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. Ibbot'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.

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
February 20, 2002

The Advisory Committee on Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on February 20, 2002. On the previous day, February 19, 2002, the Committee met with the Commission.

ACMUI members present at the meeting were:

Manuel Cerqueira, M.D.	Nuclear cardiologist, ACMUI Chairman
David A. Diamond, M.D.	Radiation oncologist
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist
Ruth McBurney	State representative
Subir Nag, M.D.	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, Ph.D.	Radiation safety officer
Jeffrey F. Williamson, Ph.D.	Radiation therapy physicist

The following NRC staff were present:

Robert Ayres, Ph.D.	NMSS/IMNS/MSIB
Frederick Brown	NMSS/IMNS/MSIB
Donald Cool, Ph.D.	Division Director, NMSS/IMNS
Joseph DeCicco	NMSS/IMNS/MSIB
Susan Frant, Ph.D.	Deputy Division Director, NMSS/IMNS
Catherine Haney	NMSS/FCSS
John Hickey	NMSS/IMNS/MSIB
Patricia Rathbun, Ph.D.	NMSS/IMNS
Angela Williamson	NMSS/IMNS/MSIB

The meeting came to order at 8:12 a.m.

Opening Remarks

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

Board Certification

In this discussion, several ACMUI members expressed concern that board certifications could not be used as a vehicle to produce qualified users under the revised 10 CFR Part 35. One specific suggestion involved a proposal that NRC restore board certification as the default pathway to qualification. This discussion culminated in a motion to form a subcommittee that would make recommendations to NRC staff as how to best modify the revised Part 35 so that board certifications in themselves would qualify authorized users.

The Committee approved the following action regarding this topic:

The ACMUI will form a subcommittee whose charge is to develop a draft rule to amend the revised 10 CFR Part 35 so that board certification in itself will become a primary pathway to qualify authorized users, radiation safety officers, and authorized medical physicists.

This discussion begins on Page 104 of the transcript.

Status of NUREG 1556, Vol. 9

In this presentation, Susan Frant, PhD, discussed the need to develop NUREG 1556, Vol. 9, so that it provides the appropriate level of guidance. Toward that goal, Dr. Frant suggested that the medical community work closely with NRC staff in creating model procedures. Dr. Frant went on to outline NRC's plan to introduce an updated version of NUREG 1556, Vol. 9, to the medical community via various mechanisms including meetings, opportunities for written comments, and workshops. This discussion begins on Page 130 of the transcript.

Status of NRC Website - Security Restrictions

In this presentation, Patricia Rathbun, Ph.D., discussed the rationale for the removal of certain documents from the NRC website after the September 11 terrorist attacks. Examples of documents she discussed were fact sheets that relayed the types and strengths of sources some medical institutions possess; ACMUI transcripts, and NUREG 6642 (a document that outlines different risk scenarios). Dr. Rathbun explained that NRC staff took a conservative approach and removed these documents, as well as many others that were less sensitive, due to the extreme concern that any information, even seemingly innocuous information, may be used inappropriately. She went on to discuss the agency's plan to reintroduce certain documents back to the newly designed NRC web site. This discussion begins on Page 164 of the transcript.

Status of NRC Website - Electronic Forms

In this presentation, John Hickey relayed the Agency's desire to make NRC's website more useful by posting more electronic forms to the site, and by making documents that are currently posted to the site easier to download. This discussion begins on Page 180 of the transcript.

Distribution of ACMUI Minutes

In this presentation, John Hickey reaffirmed the staff's intent to ensure that ACMUI minutes clearly display any action items and resolutions the committee makes for staff consideration. He also affirmed that staff would respond to ACMUI resolutions in a separate paper that would then be distributed to ACMUI. This discussion begins on Page 184 of the transcript.

Update on ACMUI Bylaws

During this discussion, Angela Williamson informed ACMUI on the procedure to update the portion of the bylaws that delineates the term of service of ACMUI members. This discussion begins on Page 187 of the meeting transcript.

IAEA Patient Protection

Donald Cool, Ph.D., gave a presentation on this topic. In his presentation, Dr. Cool explained the international community's current efforts toward improving the safety of radiation medicine in the international arena, particularly in developing countries. In doing so, he provided a brief background of the activities of the International Atomic Energy Agency (IAEA). He explained that the IAEA formed a technical committee charged with making recommendations to improve the safety of radiation medicine. Dr. Cool then promised to provided ACMUI with a draft report of the recommendations of the IAEA technical committee. He also informed ACMUI that this information was being presented only to educate them. He explained that they may consider choosing to be involved in this endeavor as part of their professional societies, but that they were not to take action on this information as representatives of ACMUI. This presentation begins on Page 190 of the transcript.

Status of Board Recognitions

Robert Ayres, Ph.D., made a presentation on this topic. Dr. Ayres provided an update to ACMUI on NRC's review of requests for board recognition. Dr. Ayres discussed the following boards:

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

Of these, the American Board of Medical Physics, the American Board of Health Physics, and the Certification Board of Cardiology were under review during the last ACMUI meeting (October 29, 2001). Staff completed review of these boards, resulting in the following action by staff:

- ▸ Partial recognition granted to the American Board of Medical Physics (ABMP). ABMP applied for recognition under the revised 10 CFR Part 35.51(a), Authorized Medical Physicist, but staff could not grant full recognition due to the board's lack of requirement to complete training for all modalities. However, the staff should be able to grant recognition in a specified modality if the physicist can demonstrate adequate training and experience in that modality.

- Denial of recognition to the American Board of Health Physics (ABHP). ABHP was not

granted recognition because its certification process does not require one year of full-time radiation safety experience with similar types of byproduct material, and it does not require a that preceptor RSO sign a written certification of experience.

- Probable recognition granted to the Certification Board of Cardiology under 10 CFR 35.2909. Although recognition had not been granted at the time of this briefing, recognition was expected to be granted.

Dr. Ayres noted that with respect to Radiation Safety Officer recognition, a large number of the boards that requested recognition were denied because their certifying processes included insufficient medical experience requirements as well as the absence of a requirement for signed preceptor statements. Likewise, with respect to Medical Physicist recognition, many boards' certifying processes were denied recognition due to non-requirement of training in all modalities as well as the absence of a requirement for signed preceptor statements.

Regarding training and experience, the Committee approved the following resolution:

The ACMUI recommends that the Commission retain, in the current 10 CFR Part 35, the training and experience requirements for authorized nuclear pharmacists, authorized medical physicists, radiation safety officers, and authorized users, until such time that a new rule is implemented that will allow board certification as a pathway for meeting the training and experience requirements in the revised 10 CFR Part 35.

This presentation begins on Page 208 of the meeting transcript, and continues on Page 266.

Report on National Materials Program-Results

Paul Lohaus and Jim Myers made a presentation on this topic. In this presentation, Mr. Lohaus informed ACMUI that the number of Agreement States is expected to continue to rise through FY 2004. In response to this anticipated rise, NRC formed the National Materials Program Working Group, comprised of NRC staff and Agreement State personnel, who were charged with analyzing the NRC's role in a future environment where 75 percent of licensees will fall under Agreement State jurisdiction. Mr. Lohaus informed ACMUI that the Working Group developed a report recommending an "alliance option" whereby the Agreement States and NRC would work together to develop regulatory products that could be smoothly implemented by both NRC and the Agreement States. Several ACMUI members expressed concern that any regulatory products born out of this alliance option could result in fragmented applications of regulations; thereby hampering the practice of medicine. In response, Mr. Myers informed ACMUI that the structure of the alliance option was designed such that any application of jointly-developed regulatory products should ensure maximum uniformity across all Agreement States and the NRC.

Most members of ACMUI were not aware of the Working Group and strongly believed that the committee as a whole should have been involved in developing the recommendations of the Working Group. Furthermore, the ACMUI expressed keen interest in being kept up-to-date on the activities of the National Materials Program Working Group. In response, Mr. Lohaus promised to provide them with a copy of a report that was sent to the Commission in May

2001, and also committed to keep them updated via briefings.

The Committee requested the following action regarding this topic:

That the Chairman, ACMUI, direct ACMUI members to review and develop a consensus statement - for distribution to the Commission - on ACMUI's position with respect to the National Materials Working Group's report to the Commission regarding the National Materials Program.

This discussion begins on Page 214 of the meeting transcript.

Security of Radioactive Material

Catherine Haney began this presentation by informing ACMUI that her purpose was to provide them with information they can pass along to members of the regulated community who may ask them questions concerning what NRC is doing to protect the public since the September 11 terrorist attacks.

Ms. Haney informed ACMUI that, in addition to the NRC's safety mission, which is well understood, the Agency also has the responsibility to promote the nation's defense, and does so through the security regulations it develops. She informed ACMUI that one of the mechanisms the agency has always employed to meet its security mission was the sharing of intelligence information with other government agencies such as the Central Intelligence Agency and the Federal Bureau of Investigation. However, subsequent to the September 11 terrorist attacks, this inter-governmental coordination has increased dramatically, and now also includes coordination with the newly developed Office of Homeland Security.

Regarding security, Ms. Haney mentioned several initiatives, some national, and others at the licensee and Agency level. In terms of national security, Ms. Haney informed the committee that NRC is working closely with other agencies in identifying key infrastructures that need to be protected. With respect to Agency-specific initiatives, Ms. Haney informed them of the Agency's top-to-bottom review of its security and safeguards program. At the licensee level, she explained that the Agency is requiring higher licensee security where risk warrants such action. Furthermore, she mentioned that NRC has proposed Interim Compensatory Measures that, in the long term, may require increased security at hospitals. Ms. Haney also gave ACMUI practical suggestions that the average medical facility could implement to enhance security. This presentation begins on Page 318 of the transcript.

Update on New Intravascular Brachytherapy (IVB) Devices

John Hickey gave a presentation on this subject. Mr. Hickey informed ACMUI that their previous advice to the staff regarding the use of IVB devices (e.g., advice regarding use of procedures not specifically reviewed by FDA and the physical presence issue during IVB procedures) helped NRC formulate an approach that appears to be working well. This presentation begins on Page 342 of the transcript.

Mixed Doses

Joseph DeCicco gave a presentation on this topic. In this presentation, Mr. DeCicco gave ACMUI an update on NRC's efforts to address the mixed dose issue. Specifically, he informed the committee that the agency re-evaluated its regulation in 10 CFR Part 20 that addresses mixed doses. He explained that the agency evaluated whether some method other than deep dose equivalent could be used to determine external exposure. Mr. DeCicco concluded his discussion by providing ACMUI with a pre-decisional Regulatory Issues Summary (RIS) that outlines different methodologies for calculating mixed doses than are currently offered in Part 20. He requested that ACMUI review the draft RIS and submit comments by March 14, 2002. This presentation begins on Page 353 of the transcript.

The meeting concluded at 3:20 p.m.

July 2, 2002

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

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

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER 29, 2001, AND THE FEBRUARY 20, 2002 MEETINGS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations/resolutions of the October 29, 2001 and February 20, 2002 meetings of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's position.

CERTIFICATION BOARD RECOGNITIONS

ACMUI October 29, 2001 recommendation: 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 response: Staff deferred a response to this recommendation until the February 20, 2002 meeting, when it was discussed under the agenda topic "Board Certifications." This discussion culminated in a resolution to form a subcommittee to amend the training and experience requirements in the revised 10 CFR Part 35.

ACMUI February 20, 2002 resolution: That ACMUI form a subcommittee whose charge is to develop a draft rule to amend the revised 10 CFR Part 35 (i.e., Part 35) so that board certification in itself will become a primary pathway to qualify authorized users, radiation safety officers, and authorized medical physicists.

Contact: Angela Williamson, NMSS/IMNS
(301) 415-5030

Staff response: The subcommittee was formed. The subcommittee met on June 21, 2002, to discuss and refine its recommendations. On July 8, 2002, the full ACMUI committee will meet in a teleconference to act on the subcommittee's recommendations, and forward final recommendations to NRC staff.

STATUS OF BOARD RECOGNITIONS

ACMUI February 20, 2002 resolution: The ACMUI recommends that the Commission retain, in the current Part 35, the training and experience requirements for authorized nuclear pharmacists, authorized medical physicists, radiation safety officers, and authorized users of Part 35.600 modalities, until such time as a rulemaking initiative can be completed to rectify the problem of recognition of the Boards as pathways for achieving this status.

Commission response: The staff, with Commission agreement, retained the training requirements in Part 35.600 and other modalities, as well as the requirements under the current Part 35, Subpart J, for a 2-year period after publication of the final rule. During that 2-year period, licensees will have the option of complying with either Subpart J or Subparts B and D-H. After the 2-year period expires, Subpart J will be deleted.