

POLICY ISSUE NOTATION VOTE

February 7, 2006

SECY-06-0028

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: RECOMMENDATIONS FOR STREAMLINING THE APPOINTMENT
PROCESS AND ENHANCING THE OVERALL EFFECTIVENESS OF
THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

PURPOSE:

To request Commission approval of the staff's recommendations to enhance the overall effectiveness of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) by reassessing member composition, streamlining the recruitment and appointment process, and modifying the procedure for ACMUI appointment and term limit. This paper does not address any new commitments, or resource implications.

BACKGROUND:

The ACMUI was established in 1958 for the purpose of providing objective and independent advice to the U.S. Atomic Energy Agency staff (subsequently, in 1975, the NRC staff) on policy and technical issues that arise in the regulation of the medical uses of byproduct material. The ACMUI further assists the staff by providing technical assistance in licensing, inspection, and enforcement; providing consultation services, when necessary, and by bringing key issues to the attention of the NRC for appropriate action.

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The ACMUI membership includes professionals from various disciplines and currently consists of 13 individuals. ACMUI members include: (1) an interventional cardiology physician; (2) a nuclear cardiology physician; (3) a radiation oncology physician specializing in brachytherapy; (4) a radiation oncology physician specializing in gamma stereotactic radiosurgery; (5) a nuclear medicine physician; (6) a patient advocate representative; (7) a health care administrator physician; (8) a radiation safety officer; (9) a Food and Drug Administration representative; (10) a therapy physicist; (11) a nuclear medicine physicist; (12) a State government representative; and (13) a nuclear pharmacist. The ACMUI reports to the Director, Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS). Several Commission papers and staff requirements memoranda (SRM) have developed the policy for recruiting, appointing, and replacing ACMUI members, and determining ACMUI composition. Enclosure 1 is a chart which summarizes key Commission papers used to develop the policy for recruiting, appointing, and replacing ACMUI members.

In SECY-05-0150, "Request to Extend Terms of Appointment for Some Members of the Advisory Committee on the Medical Uses of Isotopes," the staff stated its intent to evaluate issues associated with ACMUI membership and prepare an options paper to revise the ACMUI recruitment and appointment process, and recommend changes to membership composition on the ACMUI, if the staff determined that changes were warranted. In SRM-SECY-05-0150 dated September 12, 2005, the Commission directed the staff to evaluate all the issues associated with ACMUI membership and prepare and forward to the Commission an options paper to revise the ACMUI recruitment and appointment process. The staff has completed its evaluation, and presents five recommendations for revising the process, as described below.¹

DISCUSSION:

The ACMUI, unlike the ACRS and the ACNW, is not supported by a full-time staff. IMNS currently budgets 0.6 FTE to support the ACMUI. The staff, however, has experienced an increased need for the ACMUI's services because of implementation issues associated with the revision of Part 35 and medical event evaluation. As is discussed below, the staff's needs for various expertise on the committee changes over time, due to the continued evolution of medical modalities that cause some techniques to be sunset. Given the staff's goal to effectively and efficiently support the function of the ACMUI with its allocated resources, and given that the ACMUI should be provided the resources it needs to continue providing effective advice to the staff, the staff proposes the following:

- Reducing the composition of the ACMUI until a need for additional expertise is identified; and
- Comprehensively restructuring the current process to recruit, appoint, and replace ACMUI members.

ACMUI Composition

¹ In SECY 05-0150, the staff stated its intent to present to the Commission an options paper that would recommend options to streamline the ACMUI appointment process. Since the issuance of SRM SECY 05-0150, the staff has determined that it can better address this issue within the context of a paper that presents to the Commission for its approval, specific recommendations that will streamline the process and enhance the ACMUI's effectiveness.

As previously stated, the ACMUI is currently composed of 13 individuals, each supporting the function and mission of the ACMUI through a contribution of their specific expertise to address a broad range of issues associated with the medical use of byproduct material. Enclosure 2 provides a brief description of the function of each member.

The composition of the ACMUI is reviewed through the advisory committee evaluation process, pursuant to the requirements of COMSECY-96-028. During the 2005 evaluation, the ACMUI and the staff considered all the positions on the ACMUI. Through the combined efforts of the committee evaluation process and subsequent staff consideration of the ACMUI's composition, the staff has concluded that the effectiveness of the ACMUI could be maintained with the elimination of the interventional cardiology physician.

Interventional cardiology physicians use byproduct material for intravascular brachytherapy (IVB) procedures to treat heart disease. Recently, there has been a dramatic decline in the number of IVB procedures performed, as it has been replaced by procedures using non-radioactive devices that are logistically easier to perform and have improved long-term effects. Because this medical discipline is becoming obsolete, the staff believes there is no longer a need for a full-time interventional cardiology physician representative on the ACMUI.

Should there be, for reasons unforeseeable at this time, a resurgence of the need for advice in this area, the staff would re-evaluate this recommendation. Furthermore, should such a need arise, the staff would meet the need through the services of a consultant to the ACMUI, and/or invited guests. In addition, this action provides flexibility in the future to increase ACMUI membership to accommodate, if warranted, new and emerging medical technologies. Any future changes to the composition of the ACMUI would require Commission approval.

Recruitment and Appointment Process

The ACMUI appointment process was last restructured as a result of COMSECY-93-013, "Guidelines on the Role, Procedures, Size, and Composition of the ACMUI," dated April 16, 1993.

The current ACMUI recruitment process involves the following steps: 1) develop and obtain Commission approval of a draft *Federal Register* notice announcing the vacancy; 2) receive and evaluate responses to the announcement; 3) convene an independent panel of reviewers to review and screen applications;² 4) obtain ACMUI feedback regarding the recommended nominee; and 5) forward to the Commission the name of the recommended nominee. Once Commission approval is received, the ACMUI nominee must then obtain a security clearance, which challenges the individual's ability to fully participate effectively at the onset of the appointment. To implement this process, a time investment of approximately 14 months is required to recruit and appoint ACMUI members.

² The review panel is comprised of NRC staff and a professional specializing in the area of expertise that is being replaced. For example, if a nuclear medicine physician is being replaced, the non-NRC professional assisting staff in the review of applications must be a nuclear medicine physician. Thus, one review panel cannot review multiple applications for replacement of various positions.

The staff believes this process could be made significantly more efficient if the *Federal Register* notice announcing the vacancy of a Commission-approved ACMUI position could be approved by the Director, IMNS, in the Office of NMSS, instead of by the Commission. The staff also believes that appointments to the Committee could be made more efficient if the Director, NMSS, were authorized to approve appointments to the ACMUI. Whereas the ACRS and the ACNW report directly to the Commission, the ACMUI reports to the Director, IMNS, in the Office of NMSS. Therefore, the staff believes that it would be appropriate for the Director, NMSS, to review and approve new members. The staff believes that the Director, NMSS, could adequately review and approve new members, based on the recommendation of the screening panel and input from the ACMUI. The Commission would then be informed of any appointments and reappointments made by the Director of NMSS.

Procedure for ACMUI Appointment and Term Limit

The procedure to appoint ACMUI members is similar to that of the ACRS and ACNW. The key difference is that the procedure to appoint ACMUI members can result in several members having concurrent termination dates. To address this issue, the staff believes that ACMUI members should be appointed in the same manner as ACRS and ACNW members.

ACRS and ACNW members are appointed in accordance with Management Directive (MD) 10.12, "Use of Advisory Committee Members." This appointment procedure allows for service termination dates on the anniversary of the appointment dates of the individual members. As a result, ACRS and ACNW members have staggered termination dates, which prevents a large simultaneous attrition of membership.

By contrast, ACMUI members are appointed under the consultant appointment process, in accordance with MD 10.6, "Use of Consultants and Experts." Although ACMUI members are appointed for term durations of 3 years (with a maximum of two terms, for a total of 6 years of service), MD 10.6 nonetheless requires that the staff renew ACMUI members' service on the date of the beginning of every fiscal year, regardless of the date the members were appointed to serve on the ACMUI. Consequently, members who are approved on different dates throughout a given year have the same renewal date of October 1, and; correspondingly, the same termination date of September 30. This situation can result in a large simultaneous attrition of membership when these members have served their maximum term and are due to terminate their service on the ACMUI. Since replacement of just one ACMUI member requires a substantial time investment, the simultaneous termination of service of a significant percentage of the ACMUI severely strains the staff's resources. Large simultaneous attrition rates also challenge the ACMUI's ability to perform its function effectively. Therefore, the staff recommends that ACMUI members should be appointed in accordance with MD 10.12 rather than MD 10.6.

In addition to changing the procedure for ACMUI appointments, the staff believes that increasing the ACMUI members' terms from 3 years to 4 years (with the maximum number of terms remaining at two) would enhance committee effectiveness. The ACMUI meets at the NRC only twice per year, with teleconferences interspersed between meetings on an as-needed

basis. This infrequent meeting schedule gives newer ACMUI members fewer opportunities, relative to ACRS and ACNW members, whose members meet monthly, to become acclimated to the function and issues of the committee. The staff believes increasing the term limit will give the ACMUI members more opportunities to become accustomed to the function and business of the committee. This, in turn, will help the ACMUI more effectively advise the staff. The membership term on the ACRS and ACNW is 4 years in duration, in accordance with MD 10.12; therefore, this change would make the length of terms of membership consistent among all three advisory committees.

In summary, the staff believes that the action that was taken in SECY-05-0150, in concert with the five recommendations stated in this paper, will make the ACMUI recruitment and appointment process more efficient and effective.

RESOURCES:

Resources needed to change the appointment process are less than 0.1 FTE, and can easily be accommodated within the fiscal year 2006 budget.

The information on resources and schedule reflect the current environment. If a significant amount of time (greater than 30 days) passes or the Commission provides the staff direction that differs from or adds to the staff's recommended actions, this section of the paper would need to be revisited after issuance of the draft SRM.

RECOMMENDATIONS:

That the Commission:

1. Approve the staff's request to reduce the size of the ACMUI by eliminating the position of interventional cardiology physician.
2. Authorize the Director, IMNS, in the Office of NMSS, to approve the *Federal Register* announcements of vacancies on the ACMUI;
3. Authorize the Director, NMSS, to appoint members to the ACMUI based on the recommendations of the screening panel. The Director, NMSS, will notify the Commission following all appointments and reappointments of members to the ACMUI;
4. Approve the staff's request that ACMUI members be appointed under the advisory committee appointment process in accordance with Management Directive 10.12, "Use of Advisory Committee Members" to permit staggered termination dates;
5. Approve the staff's request that ACMUI members' terms of service be increased from 3 years to 4 years, (consistent with terms of service on the ACRS and ACNW) with the maximum number of terms remaining at two.

COORDINATION:

The Commissioners

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The Office of the General Counsel has reviewed this Commission Paper and has no legal objection.

/RA/

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Enclosures:

1. Key Commission Papers Summary
2. Chart of ACMUI Specialties and Function

KEY COMMISSION PAPERS		
SRM-SECY-90-117/SECY 89-263, "Rotation of Membership, ACMUI"	April 23, 1990	<ul style="list-style-type: none"> Staff directed to expand ACMUI membership, based on Federal Advisory Committee Act rule that Federal advisory committees ensure balanced membership; <p>Staff directed to increase ACMUI meeting frequencies to at least twice annually.</p>
SRM-SECY-92-115, "Rotation and Expansion of Membership, ACMUI"	May 20, 1992	Established 2-year term limits, with a maximum number of 3 appointments (i.e., total 6 years of service).
COMSECY-93-013, "Guidelines on the Role, Procedures, Size, and Composition of the ACMUI"	April 16, 1993	<ul style="list-style-type: none"> Reaffirmed length of service on the ACMUI to 6 total years; Requested staff to consider changes to the committee's charter that reflects ACMUI's role; Oral report should be given by ACMUI to the Commission annually; Encouraged the adoption of ACRS' bylaws addressing procedural and conflict-of-interest concerns as well as expression of minority views.
SECY-94-028, "ACMUI Rotation and Appointment of Membership"	March 4, 1994	Approved staff proposal to reduce the size of the ACMUI by two positions.
COMIS-94-003, "Expanded Input in Advisory Committee Selections"	May 4, 1994	<ul style="list-style-type: none"> Staff must seek Commission approval of the draft <i>Federal Register</i> notice soliciting replacement members on the ACMUI; Staff must form a screening panel, consisting of staff and a non-NRC Federal employee, for the screening of resumes and the recommendation of appointments to the ACMUI; The Commission must approve the screening panel member who is the non-NRC Federal employee; Staff must solicit ACMUI input, regarding the screening panel's recommended nominee to the ACMUI.
SRM-COMSECY-96-042, "Procedures for Reappointment of Advisory Committee Members"	September 26, 1996	<ul style="list-style-type: none"> Approved a shift in the length of a term from a 2-year term to a 3-year term (with total service remaining at 6 years); Approved staff request that Office Directors seek Commission approval for ACMUI candidates.
SRM-SECY-01-0160, "ACMUI Appointments"	September 7, 2001	Approved staff recommendation to add an interventional cardiology physician to the ACMUI.
SRM-SECY-0161, "ACMUI Appointments"	September 27, 2001	Approved staff recommendation to allow members of ACMUI screening panels to be appointed without Commission review. (Rescinded requirement in COMIS-94-003 that the Commission approve the non-NRC Federal employee member of the screening panel.

Enclosure 1

CHART OF ACMUI SPECIALTIES AND FUNCTION	
Interventional cardiology physician	Provides advice on issues associated with the relatively new use of intravascular brachytherapy. Advice in this area has declined, due to the use of alternative treatments.
Nuclear cardiology physician	Provides advice on issues associated with the use of nuclear materials in diagnostic and therapeutic applications. This advice includes the training and experience requirements of physicians specializing in diagnostic and therapeutic nuclear medicine.
Radiation oncology physician - brachytherapy	Provides advice on issues associated with the high-risk use of nuclear materials for brachytherapy applications such as prostate implant therapy. This advice includes the identification of medical events associated with this use, and the training and experience requirements of physicians specializing in this use.
Radiation oncology physician - gamma stereotactic radiosurgery	Provides advice on issues associated with the high-risk use of gamma stereotactic radiosurgery (GSR). This advice includes the identification of medical events associated with GSR, and the training and experience requirements of physicians specializing in GSR.
Nuclear medicine physician	Provides advice on issues associated with the use of nuclear materials in diagnostic and therapeutic applications. This advice includes the training and experience requirements of physicians specializing in diagnostic and therapeutic nuclear medicine.
Patient advocate	Represents patients' rights and provides advice that ensures that patients' issues are considered during the development and implementation of the medical rule.
Health care administrator	Provides a broad perspective of various interests, to include patients' interests, physicians interests, and hospitals' interests, as they apply to radiation safety and the treatment of patients.
Radiation safety officer	Provides advice on radiation safety issues. This advice includes the training and experience of radiation safety officers.
Therapy physicist	Provides advice on therapy medical physics. This advice includes the training and experience of authorized medical physicists (AMPs). Also provides advice on exemptions to the training and experience requirements associated with physics therapy applications of nuclear materials.
Nuclear medicine physicist	Provides advice on nuclear medicine physics applications. This advice includes the training and experience of AMPs. Also provides advice on exemptions to the training and experience requirements associated with nuclear medicine physics applications.
State government representative	Provides a State government's perspective on the medical regulations. This advice includes the training and experience requirements of all specialties. This advice also includes perspectives on compatibility issues between the State government medical regulations and the NRC's medical regulations.
Nuclear pharmacist	Provides advice on nuclear pharmacy applications of nuclear materials. This advice includes the training and experience of nuclear pharmacists.
Food and Drug Administration representative	Provides advice on current FDA requirements, as they relate to medical regulation issues.

Enclosure 2