public who want to attend or speak at the meeting. The meetings must follow 41 CFR Part 102-3 and 10 CFR Part 7 requirements on transparency. Meetings may take place in a closed (nonpublic) session when sensitive information, such as safeguards information, needs to be discussed. The regulations allow the NRC staff to close meetings for this reason.

Regardless of a meeting's status as open or closed, all meetings must be announced in the *Federal Register*. Open-session meetings are announced to afford the public an opportunity to view or speak at meetings. Closed-session meetings are announced to inform the public that the meeting will occur and to establish why the meeting is nonpublic.

1.4 Meetings

The ACMUI typically holds two public meetings per year. In-person meetings take place at NRC Headquarters in Rockville, Maryland. Virtual meetings are also an option. ACMUI meetings are held in the spring and fall (typically in March or April and September or October). In between regularly scheduled public meetings with the full committee, the ACMUI also supports virtual topical meetings on emergent issues as needed.

1.5 ACMUI Subcommittees

ACMUI subcommittees can be established based upon the needs or requests of the Commission or the NRC staff, or upon concerns brought forth by the broader medical community. In-depth reviews are generally conducted by ACMUI subcommittees. Subcommittee membership is designated by the ACMUI Chairperson. An NRC staff member should be assigned as a point of contact or staff resource to any given ACMUI subcommittee. This staff resource should attend ACMUI subcommittee meetings and provide clarification and responses to questions raised by the subcommittee. Subcommittee meetings are virtual and are led by the subcommittee Chairperson.

When the subcommittee has completed its review, a written report with the subcommittee's comments and recommendations will be issued. The subcommittee Chairperson will present the report at the next ACMUI public meeting. At this public meeting, the ACMUI members will discuss and vote on the subcommittee's comments and recommendations.

A list of ACMUI subcommittees, including their charges, membership, established dates, deactivated dates, and reports can be found here: <https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/subcommittee.html>.

1.6 ACMUI Recommendations

While conducting meetings, the recommendations put forward by the ACMUI become matters of public record. After the recommendations are endorsed with a majority vote by the ACMUI members, they are provided to the NRC staff for consideration.

After ACMUI meetings, the NRC staff reviews the ACMUI recommendations. The staff evaluates the recommendations not only for their feasibility and sound regulatory value, but also to determine whether they will likely be met with strong objections from other stakeholders such as Congress or the public.

After the staff reviews each recommendation, a formal memorandum is sent to the ACMUI to document the staff's rationale. The staff advises as to whether the recommendation should be adopted as stated, modified, or disapproved and provides a basis for this decision. Additionally, during ACMUI meetings, the NRC staff presents an update on the status of the ACMUI's recommendations during the "Old Business" portion of the meeting.

The recommendations and actions the ACMUI submits to the NRC are compiled by year and can be viewed here: <https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/recommendations.html>.

2 COMMISSION BRIEFINGS

2.1 Purpose of Commission Briefings

The ACMUI provides a public briefing to the Commission once a year, including an update on the major initiatives of the committee and an opportunity for the ACMUI to receive the Commission's feedback. The briefing is intended to keep the Commission abreast of new or evolving technologies or issues that should be potentially monitored. The Commission briefing is typically scheduled to coincide with the ACMUI meeting in the spring or fall to keep travel costs low. The Commission or the ACMUI Chairperson may decline the meeting based on priorities.

The Commission has final approving authority on agenda topics. Before each scheduled Commission briefing, the NRC staff will forward the draft agenda to the Commission for final approval.

During Commission briefings, ACMUI presentations should be limited to those approved by the full committee in an ACMUI meeting. It should be clearly stated that all opinions expressed, or recommendations made, are done so on behalf of the full committee. Individual views and opinions are not to be discussed. The Commission briefing is a public forum and should be used to communicate the work with external stakeholders and as an opportunity to engage with the Commission.

2.2 Outcome of ACMUI Commission Briefings

The ACMUI briefing to the Commission is an opportunity to obtain Commission feedback on initiatives that are important to the ACMUI, the regulated medical community, and other stakeholders. During the briefing, the Commission may expound on the numerous and divergent issues that the ACMUI raises and may appear to come to conclusions regarding those issues. These comments should not be treated as final or as official directions. After the briefing, the Commission will issue its final decisions in writing by using a staff requirements memorandum. The Commission may direct staff to take certain actions. The NRC staff may act only in accordance with the official direction provided by the Commission.

3 EVALUATIONS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

3.1 Biennial Evaluations of the ACMUI

The Commission requires two types of evaluations of the ACMUI: (1) NRC staff evaluations of the ACMUI and (2) ACMUI self-evaluations. These evaluations are conducted every 2 years. Evaluations are a tool that helps the Commission determine whether the committee is functioning as intended and identify issues that may impede the ACMUI's ability to serve the staff effectively. The Commission also uses the evaluations to justify the expenditure of NRC resources. It is important that all committee members respond to the evaluation, as requested by the NRC staff, so that the Commission receives a complete depiction of the committee's efforts to fulfill its purpose.

3.2 ACMUI Reporting Structure

Currently, the ACMUI reports to the Director, NMSS/MSST; the Medical Safety and Events Assessment Branch (MSEB) also reports to this director. The MSEB staff support the day-to-day activities of the ACMUI, but the ACMUI does not report to MSEB. Annually, the NRC staff considers whether the committee's reporting structure continues to be effective. The option for the ACMUI to continue reporting to NMSS or directly to the Commission is evaluated at the spring ACMUI meeting.

4 ROLES AND RESPONSIBILITIES

4.1 ACMUI Chairperson and Vice Chairperson

The ACMUI Chairperson has several general duties related to his or her position. These include presiding over ACMUI meetings and maintaining order and decorum; summarizing committee consensus votes or position statements; and determining the composition of subcommittees. The ACMUI Chairperson reviews the transcripts after the meetings and verifies the completeness and technical accuracy of the transcript. A complete description of the ACMUI Chairperson's duties may be reviewed in the ACMUI Bylaws (Agencywide Documents Access and Management System (ADAMS) Accession No. [ML25027A344](#)). The Vice Chairperson assumes these responsibilities when the Chairperson is absent.

4.2 Designated Federal Official

The Designated Federal Official (DFO) is a Federal Government employee charged with the proper execution of ACMUI meetings. No ACMUI meeting or subcommittee meeting may be held unless the DFO is present, in accordance with 41 CFR Part 102-3 and 10 CFR Part 7. The DFO performs several duties that support the functioning of the ACMUI. These include approving all ACMUI meetings, approving the agenda, adjourning meetings when doing so is in the public interest, and ensuring that the meeting minutes (i.e., transcripts) are publicly available.

4.3 ACMUI Coordinator

The ACMUI Coordinator is responsible for the day-to-day operations and communications with the committee. The ACMUI Coordinator drafts correspondence, coordinates ACMUI meetings, performs pre- and post-meeting tasks, and is the primary point of contact for committee members. The ACMUI Coordinator also facilitates communication between ACMUI members and the Office of the Chief Human Capital Officer for personnel matters.

5 SERVING ON THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5.1 ACMUI Appointment

The members of the ACMUI are selected and appointed by the Director, NMSS, after consultation with the Commission. The selectee does not become an appointed ACMUI member with full voting rights until he or she obtains an employment waiver or full security clearance pursuant to section 145(b) of the Atomic Energy Act of 1954, as amended (Title 42, United States Code (U.S.C.), section 2165(b)).

5.2 Special Government Employees

While conducting ACMUI business, ACMUI members are Special Government Employees (SGEs), a class of Federal Government employees.¹ The NRC staff understands that the ACMUI is composed of employees of NRC licensees and, as such, will represent licensee concerns. This is not only inevitable but desirable. Nonetheless, ACMUI members must remember that, as compensated Government employees, they are subject to laws and regulations on conflicts of interest.

5.3 Term

The term of an appointment to the ACMUI is 4 years. No member can serve more than two consecutive terms (i.e., 8 consecutive years), unless otherwise authorized by the Commission. If an ACMUI member does not wish to serve the second term, he or she should inform the ACMUI Coordinator.

5.4 Security Clearance

Candidates will work closely with a human resources specialist to begin the security clearance process. The security clearance forms will be sent directly to the candidate for completion.

5.5 Preappointment Waiver

Before the approval of the full NRC security clearance, candidates may serve on the ACMUI in a limited capacity with a 145(b) preappointment investigation waiver (see [Management Directive \(MD\) 12.3, "NRC Personnel Security Program"](#)). Candidates will not have voting rights or access to classified information, and cannot participate in subcommittees, until they are a full member. Candidates also cannot charge their hours or be reimbursed for travel expenses.

5.6 NRC Badge

Once the security clearance processing is complete, the new ACMUI member will receive an NRC employee Homeland Security Presidential Directive-12 (HSPD-12) badge. The ACMUI

¹ An SGE is defined as any employee, including a consultant or an expert, who is retained or employed with or without compensation by the NRC or any other agency for not more than 130 working days during any period of 365 consecutive days.

Coordinator will arrange for badge enrollment at NRC Headquarters for the next time the new member will be in the area (i.e., during the next ACMUI meeting).

5.7 Travel

Once an ACMUI member has obtained a security clearance, the ACMUI Coordinator will request that a travel profile be created in the NRC's travel system, Concur (ETS2). The ACMUI Coordinator will provide ACMUI members with a letter of invitation by email approximately 30–45 days before in-person meetings. The letter of invitation will include a request for ACMUI members to make lodging and travel reservations and to submit the travel authorization within the system.

5.8 Standards of Ethical Conduct for Employees of the Executive Branch

As provided in 5 CFR 2635.101, "Basic obligation of public service,"—

each [Federal] employee has a responsibility to the United States Government and its citizens to place loyalty to the Constitution, laws, and ethical principles above private gain...each employee must respect and adhere to the principles of ethical conduct....

In addition, as listed in 5CFR 2635.101, the following general principles apply to every employee and employees should, at a minimum, consider and apply the following in determining whether their conduct is proper:

- (1) Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.
- (2) Employees shall not hold financial interests that conflict with the conscientious performance of duty.
- (3) Employees shall not engage in financial transactions using nonpublic Government information or allow the improper use of such information to further any private interest.
- (4) An employee shall not, except as permitted by [5 CFR Part 2635, "Standards of Ethical Conduct for Employees of the Executive Branch," Subpart B, "Gifts from Outside Sources"], solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.
- (5) Employees shall put forth honest effort in the performance of their duties.
- (6) Employees shall not knowingly make unauthorized commitments or promises of any kind purporting to bind the Government.
- (7) Employees shall not use public office for private gain.

- (8) Employees shall act impartially and not give preferential treatment to any private organization or individual.
- (9) Employees shall protect and conserve Federal property and shall not use it for other than authorized activities.
- (10) Employees shall not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official Government duties and responsibilities.
- (11) Employees shall disclose waste, fraud, abuse, and corruption to appropriate authorities.
- (12) Employees shall satisfy in good faith their obligations as citizens, including all just financial obligations, especially those—such as Federal, State, or local taxes—that are imposed by law.
- (13) Employees shall adhere to all laws and regulations that provide equal opportunity for all Americans regardless of, for example, race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age, genetic information, or disability.
- (14) Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards [contained in 5 CFR Part 2635].

Whether particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts.

ACMUI members may request advice specific to the standards of ethical conduct by contacting the NRC's ethics program through Ethics Gateway or by contacting a [Deputy Ethics Official](#) (see [MD 7.5, "Ethics Counseling and Training"](#)).

5.8.1 Confidential Financial Disclosure

All ACMUI members are required to complete and submit a Confidential Financial Disclosure Report (U.S. Office of Government Ethics (OGE) Form 450) on an annual basis. The ACMUI Coordinator will send an email reminder to ACMUI members to prompt completion of the form 1 month before the February 15 due date. The completed forms should be submitted in Ethics Gateway or directly to a member of the NRC Ethics Team if the ACMUI member does not have access to Ethics Gateway. The OGE regulations pertaining to financial disclosure forms may be found in 5 CFR Part 2634, "Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture" (see also NRC [MD 7.6, "Public and Confidential Financial Disclosure Reports"](#)).

5.8.2 Annual Training

ACMUI members are required to have annual training in ethics, allegations, and information security. The NRC staff administers these trainings in a closed session during the fall ACMUI meeting.

5.8.3 Professional Organizations

ACMUI members are encouraged to regularly communicate with their respective professional organizations (e.g., Society of Nuclear Medicine and Molecular Imaging, American Association of Physicists in Medicine, American Society for Radiation Oncology). This is desired, as the ACMUI viewpoint represents that of the outside industry. With this, ACMUI members should avoid the perception of (or an actual) conflict of interest between their employer, outside interests, and the committee's work (see also NRC [MD 7.3, "Participation in Professional Organizations"](#)).

Every ACMUI member should review the meeting agenda beforehand and consider whether any of the regulatory issues scheduled for discussion could affect, or create the appearance of affecting, his or her financial interests or the financial interests of an entity with whom he or she has a "covered relationship." The ACMUI member should consider whether any of his or her professional organizations have taken a well-publicized stance or are actively advocating on a regulatory matter under ACMUI review. The definition of covered relationship in 5 CFR 2635.502, "Personal and business relationships," includes an organization, other than a political party, in which the ACMUI member is an active participant. This could include the ACMUI member's employer or a professional organization. For these purposes, professional organization participation is active if the ACMUI member is also serving as an official of the organization, in a capacity similar to that of a committee or subcommittee Chairperson or spokesperson; participates in directing the activities of the organization; is investing significant time in fundraising; or is promoting specific programs within the organization.

All Federal employees, including SGEs, are subject to certain restrictions on personal fundraising for nonprofit organizations (see 5 CFR 2635.808, "Fundraising activities"). This includes restrictions on the use of official title, position, and authority and the solicitation of subordinates. Additionally, SGEs may not personally solicit funds or other support from a person known by the employee to be a prohibited source whose interests may be substantially affected by the performance or nonperformance of his or her official duties (see 5 CFR 2635.808(c)(1)(ii); see also [OGE Legal Advisory 00x1, "Memorandum dated February 15, 2000, from Stephen D. Potts, Director, to Designated Agency Ethics Officials, General Counsels and Inspector General Regarding Summary of Ethical Requirements Applicable to Special Government Employees"](#)).

The ACMUI Coordinator will maintain a list of professional affiliations and other relationships as disclosed by the committee's members during the hiring process and throughout their tenure in the ACMUI. This should be reviewed periodically and kept current.

5.8.4 Conflict of Interest

ACMUI members are subject to the laws and regulations on conflicts of interest. Under those laws and regulations, they should not participate in any ACMUI matter when doing so will directly and predictably affect their financial interest or the financial interest of members of their families, their employees, or anyone else with whom they have a business relationship. In

addition, ACMUI members should be sensitive to the perception of a conflict of interest, particularly with respect to their private activities (e.g., representational services, expert witness activities). Regulations pertaining to conflict of interest are at 5 CFR Part 2635. In addition, the criminal conflict of interest statutes that may have applicability to SGEs are found in 18 U.S.C. [§ 201](#), “Bribery of public officials and witnesses”; [§ 203](#), “Compensation to Members of Congress, officers, and others in matters affecting the Government”; [§ 205](#), “Activities of officers and employees in claims against and other matters affecting the Government”; [§ 207](#), “Restrictions on former officers, employees, and elected officials of the executive and legislative branches”; and [§ 208](#), “Acts affecting a personal financial interest.”

The most significant principle of conflict of interest analysis is that employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards (from the perspective of a reasonable person with knowledge of all relevant facts). An ACMUI member should not participate in an ACMUI matter that specifically involves any of the following ***without prior written authorization***:

- an entity with whom the member has or is seeking an outside business relationship (e.g., officer, director, trustee, general partner, employee)
- a member of his or her household or a relative with whom the member has a close personal relationship
- an entity that has a business or employment relationship with the member’s spouse, parent, or a dependent child
- any person with whom the member has had an employment relationship in the previous year (e.g., a former employer or a client for whom the member provided personal services)
- any organization in which the member is an active participant

5.8.5 Conflict of Interest Waiver or Recusal

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 with an agenda item to be addressed by the ACMUI, that ACMUI member should divulge it to the DFO as soon as possible. ACMUI members should discuss with the DFO whether they qualify for an authorization waiver from the NRC that would allow them to continue participation and discussion on the agenda item or whether it is most appropriate to recuse themselves from participating in any agenda item for which they may have a conflict of interest. Since the ACMUI comprises employees of NRC licensees, these discussions are expected. If the ACMUI member believes that a conflict of interest does not exist, but the perception of a conflict of interest could exist, then he or she should discuss this with the DFO or a [Deputy Ethics Official](#).

When the NRC determines that a conflict of interest exists, the affected ACMUI member should recuse himself or herself during the ACMUI meeting and sustain from discussing and voting on the agenda item. That ACMUI member should not be added to a subcommittee charged with in-depth review of the regulatory issue in question. Before the meeting, the ACMUI member

may request that the NRC issue a waiver or grant authorization permitting the member's participation. The NRC may provide the requested relief if it determines, in light of all relevant circumstances, the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations. Regardless, the results of the conflict of interest assessment should be in writing, noted during the ACMUI meeting, and included in the transcript or meeting minutes (or both) (see [MD 7.9, "Ethics Approvals and Waivers"](#)).

The following are four examples of recusal situations:

- (1) You have been asked to review and provide input on draft licensing guidance for a specific new brachytherapy device developed by a biomedical sciences company. Within the last year, you have provided compensated consulting services to this company, though the services you provided were entirely unrelated to the particular device that the company is now seeking to license.

You must recuse unless you receive prior written authorization. Since you have served as a consultant for this company within the last 1 year, you have a covered relationship under 5 CFR 2635.502. It is irrelevant that the services you provided were unrelated to the NRC matter now under review.

- (2) You are a member of a subcommittee that has been asked to review and provide input on an NRC staff regulatory basis document, supporting a proposed change to NRC regulations governing the release of patients who have been administered radioactive material. Among other things, this rule change would increase licensee recordkeeping and reporting obligations and, beyond that, would also codify specific radiation safety methods and approaches that previously were included in nonbinding NRC guidance. Your employer, who would be directly impacted, has been a vocal critic of the proposed rule change on the grounds that the estimated benefits to health and safety would not outweigh the additional costs incurred by licensees.

You must recuse yourself unless you obtain an authorization waiver to participate. You have knowledge that your outside employer has a direct and predictable financial interest in this particular matter, which means that you have a financial conflict of interest under 18 U.S.C. § 208.

3. Same scenario as Example 2 above, but instead of it being your outside employer, the vocal critic of the proposed rule is a nonprofit scientific organization for whom you serve as a committee Chairperson. This 501(c)(3) organization has no direct financial stake in the NRC's rule change, but it is advocating on behalf of the nuclear medicine community at large, and the organization has submitted a formal comment to the NRC opposing the proposed rule.

*You still must recuse because you have a covered relationship with this organization, which is representing others in a matter before the NRC. It is not a **financial** conflict of interest, but it is nonetheless a covered matter in which a reasonable person may question your impartiality. Your participation can be authorized in writing under the standards in 5 CFR 2635.502(d)—whether the NRC's interest in your participation outweighs this reasonable appearance concern.*

4. Same scenario as Example 2 above, but instead of being a committee Chairperson within this nonprofit organization, you are merely a dues-paying member of this organization (which has thousands of such members). Other than occasionally attending the organization's annual meetings as an observer, you have no actual position within the organization.

You would not have to recuse solely on the grounds that you are a dues-paying member of the organization. The definition of covered relationship extends to outside organizations of which you are an active participant. However, it is still in your best interest to obtain that conclusion in writing from an ethics official, rather than determine on your own that you do not need to recuse yourself.

5.8.6 Gifts

ACMUI members should not accept any gift, as defined in 5 CFR Part 2635, or other item of monetary value from a prohibited source (i.e., someone who does or seeks to do business with the NRC, is seeking official action by the NRC, or engages in activities regulated by the NRC) or any gift given because of the member's official position. Gifts include any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings, and meals, whether provided in kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. A list of exclusions is given in 5 CFR 2635.203, "Definitions."

5.9 Compensation and Submitting Hours of Work

ACMUI members are compensated for their service to the Commission as SGEs. However, members of the ACMUI who serve in other areas of the Federal Government (e.g., Food and Drug Administration representatives) are not eligible for professional service pay.

To be compensated for work performed, each ACMUI member must submit his or her time through the appropriate reporting method established. Each pay period, the ACMUI Coordinator will send an email to all members requesting the submission of ACMUI work hours. Members should send an email noting the date(s) and number of hours worked for the pay period to ACMUI_MedConsultTime.Resource@nrc.gov no later than 12:00 p.m. Eastern Time on the second Thursday of the pay period, unless instructed otherwise.

For traveling to and from in-person meetings and attending the ACMUI meetings, ACMUI members may claim *up to 8 hours per day*. Official business includes the following:

- the time from when the member departed home or work to the time the member arrived at the hotel
- preparation time, including reviewing documents and preparing for presentations
- time spent attending the meeting

Outside of ACMUI meetings, the workload is smaller and ACMUI members are compensated at an hourly rate *up to 6 hours per day*.

5.10 Departures and Resignations

The ACMUI member should serve until his or her term ends or upon resignation. All ACMUI members must complete NRC Form 270, "Separation Clearance," before separating from the NRC. ACMUI members must provide their NRC HSPD-12 badge to the ACMUI Coordinator before their departure. ACMUI members should turn in their badge at their final meeting at the NRC Headquarters building or mail it to the ACMUI Coordinator.

6 WEBSITES AND DATABASES

6.1 ACMUI Public Website

The ACMUI Coordinator maintains the ACMUI website. ACMUI members can access this page at <https://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>. This is part of the NRC public website, which has a landing page at www.nrc.gov.

6.2 Medical Uses Licensee Toolkit

The toolkit is designed to assist medical use licensees with key information, but it also contains useful material such as NRC regulations, guidance documents, and medical event presentations. ACMUI members can access this public website at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>.

6.3 Nuclear Material Events Database

The Nuclear Material Events Database (NMED) contains records of events involving nuclear material reported by NRC licensees, Agreement States, and nonlicensees. NMED is a secure database that is not accessible to the public. The ACMUI Medical Event Subcommittee conducts annual assessments on the medical events and provides a report from the previous fiscal year (generally at each fall meeting). Upon appointment of a new member to the committee, the ACMUI Coordinator will arrange for his or her access to NMED. The website to log into this database is <https://nmed.inl.gov/Home/frmLogin>.

6.4 NRC Agencywide Documents Access and Management System

The Agencywide Documents Access and Management System (ADAMS) is the NRC's official recordkeeping system. ADAMS contains both publicly available documents and nonpublic records. More information about ADAMS is available at <https://www.nrc.gov/reading-rm/adams.html>.

Publicly available documents in ADAMS are organized by a special 11-character accession number (e.g., ML19058A598). To begin a search for NRC documents, ACMUI members can access web-based ADAMS at <https://adams.nrc.gov/wba/>. ADAMS permits full-text searching and enables users to view document images, download files, and print locally. ADAMS public search is a new tool that can be assessed at <https://www.nrc.gov/reading-rm/adams#aps>.

6.5 Generic Communications

The NRC issues generic communications to inform the regulated community about potential generic issues that are safety significant, require technical resolution, and possibly require generic communication or action. The most common forms of generic communications issued to medical licensees are regulatory issue summaries and information notices.

Information notices communicate operating or analytical experience to the nuclear industry. Information notices may also communicate the results of recently completed research. The industry is expected to review the information for applicability and consider appropriate actions to avoid similar problems. ACMUI members can access a list of issued information notices at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/index.html>.

Regulatory issue summaries are used to (1) communicate and clarify NRC technical or policy positions on regulatory matters that have not been communicated to or are not broadly understood by the nuclear industry, (2) inform the nuclear industry of opportunities for regulatory relief, (3) communicate previous NRC endorsement of industry guidance on technical or regulatory matters, (4) provide guidance to applicants and licensees on the scope and detail of information that should be provided in licensing applications to facilitate NRC review, and (5) request the voluntary participation of the nuclear industry in NRC-sponsored pilot programs or the voluntary submittal of information that will assist the NRC in performing its functions. ACMUI members can access a list of issued regulatory issue summaries at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/index.html>.

6.6 Regulations and Rulemakings

The regulations provided in 10 CFR Chapter 1, “Nuclear Regulatory Commission,” are maintained on the electronic *Code of Federal Regulations* (eCFR) public website at <https://www.ecfr.gov/current/title-10/chapter-I>.

The most relevant regulations for the ACMUI to access are 10 CFR, “Medical Use of Byproduct Material,” at <https://www.ecfr.gov/current/title-10/chapter-I/part-35>.

The NRC maintains a public website with information on the agency’s rulemaking process. Information about procedural requirements, public involvement in rulemaking, and planned rulemaking activities can be accessed at <https://www.nrc.gov/about-nrc/regulatory/rulemaking.html>.

7 REFERENCES

7.1 United States Code

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.)

Federal Advisory Committee Act, as amended (5 U.S.C., Appendix II)

Crimes and Criminal Procedure (18 U.S.C.)

7.2 Code of Federal Regulations

Code of Federal Regulations (CFR), “Advisory Committees”, Part 7, Chapter 1, Title 10, “Energy.”

CFR, “Federal Advisory Committee Management,” Part 102-3, Chapter 102, Title 41, “Public Contracts and Property Management.”

CFR, “Medical Use of Byproduct Material,” Part 35, Chapter 1, Title 10, “Energy.”

CFR, “Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture,” Part 2634, Chapter 16, Title 5, “Administrative Personnel.”

CFR, “Standards of Ethical Conduct for Employees of the Executive Branch,” Part 2635, Chapter 16, Title 5, “Administrative Personnel.”

7.3 U.S. Nuclear Regulatory Commission Documents

“Bylaws: Advisory Committee on the Medical Uses of Isotopes,” Revision 1, June 25, 2025 (ML25027A344). <https://www.nrc.gov/docs/ML2502/ML25027A344.pdf>

“NRC Ethics: Major Ethics Rules Affecting NRC Special Government Employees,” Office of the General Counsel internal website, March 2021 (ML092170418).
<https://www.nrc.gov/docs/ML0921/ML092170418.pdf>

“NRC Regulatory Tools,” ACMUI presentation slides, pp. 67–72, ACMUI Meeting, Rockville, Maryland, September 10–11, 2019 (ML19247E282).
<https://www.nrc.gov/docs/ML1924/ML19247E282.pdf>

“Overview of Nuclear Material Events Database (NMED),” ACMUI presentation slides, pp. 46–52, ACMUI Meeting (teleconference), March 30, 2020 (ML20115E395).
<https://www.nrc.gov/docs/ML2011/ML20115E395.pdf>

“United States Nuclear Regulatory Commission Charter for the Advisory Committee on the Medical Uses of Isotopes,” February 28, 2024 (ML24059A446).
<https://www.nrc.gov/docs/ML2405/ML24059A446.pdf>

Management Directive [\(MD\) 7.3](#), “Participation in Professional Organizations.”

[MD 7.5](#), “Ethics Counseling and Training.”

[MD 7.6](#), “Public and Confidential Financial Disclosure Reports.”

[MD 7.9](#), “Ethics Approvals and Waivers.”

[MD 12.3](#), “NRC Personnel Security Program.”

[NUREG-0544](#), “Collection of Abbreviations.”

7.4 Office of Inspector General

“Special Inquiry into the Appearance of a Conflict of Interest Involving Members of the Advisory Committee on the Medical Uses of Isotopes,” Office of the Inspector General Case No. I2200187, March 26, 2024 (ML24089A252).
<https://www.nrc.gov/docs/ML2408/ML24089A252.pdf>

7.5 Office of Government Ethics

Office of Government Ethics Legal Advisory 00x1, “Memorandum dated February 15, 2000, from Stephen D. Potts, Director, to Designated Agency Ethics Officials, General Counsels and Inspectors General Regarding Summary of Ethical Requirements Applicable to Special Government Employees,” February 15, 2000.
[https://www.oge.gov/Web/oge.nsf/Legal%20Docs/445ECB1FB63809DA852585BA005BED9E/\\$FILE/00x1.pdf?open](https://www.oge.gov/Web/oge.nsf/Legal%20Docs/445ECB1FB63809DA852585BA005BED9E/$FILE/00x1.pdf?open)

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10. SUPPLEMENTARY NOTES

J. Fisher

11. ABSTRACT (200 words or less)

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides a valuable service to the U.S. Nuclear Regulatory Commission (NRC) through advice and recommendations. To be able to advise effectively, it is important that the ACMUI members have a basic understanding of the committee's role and its responsibilities. Likewise, it is also important that members have a basic understanding of NRC processes and requirements. Effective advice serves medical patients and the public by enabling the NRC Commission to make decisions based on the issues currently impacting the medical regulated community. The ACMUI should help the NRC staff to ensure that any regulations that are developed promote safety and are useful, realistic, practical, and not overly burdensome.

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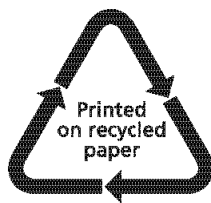
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