

POLICY ISSUE
(Negative Consent)

August 23, 2001

SECY-01-0160

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES —
EVALUATIONS AND RESULTS OF THE APRIL 18, 2001, MEETING

PURPOSE:

To provide the Commission with Advisory Committee on the Medical Uses of Isotopes (ACMUI) evaluations and results of the April 18, 2001, meeting, and to request, by negative consent, approval to conduct future evaluations at 2-year intervals.

BACKGROUND:

The ACMUI advises the Nuclear Regulatory Commission (NRC) on issues regarding the medical uses of byproduct material. The Committee members represent diverse areas within the medical community. The Committee has 12 members and meets twice per year.

As an aid for assessing and documenting the committee's contribution to NRC, the staff performs evaluations of ACMUI, and the committee performs evaluations of itself. These evaluations are performed annually, as discussed in the EDO memorandum to the Commission dated April 9, 1998.

CONTACT: Angela Williamson, NMSS/IMNS
301-415-5030

DISCUSSION:

The minutes of the most recent ACMUI meeting held on April 18, 2001, are provided in Attachment 1. The transcript is accessible in ADAMS via accession number ML011380698. The staff responses to the ACMUI recommendations for the meeting are provided in Attachment 2. The ACMUI self-evaluation and the staff evaluation are provided in Attachments 3 and 4.

As indicated in the attached evaluations, both the ACMUI and the staff continue to believe that the committee provides valuable advice to the NRC on medical matters. However, considering the fact that the ACMUI meets only twice per year, the staff believes that the evaluation process would be more efficient if formal evaluations were conducted every 2 years instead of annually. The staff notes that the Advisory Committees on Reactor Safeguards and Nuclear Waste (ACRS and ACNW) also plan to reduce the frequency of evaluations to every two years (see SECY 01-0092).

RECOMMENDATION

Staff requests action within 10 days. Action will not be taken until the SRM is received. We consider this action to be within the delegated authority of the EDO.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. April 18, 2001, Summary Minutes
2. NRC Response to ACMUI Recommendations
3. ACMUI Annual Self-Evaluation
4. ACMUI Annual Staff-Evaluation

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES
April 18, 2001

The Advisory Committee on Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the Nuclear Regulatory Commission (NRC) in Rockville, Maryland on April 18, 2001.

ACMUI members present at the meeting were:

Naomi Alazraki, MD	Nuclear medicine physician
Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
David A. Diamond, MD	Radiation oncologist
John Graham	Health care administrator
Nekita Hobson	Patients' rights advocate
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Louis Wagner, PhD	Medical physicist
Jeffrey F. Williamson, PhD	Radiation therapy physicist

The following NRC staff were present:

Robert Ayres, PhD	NMSS/IMNS/MSIB
Frederick Brown	NMSS/IMNS/MSIB
Donald Cool, PhD	Division Director, NMSS/IMNS
Catherine Haney	NMSS/IMNS/RGB
John Hickey	NMSS/IMNS/MSIB
Donna-Beth Howe, PhD	NMSS/IMNS/MSIB
Lucia Lopez	NMSS/IMNS/MSIB
Linda Psyk	NMSS/IMNS/MSIB
Frederick Sturz	NMSS/IMNS/MSIB
Angela Williamson	NMSS/IMNS/MSIB

Invited guests present at the meeting:

Jeffrey Brinker, MD	Society for Cardiac Angiography & Interventions
Dr. Michael Gillin	American Association of Physicists in Medicine (AAPM)

The meeting came to order at 8:13 a.m.

Opening Remarks

Dr. Manuel Cerqueira welcomed everyone to the meeting. He introduced John Hickey, the designated Federal official, who made a few opening remarks.

Follow-Up to Items from Previous Meeting

Frederick Brown pointed out that the Agency has begun a new process in which it now provides an answer, in writing, to the recommendations that ACMUI makes during its meetings. Such a response to the November 8-9 meeting was placed in ACMUI's briefing books for the members to review. This presentation begins on Page 13 of the meeting transcript.

Status of ACMUI Vacancies

Angela Williamson spoke on the status of Committee vacancies. There are two current vacancies-medical physicist and health care administrator. In addition, there is one approaching vacancy, nuclear medicine physician, which will open as of the end of this meeting with the departure of Dr. Alazraki. This presentation begins on Page 17 of the meeting transcript.

The Committee made a recommendation to staff on this topic.

Status of 10 CFR Part 35/Part 35.75 Rulemakings

Catherine Haney gave a presentation on the status of the Part 35 Rulemaking. Specifically, she spoke on the status of the rulemaking; clarified the rule's Notification Requirement; and addressed the status of petitions sent to NRC by the American College of Nuclear Physicians/Society of Nuclear Medicine. This presentation begins on Page 27 of the meeting transcript.

The Committee made a recommendation to staff on this topic.

10 CFR Part 35 Transition and Implementation Issues

John Hickey spoke on this matter, and he informed the committee that the focus is on what NRC and the ACMUI need to do now and over the next 11-12 months to implement the rule. This presentation begins on Page 66 of the meeting transcript.

Recognition of Certification Boards

Robert Ayres, NRC, and Michael Gillin, AAPM, spoke on the issue of recognizing certification boards. Dr. Ayres described the requests for recognition received to date, and described the status of the NRC staff review. This presentation begins on Page 70 of the meeting transcript.

Dr. Gillin expressed concern, both philosophical and practical, with paragraphs 35.51 and 35.71 of the new 10 CFR Part 35. Philosophically, he is concerned that the new criteria for becoming an authorized medical physicist might reduce the importance of board certification within the medical physics community. Since the new Part 35 requires any certification to include all the training and experience requirements of 35.51 Paragraph (b), it does not recognize board certification that does not include this training and experience. This is a problem, according to Dr. Gillin, because limited opportunities exist for medical physicists to obtain training with cobalt therapy, teletherapy units, or gamma knives prior to taking board examinations. This presentation begins on Page 97 of the meeting transcript.

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

Donna-Beth Howe provided an update on this topic, which had also been discussed in the November 2000 meeting. She presented the considerations leading to the staff position that brachytherapy licensing authorizations would not be limited to the U.S. Food and Drug Administration (FDA) approved indications for use. This presentation begins on Page 142 of the meeting transcript.

The Committee made a recommendation to staff on this topic, agreeing that license authorizations should be broad, and not limited by FDA approvals.

"Physical Presence" Issue for New Brachytherapy Procedures: Presence of Medical Physicist, Cardiologist, etc.

Frederick Sturz made a presentation on this topic. The question presented to the ACMUI was: which of the medical professionals (medical physicist, authorized user, cardiologist, etc.) must be present during intervascular brachytherapy treatments for in-stent restenosis, for both patient treatment and to ensure radiation safety is maintained? This presentation begins on Page 176 of the meeting transcript.

Authorization for Broad Licensees to Utilize New Brachytherapy Procedures

John Hickey led the discussion on this topic, and the general comment for consideration by the committee was how the currently worded regulations affect broad licensees' use of radioactive material in light of new brachytherapy procedures, and how much flexibility they should continue to possess. This presentation begins on Page 232 of the meeting transcript.

Mixed Dose Regulation and Formulation of Performance

This was not an agenda item, but was raised for discussion by Dr. Louis Wagner. His concern was twofold: 1) the appropriateness and/or legality of NRC's regulation of doses received by persons simultaneously exposed to Atomic Energy Act (AEA) and non-AEA sources of radiation; and, 2) the uniformity, or lack thereof, of regulatory agencies' conditions for licensing for the purpose of ensuring safety. This presentation begins on Page 244 of the meeting transcript.

Medical Waste By Local Landfills

John Hickey introduced the issue at hand: the disposal of radiation-contaminated medical waste that sets off alarms at local landfills, and the associated problem of determining whether such waste is authorized or unauthorized. This presentation begins on Page 259 of the meeting transcript.

Self-Evaluation Criteria

Angela Williamson introduced this topic, which was the ACMUI's requirement to perform a self-evaluation. This presentation begins on Page 287 with previous committee discussion beginning on Page 280.

April 18, 2001

The committee had some general comments on the self-evaluation. The ACMUI Chairman finished the discussion by requesting that the committee members provide input into the self-evaluation by May 2, 2001.

The meeting concluded at 4:13 p.m.

MEMORANDUM TO: Manuel D. Cerqueira, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE
APRIL 18, 2001 MEETING OF THE ADVISORY COMMITTEE
ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations of the April 18, 2001 meeting, along with the U.S. Nuclear Regulatory Commission (NRC) staff's response.

STAFFING VACANCIES THAT OCCUR ON THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

ACMUI recommendation: The ACMUI recommended that the procedure for recruiting and appointing ACMUI members begin as soon as the vacancy becomes known and not at the time of the actual vacancy.

Staff response: Staff has put in place procedures for filling vacancies more expeditiously. All three current vacancies are expected to be filled before the next ACMUI meeting.

RISK-INFORMED REPORTING LIMIT

ACMUI recommendation: Whereas the committee believes that licensees have no control over the actions of patients once patients are released from their care, the ACMUI reaffirmed its November 8, 2000 recommendation that a risk-informed reporting limit of 5 rem be limited to reporting of errors made in the release of patients, and/or reporting of errors made in the delivery of instructions to patients. The ACMUI recommended that the reporting be limited to the aforementioned conditions because the more prescriptive rule would be impossible to implement, unworkable, unenforceable, resource-intensive, and intrusive to the patient.

Staff response: The staff has included the ACMUI recommendation in a paper transmitting the proposed rule to the Commission.

FORMULATION OF SUPPLEMENTARY TRAINING REQUIREMENTS FOR AUTHORIZED MEDICAL PHYSICISTS

ACMUI recommendation: The ACMUI recommended that staff involve qualified members of ACMUI, specialists, or consultants, in the detailed discussions leading to the formulation of

supplementary training requirements that will allow board-certified radiation oncologists and medical physicists to become authorized medical physicists and authorized users in modalities in which they lack the specific training and experience thereof.

Staff response: The staff agrees with this recommendation, and will involve outside parties as recommended when guidance is developed.

BROAD AUTHORIZATION FOR BRACHYTHERAPY LICENSING

ACMUI recommendation: The ACMUI recommended that NRC immediately reaffirm the concept of broad authorizations for brachytherapy licensing, rather than restricting the licensing authorization to strictly follow the Food and Drug Administration-approved indications for use.

Staff response: Revised guidance was issued on June 12, 2001, which reflects the ACMUI recommendation.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)
SELF-EVALUATION

Spring 2001

1. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the committee?

Yes. Staff and ACMUI members continue to communicate in a manner that is both open and effective. Before meetings, staff solicits committee input into the agenda items. During the meeting, these items are discussed, usually in a presentation format. The public participates by asking questions and receiving answers by staff and/or committee members.

Additionally, staff has implemented a measure that continues to promote effective communication between ACMUI and NRC staff. This measure was discussed during the April 18, 2001, meeting. In this measure, recommendations raised during meetings are answered by the Director, Division of Industrial Medical and Nuclear Safety, and forwarded directly to the committee members.

2. Do the committee members clearly define issues for the staff and provide timely, useful, objective information to the staff when requested?

Yes. Before meetings, the committee provides staff with issues it thinks should be addressed during regular meetings. At the meetings, these issues are discussed with staff, and when appropriate, with the public. Committee members contemplate solutions before meetings, and are usually able to provide on-the-spot suggestions and formal recommendations, which are reflected in the transcript.

3. Does the committee provide critical review and oversight of issues?

Yes. Because the committee is comprised of experienced professionals, it is able to give staff practical solutions/suggestions. Because it is also diverse, opinions are varied and balanced. Furthermore, as discussed in Question 2, committee members review issues before meetings, and come prepared to suggest solutions.

4. Does the committee provide expertise/advice that is not available from within the Agency?

Yes. The committee has professionals ranging from nuclear cardiologist to patient's rights advocate. Thus, the committee is not only able to give advice from a professional stand-point, but also from a "real-world" point-of-view. The Agency does not have this broad perspective, nor does it have the kind of current professional expertise represented on the committee.

5. Does the committee meet frequently enough to address issues in a timely manner?

Yes. ACMUI continues to meet twice every year. However, when issues of pressing importance arise and they cannot be addressed during regular meetings, the committee will convene extra committee meetings, or ad hoc subcommittee meetings. This option is exercised when it is necessary to discuss evolving issues such as new technologies in diagnosis and therapy.

6. Do committee members bring issues from all elements of the medical community to the attention of NRC staff?

Yes. As discussed in Questions 2 through 4, ACMUI's diversity ensures that many viewpoints are contemplated and represented during meetings. Committee members frequently raise issues that are current within their specialties.

7. Does the committee facilitate/foster communication between the public/medical community and NRC?

Yes. The public is invited to all open meetings via Federal Register; and, when appropriate, is expressly encouraged to participate in discussions. Public participants often include members from professional societies, who sometimes participate by giving presentations to ACMUI.

Furthermore, because committee members are active in their current professions, they are able to immediately express NRC viewpoints to the medical community, while keeping NRC abreast of the medical community's current activities.

8. Does the committee consider NRC's resource constraints when recommending new or enhanced regulatory programs?

Yes. Although the committee did not recommend any new or enhanced regulatory programs during its last meeting, it does have a history of considering NRC resource constraints when doing so.

9. Does the committee make effective use of subcommittees to assist the staff on specific tasks or projects?

Yes. When necessary, the committee uses subcommittees.

10. Does the size and scope of the committee meet NRC's current needs?

Yes. The size and scope of the committee continue to provide NRC with valuable, useful advice that it cannot receive otherwise. The size and scope continue to assure that a broad perspective on contemporary issues is maintained. ACMUI's current positions are:

- Nuclear medicine physician
- Nuclear cardiologist
- Nuclear pharmacist
- Radiation oncologist (two positions that represent diverse high-risk modalities)
- Medical physicist (nuclear medicine)
- Medical physicist (therapy physics)
- Radiation safety officer
- Healthcare administrator
- Patient's rights and care advocate
- State or local government representative
- Food and Drug Administration representative

However, although the ACMUI's current size and scope are generally adequate, we believe it is prudent to recommend that the Commission continue to contemplate a point that we believe is worth further consideration. Several cardiology professional medical societies have requested that the ACMUI include an interventional cardiologist as a voting member of the committee. The expertise that such a member represents in this evolving technology is one that ACMUI lacks, and with the intra-coronary applications of brachytherapy to prevent restenosis, there are an increasing number of issues related to safety and training in the environment of the cardiac catheterization laboratory. This profession's participation was valuable at the committee's last meeting. Furthermore, the American College of Cardiology and the Society for Cardiac Angiography and Interventions have had to provide us with temporary, nonvoting members to attend committee meetings to give us the expert advice we needed. Therefore, we would suggest that the Commission continue to take the addition of this specialty to ACMUI under advisement.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI) STAFF
EVALUATION

Spring 2001

1. Does the ACMUI clearly define issues for the staff and provide timely, useful, objective information to the staff?

Yes. The committee clearly identifies current issues and trends it believes affects the medical community, and affects the way Agency guidance should be constructed to best meet the safety needs of the medical community and the public, while not adversely affecting the practice of medicine. These issues are discussed at length during committee meetings. Advice and recommendations to the staff are usually provided immediately. Balancing opinions and differing views are discussed during meetings.

2. Does the committee provide expertise/advice which is not available from within the Agency?

Yes. Several professionals who are active in their specialties are on the committee. Examples include a nuclear cardiologist, a nuclear pharmacist, and a radiation oncologist. The Agency does not have these types of individuals on staff; thus, the Agency has no practical perspective on the issues these types of professionals currently face. We gain important insight by their participation.

3. Does the committee meet frequently enough to address issues in a timely manner?

Yes. The committee continues to meet on a basis that ensures that issues are addressed in timely fashion. Furthermore, the committee convenes subcommittee meetings whenever necessary.

4. Does the committee bring issues from all elements of the medical community to the attention of NRC staff?

Yes. The diverse representation on the committee ensures that viewpoints from different medical specialties are incorporated into committee discussions. Furthermore, the committee gets input towards current issues via invited speakers, who keep the committee updated on emerging technologies and treatment modalities.

5. Does the scope and size of the committee meet the current needs of NRC?

Yes. The current scope and size is broad to the extent that a wide spectrum of medical issues are scrutinized. The current membership includes the following: a nuclear cardiologist; two radiation oncologists (representing diverse high-risk modalities); a nuclear medicine physician; a nuclear pharmacist; two medical physicists (one in nuclear medicine, and one in therapy physics); a radiation safety officer; a healthcare administrator; a patient's rights advocate; a state government representative and a Food and Drug Administration representative.

Regarding the scope and size of ACMUI, one further issue is worth mentioning. Although the current size of the committee continues to satisfactorily address current medical issues, ACMUI strongly believes that the Commission should approve the addition of an interventional

cardiologist to the committee. In order to keep abreast of developments in this new technology, ACMUI has employed invited guests. They found the guests' participation valuable; nevertheless, the committee views this action as an interim measure, because interventional cardiology is an evolving technology that continually encounters new issues related to safety and training. Therefore, to enhance ACMUI's ability to advise and update NRC on the current practices within this speciality, they believe it is best that a full-time member representing this speciality be added to the committee.