

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES
OCTOBER 29, 2001

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on October 29, 2001.

ACMUI members present at the meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
David A. Diamond, MD	Radiation oncologist
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist (designee)
Leon Malmud, MD	Healthcare administrator (designee)
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

The following NRC staff members were present:

Robert Ayres, PhD	NMSS/IMNS/MSIB
Frederick Brown	NMSS/IMNS/MSIB
Donald Cool, PhD	Division Director, NMSS/IMNS
Patricia Holahan, PhD	NMSS/IMNS/RGB
Donna-Beth Howe, PhD	NMSS/IMNS/MSIB
Mark Sitek	NMSS/IMNS/MSIB
John Szabo	OGC
Angela Williamson	NMSS/IMNS/MSIB

Invited guests present at the meeting:

Jeffrey Brinker, MD	Society for Cardiac Angiography and Interventions
Geoff Ibbott, PhD	American Association of Physicists in Medicine

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

Opening Remarks

Dr. Manuel Cerqueira welcomed everyone to the meeting. He introduced Mr. Ralph Lieto and Dr. Leon Malmud as new members to ACMUI.

Follow-Up to Items from Previous Meeting

In this presentation, Angela Williamson read the ACMUI's recommendations to NRC staff from the April 18, 2001 meeting, and provided the staff's response to those recommendations. The

recommendations are as follows: that staff fill ACMUI vacancies more expeditiously (**staff concurred**); that staff limit the 5 rem reporting requirement to those errors made in the release of patients and/or the delivery of instructions to patients (**staff concurred**); that staff involve qualified specialists or consultants in the approval of supplementary training requirements for professionals seeking recognition as authorized medical physicists (**staff concurred**); and that staff interpret the revised 10 CFR 35.57 more broadly so that current medical physicists retain their authorizations as Authorized Medical Physicists for all modalities, provided they satisfy the supplementary training requirements contained in the current regulatory guides for those modalities. **Staff is working on this recommendation. For more information, see the agenda item entitled "Status of Certification Boards/Medical Physicist Qualification Criteria" in this document.** This presentation begins on Page 22 of the meeting transcript.

10 CFR Part 35 Status/Update

Patricia Holahan updated the Committee on the current status of 10 CFR Part 35 (also known as Part 35). She informed the Committee that NRC received Office of Management and Budget (OMB) approval of the collection requirements contained within the new Part 35. OMB granted this approval on September 19, 2001. She also informed the Committee that the new Part 35 has not been published because of the Senate's proposal of language that would impact NRC's ability to implement the new rule, and informed the Committee that the House and the Senate were in conference to come to an agreement regarding the Senate's proposed language. Finally, she informed the Committee that the regulatory guide to accompany the new Part 35, NUREG 1556, Vol. 9, has been completed but is on hold pending the new Part 35's publication. This presentation begins on Page 29 of the meeting transcript.

Status of Certification Boards/Medical Physicist Qualification Criteria

Robert Ayres, Ph.D., NRC, and Dr. Geoff Ibbott, American Association of Physicists in Medicine (AAPM), gave presentations on this topic. Dr. Ayres informed the Committee on NRC's progress toward evaluation of various boards' abilities to certify their medical physicists' credentials against the training and experience requirements contained in the revised Part 35. Dr. Ayres discussed the following boards:

- ✓ American Board of Health Physics
- ✓ American Board of Nuclear Medicine
- ✓ Board of Pharmaceutical Specialties
- ✓ American Board of Medical Physics
- ✓ American Board of Radiology
- ✓ Certification Board of Nuclear Cardiology
- ✓ American Board of Science in Nuclear Medicine

Of these, the American Board of Nuclear Medicine was granted recognition for modalities specified in the revised 10 CFR Parts 35.190, 35.290, 35.390, 35.392 and 35.394. However, they were not granted recognition for Radiation Safety Officer authorizations under 10 CFR Part 35.50 (a), but were given the option of obtaining such recognition through the pathway specified in Part 35.50(c). The other boards are all under review. For details regarding each board's review status, see Page 53 of the meeting transcript.

Dr. Ibbott's presentation was a discussion of what he believed would be the effects – upon the medical physicist community – of the new Part 35's training and experience requirements for physicists. Dr. Ibbott believed that the training and experience requirements in the revised 10 CFR Part 35 may diminish the importance of board certification for medical physicists. Since, according to Dr. Ibbott, board certification is the only widely acceptable credentialing system for clinical physicists, he believed that any regulatory move that diminishes the incentive to become board certified would "jeopardize" public health.

The Committee made the following recommendation to staff on this topic:

The ACMUI recommends that NRC interpret 35.57 to mean the following: that medical physicists who are listed as authorized teletherapy physicists on any Agreement State or NRC license, or by any act of a radiation safety committee within a broad scope license, be allowed to be authorized medical physicists for all modalities without qualifications, provided that they satisfy the supplementary training requirements contained in the current regulatory guides for those modalities extent on that date.

Staff deferred discussion of this recommendation until the Spring 2002 meeting. The Spring 2002 meeting was held February 20. At that meeting, staff and ACMUI revisited this topic under the agenda item "Board Certification." For detailed information as to the disposition of this agenda topic, see "Board Certification" in Attachment 2.

Dr. Ibbott's presentation begins on Page 171 of the meeting transcript.

Update on Intravascular Brachytherapy

Two persons spoke on this topic: Dr. Jeffrey Brinker of the Society of Cardiac Angiography and Interventions, and Dr. Donna-Beth Howe, NRC. Dr. Howe gave an update on NRC's latest guidance, which had already been distributed to assist professionals in safely conducting the intravascular brachytherapy (IVB) procedure. She indicated that NRC is no longer requiring the presence of three persons during IVB (i.e., the authorized user; the medical physicist; and an interventional cardiologist). The Committee discussed the advisability of no longer requiring three persons to be present during IVB. This presentation begins on Page 97 of the meeting transcript.

Dr. Brinker discussed what he believed to be the appropriate approach to determining how many professionals should be present during IVB. With extensive commentary from ACMUI, Dr. Brinker concluded that the composition of the team that should be present during IVB should be comprised of the authorized user, who should then have the flexibility to delegate the other team members (s)he feels are most appropriate to safely and effectively perform the procedure. His comments begin on Page 103 of the meeting transcript.

Regulation of Mixed Occupational Doses involving both NRC-regulated Material and Fluoroscopy

Frederick Brown spoke on this issue. He indicated that the Agency was trying to resolve issues involving radiation doses from both NRC-regulated radioactive material, and NRC non-regulated radioactive material (i.e., "mixed doses"). The purpose of Mr. Brown's presentation was to bring to ACMUI's attention the issue of calculational methodologies. Since ACMUI members are also members of the regulated community, Mr. Brown was seeking their insights regarding the practical ramifications they have experienced when they calculated mixed doses. Furthermore, he was seeking proposed recommendations, if any, to NRC's regulatory guidance on calculating mixed doses. This presentation begins on Page 147 of the meeting transcript.

Determination on when to Recommend Radiation-exposed Individuals to Physicians for Treatment

Mr. Mark Sitek made a presentation on this topic. This topic was not an agenda item, but was addressed at the Committee's request. In this presentation, Mr. Sitek briefly outlined NRC's guidance that cites the dose thresholds at which acutely exposed individuals should be referred to a physician. He informed the Committee that this guidance includes a recommendation that physicians contact the Radiation Emergency Assistance Center/Training Site for more information on how to treat acutely exposed persons. Furthermore, Mr. Sitek informed the ACMUI that the Radiological Emergency Assistance Center/Training Site is the public's Federal resource for information on handling radiation exposures. This presentation begins on Page 201 of the meeting transcript.

The meeting concluded at 2:39 p.m.