

POLICY ISSUE
(Notation Vote)

November 25, 2009

SECY-09-0170

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: ADDITION OF A DIAGNOSTIC RADIOLOGIST ON THE ADVISORY
COMMITTEE ON THE MEDICAL USES OF ISOTOPES

PURPOSE:

To request Commission approval to expand the Advisory Committee on the Medical Uses of Isotopes (ACMUI) membership by one position to include a Diagnostic Radiologist. This paper does not address any new commitments.

BACKGROUND:

The ACMUI was established in 1958 for the purpose of providing objective and independent advice to the U.S. Atomic Energy Commission staff (subsequently, in 1975, the U.S. Nuclear Regulatory Commission (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 and inspection activities; providing consultation services; and bringing key issues to the attention of the staff and, if necessary, the Commission for appropriate action.

In Staff Requirements Memorandum (SRM) COMSECY-93-013, "Guidelines on the Role, Procedures, Size and Composition of the ACMUI," the Commission advised the staff to give consideration to additional specialties which might enhance the Committee's operations.

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In SRM-SECY-06-0028, "Recommendations for Streamlining the Appointment Process and Enhancing the Overall Effectiveness of the Advisory Committee on the Medical Uses of Isotopes," the Commission approved staff's request to reduce the ACMUI membership from 13 to 12 members. The staff's proposal was based on the 2005 advisory committee biennial evaluation that included a review of ACMUI's composition, which found that the effectiveness of the ACMUI could be maintained by eliminating a position that represented a declining technology. Currently, the ACMUI consists 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 Food and Drug Administration Representative; an Agreement State Representative; and a Health Care Administrator.

The composition of the ACMUI is reviewed through the advisory committee's biennial evaluation process in accordance with COMSECY-96-028, later amended by SRM-SECY-01-0160, "Advisory Committee on the Medical Uses of Isotopes - Evaluations and Results of the April 18, 2001, Meeting." During the 2009 evaluation outlined in SECY-09-0128, "Staff Evaluation and Self-Evaluation," a number of ACMUI members identified a need for a Diagnostic Radiologist as a voting member of the ACMUI; one member stated that adding a Diagnostic Radiologist was a necessity due to the use of "hybrid (machine/material) technology."

DISCUSSION:

The staff supports the ACMUI position to add a Diagnostic Radiologist position as a full member to the ACMUI. A Diagnostic Radiologist is a physician whose specialty encompasses a variety of diagnostic and image-guided therapeutic techniques, including all aspects of radiological diagnosis, nuclear medicine, diagnostic ultrasound, magnetic resonance, computed tomography, interventional procedures and the use of other forms of radiant energy. A Diagnostic Radiologist can provide valuable insights on these existing technologies and keep NRC staff abreast of emerging technologies (e.g., Positron Emission Tomography/Computed Tomography (PET/CT)) that combine modalities that are regulated by the NRC (e.g., PET) with those that are not regulated by NRC (CT).

The NRC staff has evaluated the 12-member composition of the ACMUI and also believes that there is a gap in expertise. While the nuclear medicine representative is able to provide insights on regulating most byproduct material uses under 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," and 35.300, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is required," his or her expertise may be limited to only nuclear medicine imaging and therapy. He or she may not be able to adequately represent the diagnostic radiology techniques described above that are often combined with uses under 10 CFR 35.200 and 35.300.

Furthermore, regulatory authority over the medical use of ionizing radiation is shared among several Federal, State, and local government agencies. The NRC and Agreement States have regulatory authority over the medical use of byproduct material (e.g., molybdenum-99 used in diagnostic nuclear medicine). The U.S. Food and Drug Administration has regulatory authority over the manufacture of radiation-producing machines (e.g., x-ray and CT devices), while the States have regulatory authority over their use. Many new technologies that blend nuclear

medicine with x-ray imaging demonstrate the need for expertise from nuclear medicine as well as diagnostic radiology. Some examples of combining nuclear medicine and x-ray modalities include PET/CT and Single Photon Emission Computed Tomography/CT (SPECT/CT). A Diagnostic Radiologist would provide advice on developing licensing guidance and training and experience requirements for new treatments, such as image guided microsphere therapy, that are often practiced by interventional radiologists (physicians with a background in diagnostic radiology).

In addition, the National Council on Radiation Protection and Measurements (NCRP) published Report No. 160, "Ionizing Radiation Exposure of the Population of the United States." A key finding of the report was that there has been a dramatic increase in the amount of radiation from medical imaging procedures, including CT and cardiac nuclear medicine examinations. Since Diagnostic Radiologists are experts in both nuclear medicine imaging procedures and CT, including a Diagnostic Radiologist on the Committee would bring an important perspective to ACMUI and would help to ensure that the unique concerns and interests of Diagnostic Radiologists are heard as staff contemplates regulations that impact the practice of nuclear medicine.

Recently, several topics on the ACMUI agenda have required input from the diagnostic radiology community. These include the impact of the training and experience requirements on authorized users approved or seeking approval for medical uses of byproduct material under 10 CFR 35.290, "Training for imaging and localization studies," and 35.390, "Training for use of unsealed byproduct material for which a written directive is required," the American Board of Radiology's planned revisions to its certification process, and interventional radiologists seeking to become authorized users for the medical use of Yttrium-90 microspheres, an NRC-regulated modality. All of these issues point to the value of a physician who specializes in these technologies of blending nuclear medicine with x-ray imaging.

Accordingly, the staff invited a Diagnostic Radiologist, nominated by the American College of Radiology, to attend the 2008 and 2009 ACMUI meetings as a non-compensated, non-voting representative. This individual was able to provide the perspectives of a Diagnostic Radiologist on existing issues as well as to raise new issues for discussion. In particular, this individual's input enhanced ACMUI's and staff's understanding of the impact of the training and experience requirements on authorized users approved or seeking approval for medical uses of byproduct material under 10 CFR 35.290 and 35.390. Additionally, this individual provided valuable input to an ACMUI subcommittee's proposed solution for fully trained, but non-certified, physicians to become authorized users. Furthermore, this individual informed the staff and ACMUI about the American Board of Radiology's ability to make changes in their certification process to address this issue and described the Board's plan to seek NRC recognition for an additional medical use of byproduct material. Lastly, this individual contributed to the discussions regarding interventional radiologists as potential authorized users for the medical use of Yttrium-90 microspheres.

The staff considers these developing topics will remain important with respect to NRC's medical regulatory programs for years to come and the staff believes the examples above demonstrate the importance of including a full-voting member of the diagnostic radiology specialty on the ACMUI.

Several professional organizations have submitted letters of support to NRC for adding a Diagnostic Radiologist position on the ACMUI: American Association of Physicist in Medicine, American Board of Radiology, American College of Radiology, and Conference of Radiation Control Program Directors, Inc. In addition to the need for a Diagnostic Radiologist identified by several ACMUI members, the ACMUI Chairman, Dr. Leon Malmud, has also expressed his strong support to expand the ACMUI to include a Diagnostic Radiologist.

Therefore, the staff has identified three options:

Option 1

Increase ACMUI membership to 13 members by adding a Diagnostic Radiologist position as a full member.

Pro: This option would provide:

- 1) Valuable expert advice on diagnostic radiology issues (e.g. better identification of issues related to (PET/CT).
- 2) The necessary input on developing topics that the NRC staff expect will be important with respect to NRC's medical regulatory programs for many years.
- 3) Diagnostic radiology issues will have a represented voice.

Con: There are currently two physicians representing therapeutic uses and one physician representing diagnostic uses on the ACMUI. Since therapeutic uses carry a higher risk than diagnostic uses, this option may be perceived by the radiation therapy community as shifting the balance from higher-risk therapeutic to lower-risk diagnostic issues.

Option 2

Employ a Diagnostic Radiologist to serve as an NRC medical consultant. This individual would attend the ACMUI meetings but he or she would not be a member of the ACMUI.

Pro: This option would provide ease of revising the composition of the ACMUI based on the needs of Committee and evolving technologies.

Con: This option:

- 1) Would not provide the consultant a permanent equal voice on the committee to adequately represent diagnostic radiology issues.
- 2) May lead to an influx of requests from stakeholders to employ consultants on the ACMUI to represent professional interests. ACMUI has never had non-ACMUI member consultants serve in this capacity.

Option 3

Maintain ACMUI membership at 12 members with no Diagnostic Radiologist representation.

Pro: No additional resources would be required.

Con: This option may lead to:

- 1) Non-responsiveness by staff to stakeholder requests of interest in the diagnostic radiology community.
- 2) Key issues not receiving attention or the necessary expertise since diagnostic and image-guided therapeutic techniques are not currently represented.

If the Commission selects Option 1, the new member will be appointed in accordance with SRM-SECY-06-0028 by the Director, Office of Federal and State Materials and Environmental Management Programs, after consulting with the Commission. The vacancy will be advertised

in the *Federal Register* to be filled through open competition, and the following text will be posted on the NRC's public website along with the other ACMUI position descriptions:

The Diagnostic Radiologist provides advice on issues associated with diagnostic applications of byproduct material. This advice includes recommendations on the training and experience requirements for Authorized Users and other diagnostic radiology issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.

If the Commission selects Option 2, the consultant will be selected and appointed by the Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs.

RECOMMENDATION:

The staff recommends that the Commission select Option 1 and approve increasing the ACMUI membership size from 12 members to 13 by adding a Diagnostic Radiologist position as a full member with voting privileges. In accordance with SRM-SECY-06-0028, "Recommendations for Streamlining the Appointment Process and Enhancing the Overall Effectiveness of the Advisory Committee on the Medical Uses of Isotopes," the composition of the ACMUI will continue to be reviewed based on new and emerging medical technologies and through the advisory committee evaluation process with specific focus on evaluating the addition of the Diagnostic Radiologist. NRC staff will request Commission approval for revisions to the ACMUI composition accordingly.

RESOURCES:

The staff estimates the cost of adding a Diagnostic Radiologist position to the ACMUI membership is 0.06 full-time equivalent (FTE). This estimate includes payment for services performed and reimbursement for travel expenses. The cost of adding a Diagnostic Radiologist will be covered using existing resources.

COORDINATION:

The Office of the General Counsel has reviewed this Commission Paper and has no legal objection. In accordance with a memorandum from the Division of Planning, Budget, and Analysis, Office of the Chief Financial Officer (OCFO) dated November 14, 2008, OCFO has determined that this Commission paper is not subject to review, since estimated resource needs are less than 1.0 FTE.

/RA/ Martin Virgilio for

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NAME	ACockerham:sxg6	CFlannery	CEinberg	BJones (NLO)	JLuehman (J Foster for)
DATE	8/6/09	8/13/09 (via email)	8/13/09 (via email)	08/25/09	09/18/09
OFC	MSSA	TechEd	FSME	EDO	
NAME	RLewis	CPoland	CMiller (CCarpenter)	MVirgilio for RBorchardt	
DATE	10/01/09	11/20/09	11/20/09	11/25/09	

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