POLICY ISSUE
NOTATION VOTE

April 1, 2011 SECY-11-0049

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES REPORTING STRUCTURE: OPTIONS, ANALYSIS, AND PROPOSED IMPLEMENTATION PLANS

PURPOSE:

Staff Requirements Memorandum (SRM) M100708B, "Briefing on Proposed Rule on Part 35 Medical Events Definitions—Permanent Implant Brachytherapy," dated July 21, 2010, directed the U.S. Nuclear Regulatory Commission (NRC) staff to work with the Office of the General Counsel to outline possible improved mechanisms for providing the Commission with feedback from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) about medical issues, including the pros and cons of restructuring ACMUI so that it reports to the Commission. The Commission also directed the staff in SRM M100708B to provide an implementation plan that would be used to effect such a restructuring should the Commission decide to move forward. This paper responds to those directives and does not address any new commitments.

SUMMARY:

This paper provides background information about ACMUI, explains how the NRC staff explored potential configurations for the ACMUI reporting structure, and provides options for the Commission's consideration, along with the staff's and ACMUI's recommendations. The first option discussed in this paper maintains the current ACMUI reporting structure. The second option provides that ACMUI report to the Commission through the Office of the Advisory Committee on Reactor Safeguards (ACRS). The staff recommends that the Commission

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approve Option 1, whereby ACMUI will continue to report to the Director of the Division of Materials Safety and State Agreements (MSSA) in the Office of Federal and State Materials and Environmental Management Programs (FSME), because the staff believes that the current reporting structure, supplemented by certain modifications to procedures governing interactions, provides for the most effective and efficient interface with ACMUI on medical policy issues. The ACMUI has also formally recommended that the staff maintain the current reporting structure with certain modifications.

BACKGROUND:

History

Congress created the Atomic Energy Commission (AEC) in 1947, and, in 1948, the Advisory Committee on Isotope Distribution (ACID) was established to advise the AEC on the development of policies for the distribution of radioisotopes. ACID was composed of two subcommittees: (1) the Subcommittee on Human Applications (SHA) and (2) the Subcommittee on General Applications. In a SECY paper dated July 9, 1958, "Proposed Advisory Committee on Medical Uses of Isotopes," (Agencywide Documents Access and Management System (ADAMS) Accession Number ML11069A046) the staff proposed that the Commission abolish ACID and create ACMUI "to provide advice to AEC on policies and standards for the licensing of radioisotopes for medical uses in humans." ACID was abolished, and, in 1959, SHA was absorbed into what is now known as ACMUI. The original ACMUI charter was created in 1959, and the Director, Division of Licensing and Regulation, served as the chair of the Committee. In 1974, the AEC's responsibilities were transferred to the NRC by the Energy Reorganization Act of 1974, but ACMUI's name, functions, and reporting structure remained unchanged.

Purpose and Structure

The Commission established ACMUI under the authority of the Atomic Energy Act of 1954. The activities of ACMUI are subject to the Federal Advisory Committee Act (FACA), and FACA's government wide implementing regulations promulgated by the U.S. General Services Administration (GSA), and NRC's regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 7, "Advisory Committees."

Under the ACMUI charter filed on March 16, 2010, ACMUI reports to the MSSA Director in FSME on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy and may provide consulting services, as requested by the MSSA Director. As an advisory body that the Commission established for the purpose of advising the staff, ACMUI provides advice that helps the staff develop medical regulations that are useful, realistic, and practical, while considering effects on the medical community and avoiding intrusion into the practice of medicine. ACMUI further assists the staff by providing technical assistance and by bringing key issues to the attention of the staff. Committee members have also served the NRC as medical consultants.

Committee membership includes health care professionals from various disciplines. ACMUI is composed of the following positions: a nuclear medicine physician, a nuclear cardiologist, a medical physicist in nuclear medicine unsealed byproduct material, a medical physicist in radiation therapy, a radiation safety officer, a nuclear pharmacist, two radiation oncologists, a

patients' rights advocate, a U.S. Food and Drug Administration representative, an Agreement State representative, a health care administrator, and a diagnostic radiologist. Enclosure 1 lists current members, and Enclosures 2 and 3 provide the ACMUI charter and bylaws, respectively.

Previous Commission Direction

In SRM SECY-97-012, "Appointments of a Physician Practicing Nuclear Cardiology, a Patients' Rights and Care Advocate, and an Individual with State or Local Government Perspective to the Advisory Committee on the Medical Uses of Isotopes," dated February 18, 1997 (Enclosure 4), the Commission directed the staff to describe the pros and cons of having ACMUI recommendations provided directly to the Commission. The staff responded in a memorandum, "Response to Staff Requirements Memorandum SECY-97-012 – Pros and Cons of Having Advisory Committee on the Medical Use of Isotopes Recommendations Provided Directly to the Commission, Concurrent with Such Provisions to the Staff," dated August 5, 1997 (Enclosure 5), with the understanding that the Commission's request focused on whether or not ACMUI should communicate with the Commission following the same process as ACRS. The staff did not recommend changes to the existing process but confirmed that, in accordance with SRM COMSECY-93-013, "Guidelines on the Role, Procedures, Size, and Composition of the ACMUI," dated April 16, 1993 (Enclosure 6), ACMUI developed bylaws and "now provides minutes to the Commission containing the Committees' recommendations, including dissenting opinions." Currently, in place of meeting minutes, ACMUI generates meeting transcripts and a meeting summary, and, with advancements in technology, makes these documents readily available on the NRC's public Web site: http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html. In the 1997 staff memorandum, the staff further stated that it believed that "the current process is adequate to deliver ACMUI recommendations and opinions to the Commission in a timely manner" and that "further movement toward an ACRS…process would add further inefficiencies and unnecessary complexity."

ACMUI Operations

A. Meetings

ACMUI meetings are typically held semiannually, and the Committee holds teleconference meetings when important issues emerge or when issues need timely resolution. Although the primary function of the Committee is to serve the needs of the NRC staff, in SRM COMSECY-93-013 (Enclosure 6), the Commission asked ACMUI to provide an annual briefing to the Commission.

B. Recommendations

Currently, the staff summarizes ACMUI's recommendations in a meeting summary, which is posted on the NRC's public Web site, and the NRC staff provides feedback to ACMUI about the outcome of all Committee recommendations in a memorandum to the Committee Chair and during subsequent meetings. For fiscal years (FYs) 2007 through 2010, ACMUI made 103 recommendations. The staff accepted approximately 91 percent of the recommendations, which have been or will be implemented (e.g., recommendations about current or future guidance and rulemaking). Approximately 4 percent of the recommendations were partially accepted, and only 5 percent of the recommendations were not accepted. In comparison, the GSA reported

for FY 2009 that, for 954 committees advising Federal agencies, only 10 percent of committee recommendations have been or will be fully implemented. The NRC staff strongly values ACMUI's input, as reflected in the high acceptance rate for recommendations.

C. Costs

As required by 10 CFR 7.17, "Reports Required for Advisory Committees," a report is sent to GSA annually of the activities and responsibilities of ACMUI, which includes the FY costs of the ACMUI. The staff calculated ACMUI direct costs at approximately 2.4 full-time equivalents (FTEs) ($350,000) and 2.0 FTEs ($300,000) for FYs 2009 and 2010, respectively. The direct costs are based on staff resources to support two full Committee meetings each year, subcommittee meetings as needed, and ongoing maintenance of Committee operations.

Over the past 10 years, ACMUI costs have increased significantly. As mentioned above, the FY 2009 annual report to GSA identified costs at $350,000, compared to just $135,000 in 1999. This 160-percent increase over a 10-year period can be attributed to the increasing costs for salaries and benefits, as well as increased workload for ACMUI, especially during times of rulemaking and development of guidance for new technologies. Because the staff is embarking on major rulemaking for 10 CFR Part 35, "Medical Use of Byproduct Material," additional ACMUI effort is expected in the coming years.

Comparison to ACRS

In addition to ACMUI, the NRC has another professional advisory committee, ACRS. ACRS was established by statute in the Atomic Energy Act of 1954. It is the only NRC advisory body that was established by Congress. By contrast, ACMUI was established by the Commission. In 2010, ACRS held 10 full committee meetings and 79 subcommittee meetings to review and report on safety studies and reactor facility license and license renewal applications, to advise the Commission on the hazards of proposed and existing production and utilization facilities and the adequacy of proposed safety standards, to initiate reviews of specific generic matters or nuclear facility safety-related items, and to provide advice in the areas of health physics and radiation protection. ACRS also submitted 61 letter reports to the NRC in 2010.

DISCUSSION:

The NRC staff worked internally, coordinating and consulting with the ACRS staff, and sought input from ACMUI in order to identify and develop options and to make recommendations for ACMUI's reporting structure. The staff received input from ACMUI on its reporting structure and possible improvements during two public teleconferences on January 5 and January 12, 2011. During the second public teleconference, ACMUI posed several questions on topics it believed

should be evaluated and answered when considering the ACMUI reporting structure. The NRC staff agreed that these questions were valuable in focusing its analysis. These questions were considered in developing the options and used to form the bases for the discussion of each option described in this paper:

- How does the Commission receive information on medical issues in order to make decisions?
- How does the staff gain access to medical expertise?
- What is the best way for ACMUI to provide advice and ask questions to staff? To the Commission?
- How should the needs of the Commission, staff, and ACMUI be considered in how the ACMUI reports?
- What are the logistical pros and cons for the ACMUI reporting to NRC staff? To the Commission?

Options for Reporting Structure

The NRC staff identified and developed the following two options for the ACMUI reporting structure:

(1) Report to the MSSA Director in FSME (current structure).
(2) Report to the Commission through the ACRS Executive Director.

FSME and ACRS offices have existing infrastructures to support Federal advisory committees, so the staff did not consider other options for ACMUI reporting through different offices because this was thought to be cost prohibitive.

A. Option 1

This option maintains the current structure of ACMUI reporting to the MSSA Director. In SRM M100708B, the Commission had also requested that the staff develop internal guidance. In accordance with SRM M100708B, the staff recently implemented FSME Policy and Procedure (P&P) 2-5 (ADAMS Accession No. ML100640259) for providing ACMUI viewpoints to the Commission. FSME P&P 2-5 was finalized on January 12, 2011, and describes how the staff includes ACMUI's recommendations and dissenting views, along with the staff's assessment of the recommendations and dissenting views, for all major medical policy issues submitted to the Commission, including proposed and final rules. The implementation of the guidance more clearly formalizes the staff's working relationship with ACMUI and provides a clear pathway for the staff to transmit ACMUI recommendations to the Commission.

Currently the FSME staff develops policy and is responsible for implementation of the medical program. ACMUI provides the staff with perspectives from the regulated medical community. The staff seeks the advice of ACMUI, as needed, and receives input from the Committee during public meetings and through Committee reports. ACMUI members can ask questions to staff during public meetings or by contacting the ACMUI Project Manager, Designated Federal Officer, or MSSA Director. ACMUI members can also provide medical expertise to the staff by serving as medical consultants to review medical events.

The staff believes that ACMUI has significant opportunities to interact with the Commission and that the Commission can proactively engage ACMUI whenever needed under the current structure. Opportunities for ACMUI members to have direct interactions with the Commission include being able to ask specific questions to the Commission during annual Commission briefings, having the ACMUI Chair ask questions or provide perspectives on behalf of the Committee during drop-in meetings with individual Commissioners, or writing a letter to the Commission to provide an opinion or ask a question. Under this option, the staff believes that the Commission's needs for advice from ACMUI can be met using the new FSME P&P 2-5 procedure, which requires Commission papers to clearly indicate the ACMUI position.

Option 1 Strengths

The primary benefit to maintaining ACMUI's current reporting structure is that the Committee is able to provide early input on medical policy issues, which leads to better informed and more effective regulations and guidance. Also, fewer additional resources are required than for restructuring ACMUI as described in Option 2, because the existing FSME administrative, technical, and managerial organizational structure can continue to support ACMUI. Lastly, maintaining the current structure would not require the staff to revise any existing documents, policies, or resources; therefore, workflow for both the staff and ACMUI would not be disrupted for restructuring activities.

Option 1 Limitations

This option has the potential of leading to the misperception among ACMUI members or the Commission of limited access or filtered communication through the staff to the Commission. Previous ACMUI members expressed concerns that they did not have the same stature or access to the Commission as ACRS. In addition, under the current structure, the Commission works through the staff to request advice or other input from ACMUI and use ACMUI's expertise.

B. Option 2

The second option that the staff considered was ACMUI reporting to the Commission through the ACRS Executive Director, which would result in the Commission receiving advice directly from ACMUI. The staff assumed that this would be the next most efficient option after Option 1 because the ACRS office currently has the infrastructure to support Federal advisory committees. By adopting a process similar to that of the current model of operations for ACRS, ACMUI could provide advice directly to the Commission through

letter reports, and the Office of the Executive Director for Operations could provide responses. Other communication models could be considered; however, other models could affect the resource assumptions made in this paper. The Commission or ACMUI may wish to increase the frequency of ACMUI public meetings or drop-in meetings to parallel that of ACRS and to further enhance communication. Under this option, ACMUI would not directly provide advice to the staff but would be able to ask questions to the staff during public meetings or by contacting designated ACRS staff members. In addition, the ACMUI bylaws, ACMUI charter, and existing FSME procedures would need to be reviewed and revised to reflect the new reporting structure and modified processes for operations.

The ACRS staff estimates that additional resources of $1,000,000, which includes contract and FTE support, would need to be added to the ACRS office budget should the ACMUI be administered by the ACRS office. This estimate is based on the current cost of the ACMUI for committee members, staff technical support, travel expenses and logistical support. The estimate is slightly higher than the current costs associated with the ACMUI due to the lack of medical expertise existing within the current ACRS staff composition.

FSME would not be able to transfer any existing staff currently budgeted to support ACMUI activities because staff dedicated to supporting ACMUI activities also perform other medical radiation safety duties, such as supporting the development of policy and implementation of the medical program. With regard to administrative support, many FSME staff members, primarily those involved in timekeeping, processing of official agency paperwork for travel and appointments of members, and other administrative functions, are not solely dedicated to supporting ACMUI business. Their time is intermittently allocated to support the Committee on an as-needed basis, along with their normal duties. Management support for the oversight of ACMUI operates in a similar manner (e.g., performed along with other responsibilities). Furthermore, FSME would need to maintain staff to interface with ACMUI during public meetings. Although FSME would not be able to transfer existing staff, FSME may be able to transfer fractional FTE to the ACRS Office to support the ACMUI.

Under this option, FSME would also need to hire or contract medical experts (e.g., radiation oncologist, nuclear pharmacist, nuclear medicine physician) to advise the staff on issues such as rulemaking. The FSME staff estimates that the hiring or contracting of medical experts to advise the staff on issues such as rulemaking would cost $76,000 (equivalent to 0.5 FTE) in addition to the resources currently allocated to support staff for the medical program. The staff expects to continue to have access to ACMUI members as medical consultants for the purposes of reviewing medical events, so no additional resources are expected in this area.

Option 2 Strengths

Under this option, the Commission may benefit from direct access to medical-expert advice from ACMUI. ACMUI may have (or attain) the same stature as ACRS, have increased access to ACRS facilities, and have more dedicated resources to support

Committee operations. In addition, this structure would not lead to any potential misperceptions that the staff filters Committee positions and recommendations in any manner.

Option 2 Limitations

The staff estimates that a change in the ACMUI reporting structure would require additional resources in ACRS and FSME to support both ACMUI and the existing medical program. As mentioned previously, FSME would need to maintain existing staff to support ACMUI functions and cannot transfer any existing staff to ACRS. Additionally, medical program implementation issues, including those that arise from Agreement States, fall under the responsibility of MSSA in FSME, so few ACMUI issues, except for rulemaking, rise to the level of policy issues for the Commission. For example, the staff seeks advice from ACMUI to develop licensing guidance and to revise regulatory guides, and these types of activities do not typically require the involvement of the Commission. Furthermore, ACMUI is not statutorily mandated by Congress to advise the Commission. In contrast, ACRS issues usually span multiple offices at the NRC, and ACRS is statutorily mandated by the Atomic Energy Act of 1954. Also, there is potential for increased ACMUI workload as a result of more frequent meetings and additional subcommittees, assuming that the Commission implements communication pathways and meeting schedules for ACMUI that are similar to those currently in place for ACRS. This may have a negative impact on the NRC's ability to recruit and retain medical experts, who may have limited time available because of their involvement in their regular professional activities, such as patient treatment or teaching. Lastly, time and resources would be required to revise procedures and Committee documents to reflect the new structure and Committee operations, which could lead to interruption in workflow during the transition period.

ACMUI Position

ACMUI formally recommended that the "staff should maintain the current reporting structure for the ACMUI with enhancements in communication as described in FSME Policy and Procedure 2-5." Furthermore, ACMUI recommended that additional staff resources are needed to support current and future ACMUI efforts. More specifically, Committee members agreed unanimously that "there needs to be additional technical and administrative staff support for ACMUI operations." Lastly, ACMUI recommended that the Committee consider its reporting structure annually as an agenda item to reevaluate ACMUI's satisfaction with it.

During the January 12, 2011, public teleconference, ACMUI agreed that "the current arrangement seems to work well," given the ACMUI Chair's experience and the assurances of ACMUI access, as needed, to the Commissioners. Additionally, the Committee did not "see a tangible advantage or a tangible benefit to changing the current arrangement" and thought that "the interactions with the staff seem to be cordial, productive, [and] effective." The ACMUI Chair further stated that "there was concern in the past by members of the ACMUI, who are not currently members of the Committee…with regard to making certain that the opinions rendered by the ACMUI were transmitted to the Commissions in an unfiltered manner." However, the ACMUI Chair did not believe that the membership thought this reflected the current state of operations and stated that the Committee was "very fortunate in [its] current relationships and staffing." Additionally, the ACMUI Chair commented, "I think that our access today is better than it ever has been and that our staff

support today is better than it ever has been, without being critical of staff support in the past." During the teleconference, members also raised concerns about the perception of ACMUI as a secondary or subordinate organization within the ACRS office, even with a direct reporting structure to the Commission, since ACRS "has traditionally been committed to reactor issues."

Implementation Plans

For Option 1, the staff implemented FSME P&P 2-5, as directed in SRM M100708B. No additional changes would be made; however, based on the ACMUI recommendation from the January 12, 2011, teleconference, the staff would consider increased resources for support staff in the 2013 budget. The Commission and ACMUI would continue to have the option to meet annually. Additionally, ACMUI tasked itself to discuss the effectiveness of its reporting structure annually during regularly scheduled meetings and to provide recommendations to the staff if improvements or changes are necessary.

For Option 2, several activities would need to be undertaken to implement the change. First, FSME staff would need to work closely with ACRS staff and ACMUI to best determine where ACMUI would fit organizationally in the ACRS office. The ACRS office proposes use of the current technical branches in combination with contractors or consultants to provide medical health physics expertise and project management support. ACMUI administrative support functions for documents, time reported, and travel paperwork could be performed by the current ACRS Program Management, Development and Analysis staff. As discussed above under Option 2, this option would require the use of new and existing resources in the ACRS office, and FSME would not be in a position to transfer any existing staff to the ACRS office.

In addition, the staff would need to examine current ACMUI policy and procedures, compare them to those of ACRS, and revise them, as needed, to accommodate the new reporting structure and operations. ACMUI would also need to consider a revised meeting schedule to meet potential new workload demands. Finally, FSME would need to examine options and determine an approach for hiring or contracting independent medical experts.

RECOMMENDATION:

The staff recommends approval of Option 1. The staff believes that Option 1, with the implementation of FSME P&P 2-5, provides appropriate opportunities for ACMUI to interact with the Commission and to advise the staff on policy and technical issues that arise in the regulation of the medical uses of byproduct material in diagnosis and therapy, while minimizing cost to the agency by making effective use of existing agency resources. It also would not be disruptive to current activities or require time and resources to support changes in reporting structure or operations.

During the January 12, 2011, ACMUI public teleconference, the ACMUI members also supported Option 1 because they did not identify any clear advantages or benefits to changing the current reporting structure. Furthermore, the ACMUI members indicated that the quality of current staff and management support is of very high caliber and that current interactions with the staff were effective. The ACMUI members also indicated that they had available means to directly communicate with Commissioners if they chose to do so. The ACMUI members requested additional support staff, which the NRC staff is considering, and committed to reviewing the efficacy of their reporting structure annually during meetings.

Under Option 1, the staff would continue to interact with ACMUI in accordance with FSME P&P 2-5 for major medical policy issues, including rulemaking, and provide ACMUI recommendations, along with the staff's evaluation of the recommendations, to the Commission.

RESOURCES:

Under Option 1, FSME plans to address the ACMUI recommendation to increase resources to support Committee activities as part of the NRC's official FY 2013 Planning, Budgeting, and Performance Management process. At this time, implementation of this option (e.g., procedure development and implementation) are budgeted for 2.3 FTE in both the President's Budget for FY 2011 and Budget Request for FY 2012.

Option 2 would require new additional budgeted resources and would be developed during the FY 2013 Planning, Budgeting, and Performance Management process.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. This paper represents the views and recommendations of ACMUI, and ACMUI received a draft for information during the concurrence process.

The staff requests that this paper be made publicly available. It is currently marked as official use only because Enclosures 4, 5, and 6 are non-public legacy documents that relate to internal procedural matters. However, the staff concludes that in the current environment of openness, they should be made publicly available because they no longer contain sensitive information.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:
1. ACMUI Membership
2. ACMUI Charter
3. ACMUI Bylaws
4. SRM SECY-97-012
5. 8/5/97, Response to SRM SECY-97-012
6. SRM COMSECY-93-013

ACMUI Membership

Name	Position	
Darrell Fisher, Ph.D.	Patients' Rights Advocate	
Debbie Gilley	State Government Representative	
Milton Guiberteau, M.D.	Diagnostic Radiologist	
Susan Langhorst, Ph.D.	Radiation Safety Officer	
Leon Malmud, M.D.	Hospital Administrator	Chairman
Steve Mattmuller	Nuclear Pharmacist	
appointment currently being processed	Nuclear Medicine Physician	
John Suh, M.D.	Radiation Oncologist	
Orhan Suleiman, Ph.D.	U.S. Food and Drug Administration	
Bruce Thomadsen, M.D.	Therapy Physicist	Vice Chairman
William Van Decker, M.D.	Nuclear Cardiologist	
James Welsh, M.D.	Radiation Oncologist	
Pat Zanzonico, Ph.D.	Nuclear Medicine Physicist	

UNITED STATES NUCLEAR REGULATORY COMMISSION
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

1. **Committee's Official Designation**:

   Advisory Committee on the Medical Uses of Isotopes (ACMUI)

   Established Pursuant to Section 9 of Public Law 92-463 as an NRC discretionary committee.

2. **Committee's objectives, scope of activities and duties are as follows:**

   The Committee provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, MSSA.

3. **Time period (duration of this Committee):**

   Continuing Committee.

4. **Official to whom this Committee reports:**

   Director, Division of Materials Safety and State Agreements
   Office of Federal and State Materials and Environmental Management Programs
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. **Agency responsible for providing necessary support to this Committee:**

   U.S. Nuclear Regulatory Commission.

6. **The duties of the Committee are set forth in Item 2 above**.

7. **Estimated annual direct cost of this Committee:**
   Members are appointed by the Director, FSME as Special Government Employees (SGEs). Approximately 13 members utilize 2.3 full-time equivalents (FTE) (includes approximately 1.6 FTE for NRC staff and 0.7 FTE for ACMUI member compensation and travel).

8. **Estimated number of meetings per year:**

Five meetings per year, three of which are teleconferences.

9. **The Committee's termination date.**

Continuing Committee subject to Charter renewal on March 17, 2012.

10. **Filing date:**

March 16, 2010.

Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the Commission

ACMUI
OCTOBER 24, 2006

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

Enclosure 3

CONTENTS

PREAMBLE

These bylaws describe 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 the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the ACMUI's responsibility to provide objective and independent advice to the Commission through the Office of Federal and State Materials and Environmental Management Programs (FSME), with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, and that the resulting reports represent, to the extent possible, the best of which the ACMUI is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

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

1.1 Scheduling of Meetings:

1.1.1 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the ACMUI will be scheduled each year, one in the spring and one in the fall. Additionally, the ACMUI will meet with the Commission, unless the Chair or designated Chair declines or the Commission declines.

1.1.2 Special meetings (e.g., teleconferences and subcommittee meetings) will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the ACMUI will be transcribed. During those 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.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the ACMUI (referred to below as “the Chair”) in consultation with the FSME staff. The Designated Federal Officer must approve the agenda. The Chair, with the FSME staff’s assistance, will query ACMUI members for agenda items prior to agenda preparation. A draft agenda will be provided to ACMUI members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the ACMUI will review the findings of the Office of the General Counsel (OGC) regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the U.S. Nuclear Regulatory Commission's (NRC) OGC.

1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.

1.3.4 The Chair 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 Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

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

2. MINUTES/TRANSCRIPTS

2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.

2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.

2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.

2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

3.1 The members of the ACMUI are appointed by the Director, FSME, 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, FSME. The term of an appointment to the ACMUI is 4 years, and the Commission has determined that no member may serve more than 2 consecutive terms (8 years).

3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.

3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

4. CONDUCT OF MEMBERS

4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

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

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

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

5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.

5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 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.

February 18, 1997

MEMORANDUM TO: Leonard J. Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-012 - APPOINTMENTS OF A PHYSICIAN PRACTICING NUCLEAR CARDIOLOGY, A PATIENTS' RIGHTS AND CARE ADVOCATE, AND AN INDIVIDUAL WITH STATE OR LOCAL GOVERNMENT PERSPECTIVE TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The Commission has approved publication of the proposed Federal Register notice calling for nominations for the three positions on the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

In addition to sending the notice calling for nominations to each of the State radiation control program offices, or equivalent offices, and soliciting the organizations listed in Attachments 3 and 4 for nominations, the staff should also solicit the Conference of Radiation Control Program Directors (CRCPD) and the Organization of Agreement States for nominations. Additionally, the staff should provide the notice calling for nominations to the Health Physics Society and any other national organizations whose members include health physicists who could represent the State or local government perspective.

Regarding the earlier direction of the Commission in the April 19, 1993 SRM on COMSECY-93-014, the Commission directed the staff to expand its recruitment beyond individuals from Agreement States, but it did not intend that the staff exclude them.

SECY NOTE: THIS SRM AND SECY-97-012 AND THE COMMISSION VOTING RECORD CONTAIN PERSONNEL ISSUES AND WILL BE LIMITED TO NRC UNLESS THE COMMISSION DETERMINES OTHERWISE.

The following changes should be made to the proposed Federal Register notice:

1. The summary paragraph should be repeated in the Supplementary Information section by inserting it as the third paragraph, i.e., before the paragraph that provides instructions on filing of resumes.

2. On page 1 of the Federal Register notice, in the SUMMARY section, the following should be added to the end of the first sentence: 'to fill current and upcoming committee vacancies.'

3. On page 1 of the press release, the following should be added to the end of the first sentence: 'to fill current and upcoming committee vacancies.'

(EDO) (SECY Suspense: 3/14/97)

In addition, the staff should report back to the Commission on the pros and cons of having ACMUI recommendations provided directly to the Commission, concurrent with such provision to the staff.

(EDO) (SECY Suspense: 6/27/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
OCA
OIG

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 5, 1997

MEMORANDUM TO: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM SECY-97-012 - PROS AND CONS OF HAVING ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES RECOMMENDATIONS PROVIDED DIRECTLY TO THE COMMISSION, CONCURRENT WITH SUCH PROVISION TO THE STAFF

Staff Requirements Memorandum - SECY-97-012, "Appointments of a Physician Practicing Nuclear Cardiology, a Patients' Rights and Care Advocate, and an Individual with State or Local Government Perspective to the Advisory Committee on the Medical Use of Isotopes" (ACMUI), directed the staff to "report back to the Commission on the pros and cons of having ACMUI's recommendations provided directly to the Commission, concurrent with such provision to the staff" (Attachment 1). Staff's understanding of the Commission's request focuses on whether or not ACMUI should communicate with the Commission following the same process as that used by the ACRS and ACNW. The ACRS and ACNW are Commission level Committees with dedicated staff to accommodate the technical and administrative issues associated with conducting the affairs of those Committees including providing their recommendations to the Commission. In contrast, ACMUI functions are supported by staff within the Division of Industrial and Medical Nuclear Safety.

The current process for providing ACMUI comments is based on direction from the Commission on April 16, 1993, in COMSECY-93-013, "Guidelines on the role, procedures, size, and composition of the Advisory Committee on the Medical Use of Isotopes" (Attachment 2). This guidance was developed in response to a review of all government advisory committees in accordance with President's general directions on the use of advisory committees. At that time, the Commission explored the role of all NRC Advisory Committees including the ACMUI and provided specific direction to staff. Some of the key points of the Commission direction were: ACMUI should provide an annual briefing to the Commission, develop bylaws governing communication between the Committee and the Commission similar to ACRS, and "the Committee should continue to interact with staff to provide such support as the staff may deem warranted to help accomplish its regulatory missions."

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Enclosure 5

As a result of this direction, substantial changes were made in the conduct of ACMUI affairs including the development of bylaws for the Committee. ACMUI now provides minutes to the Commission containing the Committees' recommendations, including dissenting opinions which was not done previously. In providing this direction, the Commission appears to have explored ACMUI as a Commission level Advisory Committee but chose to continue with the Committee as a staff level advisory Committee but "encouraged the Committee to adopt bylaws governing communications between the Committee and the Commission along the lines of the bylaws that have been adopted by the ACRS."

Recently, ACMUI raised concerns as to how its recommendations are considered with respect to the ultimate outcome of regulation and guidance development. Staff has in response, initiated two significant changes in this regard which were discussed with the ACMUI during its last meeting. First, the staff will include a line item in the Statements of Consideration for all medical use rulemakings that would address the outcome of ACMUI recommendations. Secondly, the staff now provides feedback to ACMUI, during subsequent meetings on the outcome of all Committee recommendations other than rulemaking.

The staff believes the current process is adequate to deliver ACMUI recommendations and opinions to the Commission in timely manner. Currently, the minutes are prepared by the staff in close coordination with the Chairman of the ACMUI, then reviewed and signed by the Chairman. Staff believes further movement toward an ACRS and ACNW process would add further inefficiencies and unnecessary complexity.

In light of the above, the staff does not recommend any change to the current procedures or process.

Attachments: 1. SRM - SECY-97-012
2. COMSECY-93-013

cc: SECY
OGC
OCA
OPA
CFO
CIO

April 16, 1993

MEMORANDUM FOR: James M. Taylor, Executive Director for Operations

FROM: Samuel J. Chilk, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - COMSECY-93-013 GUIDELINES ON THE ROLE, PROCEDURES, SIZE AND COMPOSITION OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The Advisory Committee on the Medical Uses of Isotopes has served the Commission and the NRC staff well and should continue to do so. The Committee's role and function of providing sound technical and policy advice to the NRC are even more important now that medical use regulatory issues are under active, high-priority review. To help ensure continued high-quality support from the Committee, the Commission wishes to maintain direct access to the Committee and visibility of Committee activities. For this reason, the Commission has determined that certain adjustments are needed with respect to the Committee's role, size, composition and operating procedures. The purpose of these adjustments is to allow the Commission to take maximum advantage of the special resources provided by the Committee at minimum cost to the government, in keeping with the President's general direction on the use of advisory committees.

The Commission has determined that the following guidelines should be implemented regarding the role, procedures and composition of the Advisory Committee on the Medical Uses of Isotopes (ACMUI):

1. In making future selections for Committee membership, consideration should be given to additional specialties which might enhance the Committee's operations. Also, more weight should be given to candidates who represent more than one area of expertise (e.g., a hospital administrator with experience as a nurse); such candidates should be sought.

2. The Committee should be maintained at or near its present size of 12 members. The six-year limit on length of service should be maintained. The Commission does not believe that the approach to length of service and number of terms should be any different for State representatives than for other Committee members. Accordingly, the approach to length of service and number of terms currently in effect for all but the State

representatives should be extended and applied uniformly for all Committee members. However, all Committee members should be clearly informed and understand that continued service is dependent on continued agency need, and that the mix of representation on the Committee will be reexamined as regulatory needs change. Therefore, members may not be asked to serve a second or third term if they are no longer needed for purposes of representation, or if their contribution to the work of the Committee has been lacking.

3. Although the primary function of the Committee is to serve the needs of the NRC staff, the Commission wishes to receive an oral report from the Committee annually and will meet with the Committee at least once a year to receive the Committee's report. The Committee may, if it chooses to do so, also provide its report in letter form, but this is not required. The Committee should interact with the Commission in accord with the following guidance:

   a. The Committee's report to the Commission should be a consensus report and be approved by the Committee. Members having views different from those in the report should be allowed to express them in writing or when the report is presented to the Commission.

   b. The Commission would encourage the Committee to adopt bylaws governing communications between the Committee and the Commission along the lines of the bylaws that have been adopted by the ACRS. Such bylaws, applied to ACMUI would provide that members of the Committee write to the Commission on medical matters only when it is appropriate to do so: (1) as Committee business in a Committee report, (2) in carrying out assigned responsibilities as an NRC medical consultant; and (3) in commenting, during the official public comment period, as members of the public on matters where public comment has been requested.

      There may be occasions on which a member feels a subject is of medical significance, but is unable to persuade the majority of the Committee that it warrants a Committee report. In such cases, the member should make a good-faith effort to persuade the Committee to take action, whether by writing a report on the subject, or by conducting further exploration. If the Committee decides to do neither, or if the member involved feels that the importance of the subject warrants prompt action, he/she is then

free to write an individual report on the subject. Such a report should clearly state, up front, that the member is not speaking for the Committee, and that the Committee has declined to act to his/her satisfaction on the subject. A member using this mechanism should make every effort to apply the same professional standards to their individual communication as is fair to expect from the Committee as a whole. The Committee in turn will make every effort to protect members' opportunities to address individual views.

c. The staff should consider whether it would be advisable for the Committee to operate under a set of by-laws to address procedural and conflict-of-interest concerns, including appearances of such conflict as well as for expression of minority views. The Commission also suggests consideration of the by-laws of the ACRS in this regard.

d. Consistent with the foregoing, the Committee should continue to interact with the staff to provide such support as the staff may deem warranted to help accomplish its regulatory mission.

As a separate but related matter, the staff should consider what changes to the Committee's charter may be appropriate to more adequately reflect the Committee's role as delineated above.

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
OGC