

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. Gillen 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. Gillen, 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.

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.