

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

**U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001**



AVAILABILITY OF REFERENCE MATERIALS IN NRC PUBLICATIONS

NRC Reference Material

As of November 1999, you may electronically access NUREG-series publications and other NRC records at NRC's Public Electronic Reading Room at <http://www.nrc.gov/reading-rm.html>.

Publicly released records include, to name a few, NUREG-series publications; *Federal Register* notices; applicant, licensee, and vendor documents and correspondence; NRC correspondence and internal memoranda; bulletins and information notices; inspection and investigative reports; licensee event reports; and Commission papers and their attachments.

NRC publications in the NUREG series, NRC regulations, and *Title 10, Energy*, in the Code of *Federal Regulations* may also be purchased from one of these two sources.

1. The Superintendent of Documents
U.S. Government Printing Office
Mail Stop SSOP
Washington, DC 20402-0001
Internet: bookstore.gpo.gov
Telephone: 202-512-1800
Fax: 202-512-2250
2. The National Technical Information Service
Springfield, VA 22161-0002
www.ntis.gov
1-800-553-6847 or, locally, 703-605-6000

A single copy of each NRC draft report for comment is available free, to the extent of supply, upon written request as follows:

Address: Office of the Chief Information Officer,
Reproduction and Distribution
Services Section
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
E-mail: DISTRIBUTION@nrc.gov
Facsimile: 301-415-2289

Some publications in the NUREG series that are posted at NRC's Web site address <http://www.nrc.gov/reading-rm/doc-collections/nuregs> are updated periodically and may differ from the last printed version. Although references to material found on a Web site bear the date the material was accessed, the material available on the date cited may subsequently be removed from the site.

Non-NRC Reference Material

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions, *Federal Register* notices, Federal and State legislation, and congressional reports. Such documents as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings may be purchased from their sponsoring organization.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at—

The NRC Technical Library
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

These standards are available in the library for reference use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from—

American National Standards Institute
11 West 42nd Street
New York, NY 10036-8002
www.ansi.org
212-642-4900

Legally binding regulatory requirements are stated only in laws; NRC regulations; licenses, including technical specifications; or orders, not in NUREG-series publications. The views expressed in contractor-prepared publications in this series are not necessarily those of the NRC.

The NUREG series comprises (1) technical and administrative reports and books prepared by the staff (NUREG-XXXX) or agency contractors (NUREG/CR-XXXX), (2) proceedings of conferences (NUREG/CP-XXXX), (3) reports resulting from international agreements (NUREG/IA-XXXX), (4) brochures (NUREG/BR-XXXX), and (5) compilations of legal decisions and orders of the Commission and Atomic and Safety Licensing Boards and of Directors' decisions under Section 2.206 of NRC's regulations (NUREG-0750).

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

Manuscript Completed: February 2004

Date Published: March 2004

Prepared by
A.R. Williamson

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001



Abstract

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides a valuable service to the staff of the Nuclear Regulatory Commission (NRC) through the advice and recommendations it gives staff.

To be able to advise staff effectively, it is important that the ACMUI have a basic understanding of its role and its responsibilities. Likewise, it is also important that the committee have a basic understanding of NRC processes and requirements. Such understanding creates an environment where the ACMUI can effectively advise the NRC staff. Effective advice, in turn, serves patients, the public, and the medical regulated community by helping the NRC staff develop regulations that promote safety and are useful, realistic, practical, and not overly burdensome on NRC medical licensees.

CONTENTS

Abstract	iii	
ESTABLISHMENT AND PURPOSE OF ACMUI		
Establishment of ACMUI	1	
Purpose of ACMUI.....	1	
INTERACTION BETWEEN THE ACMUI AND THE NRC STAFF		
Working Relationship Between the NRC and the ACMUI	2	
Nature of the NRC and the ACMUI Interaction	2	
The Designated Federal Official and the ACMUI Chairman	2	
Open Session and Closed Session Public Meetings.....	3	
ACMUI Compensation and Conduct	3	
INTERACTION BETWEEN THE ACMUI AND THE COMMISSION		
Purpose of Commission Briefings	5	
Briefing the Commission	5	
Outcome of ACMUI Commission Briefings.....	6	
STAFF HANDLING OF ACMUI RECOMMENDATIONS		7
TYPES AND PURPOSES OF ACMUI EVALUATIONS		8
References	9	

ESTABLISHMENT AND PURPOSE OF ACMUI

ACMUI'S Establishment

The U.S. Nuclear Regulatory Commission (hereafter, the NRC or Commission) established the Advisory Committee on the Medical Uses of Isotopes, or the ACMUI, in 1958. The ACMUI was established under the authority of the Federal Advisory Committee Act, and is executed under the provisions of 41 CFR Part 102, "Federal Advisory Committee Management", and the NRC's regulations contained within 10 CFR Part 7, "Advisory Committees."

As an advisory body that the Commission established for the express purpose of advising the NRC staff, the ACMUI provides advice that helps staff create medical regulations that are useful, realistic, practical, not overly burdensome, and not inappropriately intrusive in the practice of medicine. The ACMUI further assists the NRC staff by providing technical assistance in licensing, inspection, and enforcement cases; providing consulting services when necessary; and by bringing key issues to the attention of NRC staff for appropriate action.

The Commission has other professional advisory committees in addition to the ACMUI, and these other advisory committees may differ from the ACMUI somewhat in the manner in which they were established. For instance, the Advisory Committee on Reactor Safeguards (ACRS) was established by statute in the Atomic Energy Act of 1954. This is the only advisory body at the NRC that was established by statute, meaning that the ACRS can be disbanded only by an amendment to the Atomic Energy Act. By contrast, the ACMUI and the Advisory Committee on Nuclear Waste (ACNW) were both established by the Commission to serve at the pleasure of the Commission. Regardless how any particular advisory committee was established, all provide the same basic service and are equally valued and heard by the Commission.

Purpose of the ACMUI

The ACMUI's charter defines its purpose as providing advice on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The purpose statement in the charter further explains that the ACMUI provides this advice as requested by the Director, Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Materials Safety and Safeguards. In addition, the ACMUI provides consulting services to staff, as requested by the Director, IMNS. Administratively, the ACMUI reports to the Director, IMNS.

INTERACTION BETWEEN THE ACMUI AND THE NRC STAFF

Working Relationship Between the NRC and the ACMUI

As explained in the previous section, the ACMUI provides advice and consulting services directly to the NRC staff. The need for the ACMUI to provide this advice to staff necessitates a close working relationship. This means that staff and the ACMUI must communicate effectively so that staff fully understands the ACMUI's opinions regarding implications or consequences of proposed regulation.

Nature of the NRC and the ACMUI Interaction

The ACMUI is comprised of professionals from all over the country who have full-time positions with their primary employers. Because the ACMUI's busy professionals provide its services on a part-time basis, the ACMUI holds public meetings infrequently relative to the other NRC advisory committees. Furthermore, when the ACMUI meets, it often brings many regulatory issues to the attention of NRC staff. While the NRC staff always attempts to address these issues in a timely manner, the relative infrequency of the ACMUI's meetings, combined with the volume of issues, plus the diverse locations of the ACMUI members, are factors that can sometimes make maintaining adequate and accurate communication a challenge. Nonetheless, when the NRC staff and the ACMUI make an effort to interact sufficiently, important issues are kept at the forefront and the ACMUI's advice continues to help the NRC staff maintain public safety, while favorably impacting the regulated medical community.

The ACMUI typically holds public meetings twice per year. However, the committee meets more frequently when necessary.

The Designated Federal Official and the ACMUI Chairman

Two key persons help maintain effective ACMUI and NRC staff interaction: the ACMUI Chairman and the NRC's Designated Federal Official (DFO).

The ACMUI Chairman has several general duties related to position as Chair. These include presiding over ACMUI meetings and maintaining order and decorum; summarizing committee consensus votes or position statements; determining the composition of subcommittees; and adjourning ACMUI meetings. A complete description of the ACMUI Chairman's duties may be reviewed in the ACMUI Bylaws.

The DFO is a Federal government employee charged with the proper general execution of ACMUI meetings. No ACMUI meeting may be held unless the DFO is present, in accordance with the General Service Administration's regulations in 41 CFR Part 102 and the NRC's regulations in 10 CFR Part 7.

The DFO performs several duties that support the functioning of the ACMUI. These include convening and approving all ACMUI meetings; approving the agenda; attending all meetings; adjourning meetings when doing so is in the public interest; ensuring compliance with 10 CFR Part 7 in the generation of the minutes of ACMUI meetings; and chairing ACMUI meetings when so directed by the Commission. The DFO may also chair ACMUI meetings when the Chair is recused or in the absence of the Chair.

The ACMUI Chairman and the DFO work closely together to accomplish two overall objectives: (1) the effective use of ACMUI expertise to address and resolve emergent, timely, and relevant issues that affect the public and the regulated medical community; and (2) the officiation of ACMUI meetings in an open, orderly, publicly assessible manner.

Open Session and Closed Session Public Meetings

Because the ACMUI is an advisory committee whose activities are regulated under 41 CFR Part 102 and 10 CFR Part 7, the ACMUI must conduct its activities in an open forum that gives reasonable access to members of the public who may want to witness the meeting's proceedings or speak at the meeting.

Although most ACMUI meetings are held in a public forum, some meetings cannot be held publicly, because the ACMUI and NRC staff need to discuss certain sensitive information, such as safeguards information, that can be protected from public disclosure under the Government in the Sunshine Act. The regulations in 41 CFR and 10 CFR Part 7 allow the NRC staff to close meetings for such purposes.

Regardless of a meeting's status as open or closed, all meetings must be announced in the *Federal Register*, in accordance with the regulations in 41 CFR and in 10 CFR Part 7. While open-session meetings are announced to afford the public opportunities to view and/or speak at meetings, closed-session meetings are announced to inform the public of these meetings' occurrence, and why it is necessary that such meetings be closed.

ACMUI Compensation and Conduct

ACMUI members are compensated for their service to the Commission. This means that, while conducting ACMUI business, ACMUI members are a special class of Federal Government employees, working for the NRC. The NRC staff understands that the ACMUI is composed of stakeholder licensees, and as such, will represent licensee

concerns to some extent. This is not only inevitable, but desirable. Nonetheless, ACMUI members must remember that, as compensated Federal Government employees, they are subject to the laws and regulations on conflict of interest. Under those laws and regulations, they should not advise the NRC or 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 employers; or anyone else with whom they have a business relationship. ACMUI members also must not inappropriately advance the views or positions of professional associations or the regulated community.

Whenever a conflict-of-interest issue arises, the affected ACMUI member must recuse himself or herself from voting on the particular activity that will cause the conflict of interest.

INTERACTION BETWEEN THE ACMUI AND THE COMMISSION

Purpose of Commission Briefings

The ACMUI interacts with the Commission primarily through formal, publicly announced briefings. Briefings are scheduled adjacent to the Spring ACMUI public meetings, whenever possible.

The ACMUI's briefing to the Commission typically consists of an update of major initiatives for which the Committee has provided advice to staff. The briefing is also an opportunity for the ACMUI to receive the Commission's feedback and/or positions on initiatives that are important to the ACMUI, the regulated medical community, and other stakeholders.

The Commission has a strong interest in being kept abreast of new or evolving technologies or issues that it should monitor, so that NRC staff can respond in a timely and effective fashion to those issues, in its regulations or regulatory guidance. Therefore, the ACMUI should always brief the Commission on such items.

Before each scheduled Commission briefing, the Commission requires the ACMUI to forward, via the NRC staff, an agenda of the items to be discussed. The Commission has final approving authority on agenda topics.

Briefing the Commission

It is desirable for the ACMUI to brief the Commission at least annually, but this is not always possible. Conflicting schedules and competing priorities amongst the ACMUI and the Commission can interfere with Commission availability, although such conflicts are rare. The NRC staff is responsible for scheduling committee briefings to the Commission.

Although the Commission appreciates any updates and insights the ACMUI may disclose during briefings, ACMUI members should note that briefing the Commission should not be viewed as a perfunctory exercise. Rather, it is desirable that the ACMUI limit briefings to the Commission to instances when the committee has meaningful information to share.

Outcome of ACMUI Commission Briefings

As stated previously, the ACMUI's briefing to the Commission is a good opportunity to obtain Commission feedback and/or positions on initiatives that are important to the ACMUI, the regulated medical community, and other stakeholders. During the course of a briefing, the Commission may expound, to some extent, on the numerous and divergent issues that the ACMUI raises, and may appear to come to conclusions regarding those issues. After the briefing, however, the Commission will thoroughly consider those issues, and its final decisions may be slightly different than what the ACMUI anticipated. The ACMUI should be aware of this possibility, and keep in mind that the Commission will commit to a certain course of action only after thorough, thoughtful consideration of issues.

Based on its decision, the Commission will then direct staff, by use of a Staff Requirements Memorandum (SRM), to take a certain course of action. The staff may take action only in accordance with the mandates in the SRM, and may not take action based on conversations between the Commission and the ACMUI during briefings.

STAFF HANDLING OF ACMUI RECOMMENDATIONS

While conducting public meetings, the ACMUI often forms recommendations, which become matters of public record. These recommendations usually require some sort of formal staff action.

After ACMUI meetings, the staff reviews the ACMUI's recommendations and determines whether they should be modified, disapproved, or adopted as stated. Whether modified, disapproved or adopted, NRC staff will provide a basis for its decision. The NRC staff will always carefully consider the ACMUI's recommendations, but not all may be accepted. When there is strong ACMUI disagreement with the NRC staff regarding a recommendation, the ACMUI should consider revising the recommendation, for further NRC consideration and review.

It is helpful if the ACMUI keeps in mind that the NRC staff evaluates recommendations not only for their feasibility and sound regulatory value, but also to determine if they will likely be met with strong objections from other stakeholders such as Congress or the general public. If the NRC staff determines that any recommendation will likely be met with strong public disapproval, the ACMUI should consider modifying that recommendation.

Whether the NRC staff accepts or rejects any ACMUI recommendation, the staff forwards all recommendations to the Commission. The ACMUI should be aware that it is not normal Commission practice to respond directly to the ACMUI (or any other advisory committee) regarding a recommendation the committee made. Rather, the Commission reviews the recommendation(s), makes regulatory decisions, and directs staff to take further action through an SRM.

TYPES AND PURPOSES OF ACMUI EVALUATIONS

The Commission requires two types of evaluations of the ACMUI:

- 1) Staff evaluations of the ACMUI, and;
- 2) ACMUI evaluations of itself.

The staff evaluates the ACMUI to give the Commission feedback on the performance of the committee. Likewise, the purpose of ACMUI self-evaluations is for the committee to inform the Commission as to how well it is fulfilling its purpose.

Evaluations are important for several reasons. First, they are a tool that helps the Commission determine whether the committee is functioning as intended. Second, they help identify any issues that may impede the committee's ability to serve the staff effectively. Finally, they help the Commission justify the expenditure of NRC resources to support committee activities.

Evaluations are due every 2 years, and the NRC staff will initiate them. It is important that all committee members respond to the evaluation, so that the Commission receives a complete depiction of the committee's efforts to fulfill its purpose.

References

Code of Federal Regulations, *Title 10, Energy*, Part 35, "Medical Use of Byproduct Material."

Code of Federal Regulations, *Title 41, Public Contracts and Property Management*, Part 102, "Federal Advisory Committee Management."

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev.,
and Addendum Numbers, if any.)

NUREG/BR-0309

2. TITLE AND SUBTITLE

Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI):

A Member's Guide

3. DATE REPORT PUBLISHED

MONTH | YEAR

March | 2004

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

Angela R. Williamson

6. TYPE OF REPORT

7. PERIOD COVERED *(Inclusive Dates)*

8. PERFORMING ORGANIZATION - NAME AND ADDRESS *(If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)*

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

9. SPONSORING ORGANIZATION - NAME AND ADDRESS *(If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)*

Same as above.

10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) provides a valuable service to the staff of the Nuclear Regulatory Commission (NRC) through the advice and recommendations it gives staff.

To be able to advise staff effectively, it is important that the ACMUI have a basic understanding of its role and its responsibilities. Likewise, it is also important that the committee have a basic understanding of NRC processes and requirements. Such understanding creates an environment where the ACMUI can effectively advise the NRC staff. Effective advice, in turn, serves patients, the public, and the medical regulated community by helping the NRC staff develop regulations that promote safety and are useful, realistic, practical, and not overly burdensome on NRC medical licensees.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

ACMUI
Medical
Designated Federal Official

13. AVAILABILITY STATEMENT

unlimited

14. SECURITY CLASSIFICATION

(This Page)

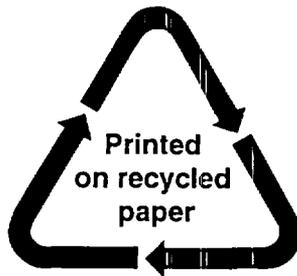
unclassified

(This Report)

unclassified

15. NUMBER OF PAGES

16. PRICE



Federal Recycling Program

NUREG/BR-0309

SERVING ON THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES (ACMUI): A MEMBER'S GUIDE

MARCH 2004

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS