SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
March 1-2, 2004

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland, on March 1-2, 2004.

The ACMUI members present at the March 1 meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
Ralph P. Lieto	Medical physicist
Leon S. Malmud, MD	Healthcare administrator
Ruth E. McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz, RPh	Nuclear pharmacist
Orhan Suleiman, PhD	Food and Drug Administration (FDA) representative
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

ACMUI member absent:

David A. Diamond, MD	Radiation oncologist

Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB) participated in the meeting. Staff from the Office of Nuclear Security and Incident Response (NSIR) and the Office of the General Counsel (OGC) also participated. Specific participating staff members are listed below:

Roger W. Broseus, PhD	NMSS/IMNS/RGB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Patricia K. Holahan, PhD	NMSS/IMNS
Michael Layton	NSIR
Charles L. Miller, PhD	NMSS/IMNS
Trip Rothschild	OGC
Angela R. Williamson	NMSS/IMNS/MSIB

Also present were:

Andrew Kang	Food and Drug Administration
Raymond Horn	Nucletron Corporation
James Goetz	St. Luke's Hospital, Bethlehem, Pennsylvania
Richard Fejka	Food and Drug Administration
Lynne Fairobent	American College of Radiology
James Boxall	American College of Cardiology
William D. Nelligan	Certification Board of Nuclear Cardiology

Gerald A. White	American Association of Physicists in Medicine
Lisa Dimmick	
John Coats	
Howard Griffith	
Roshunda Drummond	American Society of Therapeutic Radiology and Oncology

The meeting came to order at 10:22 a.m.

OPENING REMARKS

Thomas H. Essig, Designated Federal Officer, introduced each ACMUI member and presented certificates of appreciation to Ruth E. McBurney, State government representative, and Nekita Hobson, Patient advocate. Ms. McBurney's and Ms. Hobson's terms on the committee end after the March 2004 meeting.

DOSE RECONSTRUCTION SUBCOMMITTEE FINDINGS IN THE ST. JOSEPH MERCY HOSPITAL CASE

Jeffrey F. Williamson, PhD, gave a presentation on this topic.

Remarks: Dr. Williamson gave this presentation in response to a Commission request that the ACMUI review the staff's method of dose reconstruction. The Commission requested this activity in response to the Society of Nuclear Medicine's (SNM) assertions that the NRC uses excessively conservative methods to reconstruct doses in instances when overdoses have occurred. The particular event that triggered the SNM's assertions is the St. Joseph Mercy Hospital event, whereby a member of the public received excessive radiation exposure while caring for her dying mother. In response to the Commission request, the ACMUI formed a Dose Reconstruction Subcommittee, chaired by Dr. Leon S. Malmud. Dr. Williamson is a member.

As Dr. Williamson began reporting on his findings, he informed everyone that the findings were not fully reviewed by the other subcommittee members. Therefore, these findings were actually his independent views.

Dr. Williamson then gave an overview of his understanding of the particulars of the event. He also noted some of SNM's general assertions regarding what they believed were shortcomings in the NRC's approach to dose reconstruction. These assertions include:

- An unrealistic estimate of the daughter arm-to-patient center distance;
- The Iodine-131 source was not allowed to decay continuously;
- The total effective dose equivalent is an inappropriate endpoint for risk assessment;
- Tissue attenuation in the daughter should have been considered.

Dr. Williamson stated that he performed a Monte Carlo assessment of the dose the daughter may have received. He concluded that NRC's dose estimate to the daughter did seem a bit conservative. Nevertheless, a less conservative estimate would not have changed the outcome: that the daughter received a dose many times higher than the regulatory limit, which is true even if the most liberal methods to assess her dose were applied. While Dr. Williamson agreed that the daughter was excessively exposed, he believed that a more "sophisticated"

assessment of dose would "enhance the (NRC's) scientific credibility of future dose calculations."

After asking Dr. Williamson to clarify several points, the ACMUI expressed concern over possible overestimation of doses in cases where an overestimation may cause unnecessary patient notification, and/or excessive regulatory response. Nonetheless, the ACMUI acknowledged that the subcommittee needs more time so that it may thoroughly assess the NRC's method of dose reconstruction, and come to better defined conclusions. Charles Miller, NRC, suggested that the ACMUI delay reporting any findings to the Commission until such re-assessment is completed.

This discussion begins on Page 8 of the meeting transcript.

STATUS OF RULEMAKING

Roger Broseus, NRC, presented information on this topic.

Dr. Broseus explained that he would use this time to provide an overview of public comments that have been received to date, regarding the proposed 10 CFR Part 35, Medical Use of Byproduct Material. The official comment period ended February 23. At that date, NRC received approximately 15 letters and e-mails. By February 27, NRC had received a total of 25 public comments. Dr. Broseus noted that these comments can be viewed at the NRC website.

Dr. Broseus reminded the ACMUI that the Federal Register notice that announced the proposed rule posed three questions to the public. They were

1. Do the proposed changes adequately cover safety?
2. Should the Agreement States establish requirements in their rules by October 24, 2005, or should they be given three full years to develop compatible rules?
3. Regarding the preceptor's role in verifying the adequacy of training, should the word "attestation" or "attest" be used in place of "certification"?

Dr. Broseus explained that, of the initial 15 comments, five supported the proposed rule. Other comments made included the belief that preceptors should not be required to attest that a candidates passed a board certification. This comment was made in response to the language in 35.390(c), which can be interpreted to mean that preceptors must attest that a candidate took a board exam and passed it. However, several commenters agreed that preceptors should be required to attest that a candidate is able to adequately function as an authorized user (AU), but should not be required to "certify" that a person is competent.

Regarding the certification boards, Dr. Broseus explained the boards believed that if the new rule is made effective immediately after the expiration of Subpart J in the current rule, they will not have enough time to submit applications for recognition for NRC staff evaluation. Therefore, these boards suggest that staff allow them a grace period to apply for recognition.

One commenter suggested that radiation oncologists be exempt from the proposed training and experience (T&E) requirements in 35.390(b)(1)(ii).

Dr. Broseus then briefly overviewed comments submitted by the Agreement States. These include:

< A request for three full years to adopt any final rules;
< The NRC should specify the precise number of hours of training AUs must obtain to fulfill the requirements of 35.190, 35.290, and 35.390, so that there is an assurance of compatibility between the Agreement States and NRC in this area;
< The NRC should clarify the definitions in 35.2;
< Support for retention of the preceptor function;
< General support for the concept of requiring those who passed boards to independently obtain preceptor attestation, rather than requiring boards to ensure they have obtained attestation.

Next, Dr. Broseus reminded the ACMUI that staff had previously drafted some revised Part 35 implementation guidance that it passed to the ACMUI and the Agreement States for comment. Staff received ACMUI comments on December 15, and a few Agreement State comments as well. The ACMUI consensus position was the NRC does not understand clearly the purpose and process of board certification procedures and requirements. Furthermore the ACMUI believes the draft implementation guidance included redundant requirements (e.g., "boards must declare that candidates complete T&E to sit for an examination"). The ACMUI also believed that it is inappropriate for the NRC to examine board processes, such as reviewing examinations and grading procedures. Other ACMUI comments included:

< Why should certification boards be required to renew their certifying processes every 5 years, as proposed, when boards' certifying programs are static?
< NRC should individually address those boards who do not apply for recognition. NRC should not automatically refuse recognition of any board that did not respond to the NRC's written request that the board apply for recognition.
< NRC should invest time to interact with boards so as to better understand board processes. This may be accomplished via public workshops, for example.

Dr. Broseus stated that the Agreement States' comments tended to echo those of the ACMUI. Specific to obtaining AU status, the Agreement States requested common performance indicators to evaluate the training programs of board pathway to obtaining AU status, and to evaluate the alternate pathway to obtaining AU status.

Dr. Broseus then stated planned future actions, but stipulated that what was being presented is subject to adjustment. Dr. Broseus stated that staff will continue to compile and analyze comments, after which a final draft rule will be prepared. This final draft will be presented to the ACMUI and the Agreement States simultaneously. Staff will then forward ACMUI and Agreement State comments and present them to the Commission. Once comments are reconciled, they will be published in the Federal Register. Staff plans to publish these comments by the end of October, 2004, and post the revised board certification implementation procedures on the NRC web site in September, 2004. In closing, Dr. Broseus re-emphasized the staff's objectives - to publish supplementary information in the Federal Register that clearly explains the rationale for the revised T&E rule and also addresses everyone's comments; to provide a clear basis for the rule change, and to have the rule in place before the expiration of Subpart J in the current 10 CFR Part 35.

The ACMUI asked a couple of clarifying questions, made a few additional comments, but offered no recommendations.

This discussion begins on Page 47 of the meeting transcript.

EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON MISSION AND MEETING PROCEDURES

The Emerging Technology Subcommittee, chaired by Ruth McBurney, presented information on this topic to the ACMUI.

Ms. McBurney began by reminding everyone that the NRC staff sent the draft Seedselectron licensing guidance to the Subcommittee in December (2003) for review.

One committee member made a general statement about the nature of reviewing newer devices. He stated his belief that, because of the extreme technical nature of newer devices such as the Seedselectron, the ACMUI must be able to meet more often, via teleconference if necessary, to discuss these devices and provide effective advice to the NRC on how to best license them. He further noted that in order to be able to fully appreciate the capabilities of the Seedselectron, he had to make a site visit to the manufacturer.

This member further suggested that NRC staff form working groups when necessary, to review any draft guidance associated with these newer devices whose use is not regulated adequately under existing regulations. He believed that working groups will improve the accuracy of such guidance, as well as help in developing the guidance more quickly.

Ms. Burney then stated, that, in harmony with the working group idea just mentioned, she is part of the National Materials Program (NMP) pilot project working group, looking to establish priorities of regulatory needs. As part of that effort, the NMP is recommending that centers of expertise be identified, that alternate resources be identified, and that outside expertise be brought in when necessary.

A member of the public, Lynne Fairobent, stated that bringing in outside expertise is consistent with how NRC's other advisory committees, the Advisory Committee on Reactor Safeguards and the Advisory Committee on Nuclear Waste (ACRS/ACNW) operate. She believed that in this effort of providing recommendations on newer technologies, the ACMUI could benefit from following their example.

The ACMUI Chair, Dr. Cerqueira, then asked NRC staff for its position regarding the ACMUI's soliciting assistance from professional medical societies, in light of potential conflicts of interest (since many ACMUI members also serve on professional societies) and budget concerns. Thomas Essig, NRC, stated that ACMUI would have the same privilege as do ACRS and ACNW, with respect to solicitation of outside help, but that any such privilege is constrained by the ACMUI budget. (Any conflict of interest issues will be addressed as they emerge).

Since Ms. McBurney is rotating off the committee, it was suggested that Dr. Vetter replace her as the Emerging Technology Subcommittee Chair. Dr. Vetter agreed.

This discussion begins on Page 67 of the meeting transcript.

EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON SEEDSELECTRON LICENSING GUIDANCE

Donna-Beth Howe, NRC discussed this subject with the ACMUI.

The ACMUI mentioned that a stakeholder, Nucletron Corporation, submitted a letter to them with concerns about how the NRC will license the Seedselectron device at St. Luke's hospital. Dr. Howe addressed this letter, in part, by mentioning that NRC staff recently completed a technical assistance request (TAR) submitted to NRC Headquarters by Region I, on behalf of St. Luke's Hospital. The Region requested assistance in licensing the SeedSelectron device for St. Luke. She stated that the TAR response addressed some of the concerns in Nucletron's letter. Dr. Howe further mentioned that staff recently put the SeedSelectron licensing guidance on the NRC website. Dr. Howe informed everyone that the SeedSelectron guidance should be considered a living document, subject to amending as necessary.

After the ACMUI and the NRC staff briefly discussed logistical issues associated with inviting vendors of new devices to brief the ACMUI, Dr. Jeffrey Williamson gave an summary of Nucletron's demonstration of its Seedselectron device to him.

Dr. Williamson explained that the SeedSelectron is basically an enhanced manual brachytherapy device. The primary method by which it delivers sources (to a position within the patient) is by automatic positioning of the needles, which are guided by a template. This is similar to manual brachytherapy, which uses a template to position the needles, but the positioning is done manually. Dr. Williamson mentioned that the version of the Seedselectron licensing guidance in his possession contains provisions that would (unnecessarily) burden users of the Seedselectron. An example he gave was the guidance's proposal for modifying the written directive. Staff believes that the written directive, as currently defined, may not be adequate for permanent seed implants. Although this may be true, according to Dr. Williamson, staff should not attempt to address this issue in the licensing guidance. In response, Dr. Howe replied that she had already removed the references to the written directive.

However, there were other issues associated with this guidance, according to Dr. Williamson. One was verifying the needle position. Dr. Williamson does not believe that using the SeedSelectron always mandates special precautions to verify needle positions. He believes that verifying needle positions is supportable only when using the Seedselectron's treatment planning system.

In response, Dr. Howe stated that this proposal was added to ensure the administration was performed in accordance with the written directive. However, the staff tried to stress that it was put into the notes to licensees. This section provides guidance the licensee should consider, but are neither requirements the licensee must implement nor information the licensee must provide to NRC. Even so, Dr. Williamson believed that including this language may give licensees the impression that using the Seedselectron carries with it excessive regulatory burden (another ACMUI member agreed). Dr. Williamson went on to suggest his belief that the guidance should be crafted in such a way that there is a reasonable protocol for daily and quarterly quality assurance, to verify that seeds are inserted properly into needles. If staff has broader concerns about permanent seed implants, he suggests staff notify the public via using

normal Agency processes, such as Information Notices, that do not name specific vendor products.

Dr. Williamson also mentioned the FIRST system (**F**ully **I**ntegrated **R**eal-time **S**eed **T**reatment) , (This integrated system allows the physician to plan the treatment, image the treatment, and adjust the treatment in real time). Although Dr. Williamson believed that much of the guidance is appropriate, he stated that the staff's requirement regarding the positive confirmation of seed location cannot be implemented because quantitative localization of seeds in ultrasound images is not yet possible. This is an active area of research, according to Dr. Williamson. He suggested that staff remove that requirement from the guidance.

Finally, Dr. Williamson made comments regarding high-dose rate brachytherapy. He stated that 35.600 requires a series of tests to be performed daily, quarterly, and annually, to give licensees reasonable assurance that radioactive seeds are placed in the desired location within patients. Dr. Williamson said there is no reason to depart from this paradigm in guidance space. Dr. Howe agreed with Dr. Williamson's earlier points on confirmation of seed location, and had already modified the guidance to focus on initial visualization of the needle placement. She stated that crafting this guidance is in its developmental stage, and so it is subject to updates. She also confirmed that she expects comments on the "living document" and will be working with Dr. Williamson and the subcommittee to improve the guidance.

One ACMUI member suggested that, as staff develops guidance, it does so for system components rather than for any particular vendor's radioactive seeds. This would give the guidance broader applicability.

Dr. Williamson and staff then agreed that the Emerging Technology Subcommittee should undertake a detailed review of the existing version of the Seedselectron guidance and forward its views to NRC staff.

ACTION ITEM

The Emerging Technology Subcommittee will undertake a detailed review of the existing version of the Seedselectron guidance and forward its views to NRC staff.

Next, a Nucletron representative, Raymond Horn, spoke to the ACMUI. He stated that he was "enheartened" by the discussion on how to improve the Seedselectron guidance. However, he feels strongly that the pending guidance be reviewed. Mr. Horn also urged staff to amend St. Luke Hospital's license using current guidance, so they can begin using their Seedselectron device. He stated that St. Luke is willing to amend its license again if the guidance changes substantially. In further support of a quick amendment, Dr. Goetz, Director of the Cancer Center at St. Luke's Hospital, informed the ACMUI and the NRC staff that, in the past 6 months, St. Luke's has had to refer upwards of 15 individuals to outside locations, creating inconvenience and potentially affecting quality of care. The ACMUI agreed that staff should license St. Luke's Seedselectron expeditiously.

This discussion begins on Page 83 of the meeting transcript.

REMOVING MODALITIES OUT OF PT. 35.1000

Donna-Beth Howe, NRC, led the discussion on this agenda topic.

Dr. Howe began by stating that to move modalities out of 10 CFR 35.1000, staff must undertake rulemaking. There are no other options.

There are two ways to initiate rulemaking: 1) staff initiates rulemaking, or 2) stakeholders initiate rulemaking via a 2.202 rulemaking petition. The question NRC wrestles with is "At what point in time is it appropriate to move modalities out of 10 CFR 35.1000?" In this case, calendar time is not the driving factor that answers this question. Rather, the following is considered: 1) the cost-effectiveness of rulemaking, and 2) whether NRC has enough licensees seeking the technology to justify rulemaking. Regarding the 2nd point, it is not cost effective to initiate rulemaking for a technology that only a few licensees are using, regardless of how advanced that technology may be. Further points staff must consider are:

T How clear and well-established the guidance is.
T If the staff creates rules in instances when the licensed community has little experience with the technology, then more rulemaking will be required, if modifications are needed.

Thus, for technologies that have not been widely used, it is better to leave them in §35.1000 and create web site guidance, which can be easily modified when necessary.

Dr. Howe expanded on things the staff looks for when determining a technology is not new and our guidance can be codified into regulation. These include:

< The guidance on the rule has stabilized.
< NRC has sufficient experience licensing the technology.
< NRC has sufficient experience inspecting the technology.
< There is adequate medical event experience.
< Licensees and other stakeholders have good medical use experience with the technology.

Dr. Howe then explained that, in relation to inspection experience, staff recently developed a new program code. This program code drives the frequency for NRC inspection of therapy-emerging technologies. Only those devices that staff believes should be placed into that program code are put there. Any licensee who has a device in that code will receive an inspection within 12 months of the license being issued for that device. Thereafter, the licensee will be inspected every 2 years. If inspection and use experience reveals that the device does not need to be categorized under that code, staff will remove that device from the code. The licensee will then be inspected according to its normal inspection schedule.

Dr. Howe then reiterated staff's preference for leaving newer technologies in §35.1000 and issuing regulatory guidance: it is much easier and simpler to adjust the regulatory environment by updating the guidance as both staff and licensees gain insights and experience with the newer devices.

After complimenting Dr. Howe on a nice summary of this situation, an ACMUI member commented that there appears to be several advantages to leaving newer technologies in §35.1000. He wanted to know why anyone would want to remove newer technologies out of

§35.1000. Another member responded that devices that are moved into regulation are given considerable public scrutiny and comment, therefore, there is an opportunity for the regulated community to have input into how the device will be regulated. Furthermore, Lynne Fairobent, representing the American College of Radiology, added two more reasons: 1) that NRC stated, and it was clearly understood by the public, that newer devices would be promptly removed from §35.1000, and 2) as long as devices remain in §35.1000, licensees who want to use those devices must apply for a license amendment, unless the license is a broad scope license. Thus, when devices are removed from §35.1000 into a permanent regulatory section, licensees do not need to apply for amendments.

Another issue with leaving devices in §35.1000 had to do with guidance. An ACMUI member stated that as guidance changes, licensees are not necessarily aware of the changes. Dr. Howe responded that licensees are held only to the commitments they made when they applied for a license amendment; they are not held to guidance that is later amended. However, staff received the point that staff may need to be more active in making licensees aware of changes to the guidance.

Everyone agreed that leaving newer technologies in §35.1000 is not necessarily inappropriate. The question was what is the appropriate length of time a device should remain in §35.1000, and "regulated" by guidance? With that question in mind, Lynne Fairobent believed that intravascular brachytherapy (IVB), having been in §35.1000 for three years, should be moved out of §35.1000 into a permanent regulatory section. An ACMUI member agreed.

Dr. Howe responded to this perceived need for urgent IVB rulemaking by pointing out that last year, it appeared that drug-coated stents would replace IVB use, and, in fact, one manufacturer ceased making IVB sources. While it is true that the new drug-coated stents caused a sharp decrease in the use of IVB, there have been problems with the new stents. Until this environment stabilizes, and IVB appears to be permanent, IVB should remain in §35.1000.

There was more discussion about the general climate of IVB, but ACMUI made no recommendations on this subject.

This discussion begins on Page 121 of the meeting transcript.

DEFINING MEDICAL EVENTS INVOLVING PROSTATE SEED IMPLANTS

Ronald E. Zelac, NRC, presented this topic to the ACMUI.

As Dr. Zelac began, he explained that staff does not really expect a resolution for this topic. It is being presented for the committee's information, and staff hoped to use this meeting to gather from the ACMUI some additional information that might be helpful.

Staff is having difficulty defining "medical event," as the term applies to permanent seed implants in the prostate. The regulation in 10 CFR Part 35.3045 defines medical event, in part, as a deviation from the prescribed dose by more than 50 rem to an organ or tissue; and a total dose that deviates from the prescribed dose by 20 percent or more. Regarding prostate seed implants, the ACMUI recommended, at its November 2003 meeting, to use D90 as the criterion to determine when a medical event occurred. ("D90" refers to 90 percent of the target organ

receiving the prescribed dose. A medical event has occurred if there is an unacceptable percentage of dose that was delivered to 90 percent of the target organ).

Dr. Zelac explained that D90 is acceptable for defining under dosing. For a D90 that is less than 80 percent, it is clear a medical event occurred (i.e., if 90 percent of the organ receives less than 80 percent of the dose, a medical under dosing event has occurred). However, D90 does not work as well for determining whether an overdose occurred. In overdoses, a D90 that is greater than 120 percent meets the definition of a medical event; however, in many standard treatments, it is desirable to have a dose that exceeds 120 percent. Further compounding this issue is that in standard treatments, a significant portion of the target organ may receive a dose exceeding 200 percent of the prescribed dose. Dr. Zelac then asked the ACMUI to answer two questions regarding the standard practice of prostate implant doses: Are D90s that exceed 120 percent standard practice? Are D90s that exceed 200 percent standard practice?

The ACMUI responded that there is not a simple answer to these questions. Factors such as the volume of the target organ and characteristics of the tumor will determine if a medical event has occurred. Other factors mentioned are the limitations of computed tomography (CT), used to image the organ during treatment planning, and each institution's individual protocol regarding when to image the organ. With respect to CT, it does not produce images as clear as those that can be produced with ultrasound or magnetic resonance imaging. The use of CT, therefore, makes it difficult to determine the treatment volume within the target organ. With respect to post treatment planning imaging, some institutions image the organ the day of the treatment, some image it the day after treatment. Because maximum organ edema can occur the day after, this will affect the dose distribution within the organ.

This member suggested that, to determine when a medical overdose occurs, that the NRC err on the side of generosity to collect gross errors. Otherwise, the NRC will wind up including many events simply because of variations in clinical practice. The ACMUI stated that, for this particular procedure, the determination of a medical event should be based upon excessive dose to normal tissue, not excessive dose to the tumorous tissue.

There was much discussion regarding the clinical difficulties surrounding this issue. Finally, Dr. Zelac surmised that a way to approach defining a medical event for this modality would be to craft the written directive to state the number of seeds to be used and the total seed strength and exposure time desired, then the using those factors, determine the desired dose equivalent to the target organ. To determine if a medical event occurred, apply the existing rule criteria to dose equivalent rather than to dose. The ACMUI agreed with this approach, and Dr. Zelac thanked them for providing insight into the challenges surrounding this modality.

This discussion begins on Page 141 of the meeting transcript.

UPDATE: RECOMMENDATIONS FROM THE FALL 2003 MEETING

Angela R. Williamson, NRC, gave the ACMUI an update on this subject.

Ms. Williamson stated that the ACMUI gave the staff only one recommendation, and it was in response to an issue the staff brought before the committee. The issue was whether the staff should impose a threshold of dose for the treatment of hyperthyrodism, in response to licensee requests to use any activity of radioiodine they requested to use. The ACMUI recommended that the NRC staff allow licensees to use the activity they believed was necessary to treat their patients, and the NRC staff agreed with that recommendation.

The ACMUI and the NRC staff then launched into a general discussion about the ACMUI's March 2, 2004, briefing to the Commission. The ACMUI ended that discussion with no recommendations to the staff.

This discussion begins on Page 179 of the meeting transcript.

The meeting adjourned at 4.33 p.m.

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Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
Ralph P. Lieto	Medical physicist
Leon S. Malmud, MD	Healthcare administrator
Ruth E. McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz, RPh	Nuclear pharmacist
Orhan Suleiman, PhD	Food and Drug Administration (FDA) representative
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

ACMUI member absent:

David A. Diamond, MD	Radiation oncologist

Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB) participated in the meeting. Staff from the Office of Nuclear Security and Incident Response (NSIR) and the Office of the General Counsel (OGC) also participated. Specific participating staff members are listed below:

Roger W. Broseus, PhD	NMSS/IMNS/RGB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Patricia K. Holahan, PhD	NMSS/IMNS
Charles L. Miller, PhD	NMSS/IMNS
Angela R. Williamson	NMSS/IMNS/MSIB
Ronald E. Zelac, PhD	NMSS/IMNS/MSIB

Also present were:

Lynne Fairobent	American College of Radiology
James Boxall	American College of Cardiology
William D. Nelligan	Certification Board of Nuclear Cardiology
Gerald A. White	American Association of Physicists in Medicine
Roshunda Drummond	American Society of Therapeutic Radiology and Oncology

The meeting came to order at 8:05 a.m.

PREPARATION FOR THE COMMISSION BRIEFING

The ACMUI began by discussing Ralph Lieto's briefing to the Commission, "Proposed Rulemaking on Pt. 35 Revision." Mr. Lieto stated his intent to bring three ongoing issues to the Commission, Pt. 35 revision on proposed rulemaking: the obtaining of board certification and the regulated community's belief that it attests to the understanding of a body of knowledge, rather than determining competency; the issue of preceptor statements and the use of the term "attestation" as opposed to "certification"; and transitional issues associated with the proposed rule.

The ACMUI then discussed the particulars of each topic, to help Mr. Lieto fine tune his discussion points.

Next, Thomas Essig, NRC, discussed his presentation, "NRC Method of Dose Reconstruction." (During the March 1, 2004, ACMUI public meeting, Charles Miller clarified that the staff would not launch into a technical discussion of the dose reconstruction issue, since it is still a work in progress. Rather, Mr. Essig would provide an overview of the status of this effort.)

In this overview, Mr. Essig explained that he intended to tell the Commission that staff plans to use the ACMUI's evaluation of the NRC method of dose reconstruction, combined with the NRC's self-assessment of its dose reconstruction method, to respond to the Society of Nuclear Medicine/American College of Nuclear Physician's criticism that the NRC uses excessively conservative methods to reconstruct doses.

Dr. Malmud then briefly discussed what he planned to say to the Commission, as the Chairman of the ACMUI Subcommittee that is reviewing the NRC's method of dose reconstruction.

This discussion begins on Page 4 of the meeting transcript.

PROPOSED CHANGES TO ABNORMAL OCCURRENCE CRITERIA

Angela R. Williamson briefed the ACMUI on this topic.

Ms. Williamson began by clarifying that changes to the abnormal occurrence (AO) criteria are within the authority of NRC's Office of Nuclear Regulatory Research (RES). The staff at this time welcomes any recommendations that the ACMUI may have regarding changes to the criteria, but final decisions regarding whether the criteria will be changed is within the purview of RES.

Next, Ms. Williamson defined AO: "an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health and safety." Then Ms. Williamson explained that the staff is considering adding language to the current criteria which would enable staff to capture events of a certain threshold that involve intravascular brachytherapy (IVB).

At this point, an ACMUI member asked Ms. Williamson to explain the purpose of the AO report to Congress. Ms. Williamson explained that the report, as far as can be established, is for their information. It is unclear if they use the report in any manner.

Ms. Williamson then briefly outlined the proposed change. The proposed change is to add, to the medical event criteria the phrase "or to tissue, which results in permanent functional damage." Ms. Williamson explained that this addition should capture only those IVB events, for reporting as AOs, where serious potential harm was done to the patient, but would exclude IVB events where the serious potential harm does not exist.

The ACMUI suggested this language: "...or to a portion of an organ, or part of an organ, which results in permanent functional damage to the tissue."

After some ensuing discussion, the ACMUI made a recommendation:

Insert a 3rd condition into the AO criteria to read as follows: "3) equal to or greater than 10 Gray to any portion of an organ which results in permanent functional damage."

The ACMUI suggests the above recommendation, conditional upon the agreement of the committee's two radiation oncologists, Dr. David Diamond and Dr. Subir Nag. Dr. Diamond was not present for the meeting, and Dr. Nag left early to attend another engagement.

This discussion begins on Page 72 of the meeting transcript.

TRANSITION ISSUES ON PT. 35 IMPLEMENTATION

Mr. Ralph Lieto ACMUI, gave a briefing on this topic.

Mr. Lieto discussed issues revolving around the new training and experience (T&E) rule, to become effective October 2004.

Regarding the preceptor issue, Mr. Lieto stated his belief that the preceptor requirement in the revised rule should apply to those professionals who are entering training programs this year, and not to individuals currently in training programs. Roger Broseus, NRC, clarified that under the proposed rule, anyone certified by a board that NRC recognizes, must submit a preceptor statement. The combination of the board certification and the preceptor statement would thus qualify the person for recognition (as an Authorized User, Authorized Medical Physicist, etc.) Dr. Donna-Beth Howe clarified that the preceptor statement must affirm that the person is board certified, and must include a statement that the individual is competent to function independently as an AU, AMP, etc. Regarding the alternate training pathway, Dr. Broseus clarified that a preceptor statement is needed, but the individual will need to submit detailed documentation of the training that was taken.

The ACMUI acknowledged that the structure of the new rule - with its risk informed stature - would put a new burden on the stakeholder community to determine when it is prudent to act as a preceptor for an individual. However, as the ACMUI supported the new risk-informed stature, they acknowledged that this new burden was preferential to a prescriptive rule.

Regarding the diagnostic use of Iodine-131, Mr. Lieto explained the focus of the revised rule is based on isotope activity, so that certain diagnostic uses now require a written directive. This may result in some AUs needing to meet therapy-related application criteria, for which they may not have documented T&E. Dr. Howe clarified that NRC no longer regulates according to diagnostic versus therapy uses. NRC now regulates according to whether a written directive is required. Accordingly, the NRC will grandfather those AUs experienced in 10 CFR 35.200 uses, who, because of the revised regulatory structure, will not otherwise be authorized to use Iodine-131, for which a written directive is required. Grandfathering these experienced AUs who were using I-131 for diagnostic whole body scans, will therefore enable them to keep their authorization to practice under the revised rule.

The ACMUI made the following recommendation:

That licenses be amended so that current authorized users of sodium iodide-131, in activities greater than 30 microcuries, for imaging and localization studies, be granted authority to continue operating in this manner.

The ACMUI then discussed the issue of grandfathering AMPs. One ACMUI member mentioned that this issue seems to be pretty much limited to concerns in Agreement States in which AMP is not a defined item; therefore, physicists who acted as AMPs were not listed on licenses as such. She stated that she is unsure how any more comments from ACMUI will affect the final rule. Nevertheless, other members believed that it was necessary that the ACMUI make a motion to encourage staff to think about the necessity of grandfathering AMPs so that those practicing in Agreement States will be able to continue practicing should they move to a state regulated by the NRC.

The ACMUI made the following recommendation:

That the NRC consider alternative rule language and/or guidance procedures to ensure that physicists currently practicing in Agreement States as HDR physicists; intravascular brachytherapy physicists; or Cobalt-60 teletherapy physicists, be grandfathered as AMPs, regardless of whether they are named on an Agreement State or NRC license.

Next, an ACMUI member brought up a related grandfathering issue, this one concerning uses under 10 CFR 35.200. This member believed there is a need to ensure that future practitioners of localization and imaging are able to practice I-131 imaging using non-sodium iodide, after completing the normal training pathway for 35.200 uses.

Toward that end, ***the ACMUI made the following recommendation***:

That the NRC staff amend the revised 10 CFR Part 35.200 to allow future 35.200 practitioners to use any desired form and activity of I-131 for imaging - with the exception of sodium iodide in excess of 30 microcuries - without additional training and experience.

With regard to diagnostic use of sodium iodide, the ACMUI made another motion to “convey the spirit” of the committee.

The ACMUI made the following recommendation:

That diagnostic use of sodium iodide, falling under 35.392 be included in the 700 hours of training for 10 CFR Part 200 uses, as long as use is limited to diagnostic imaging and localization, and the AU meets the specific experience requirements listed in 35.392.

Later, the ACMUI made a motion to amend the current definition of preceptor. The current definition is "an individual who provides or directs the training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." As illustrated graphically below, the ACMUI desires to remove the article "the" that is between the words "directs" and "training." In doing so, the ACMUI believes the rule will become more flexible by allowing multiple persons to act as preceptor for different modalities.

Thus, the ACMUI made a recommendation to redefine preceptor as follows:

"An individual who provides or directs ~~the~~ training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO."

In the ensuing discussion, the ACMUI moved again to redefine preceptor, this time to

Thus, ACMUI moved to again redefine preceptor as follows. (The redline/strikeout indications are meant to demonstrate the suggested change.)

"An individual who provides, ~~or~~ directs ~~the~~ or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO."

In this extensive and detailed discussion, one more item related to T&E was mentioned. An ACMUI member mentioned that, as is currently worded, §35.390 can be construed to mean that a physician with a residency in radiation therapy or nuclear medicine need not satisfy to the letter, all the requirements in paragraph B.1, which includes 700 hours of T&E and lists various technical duties. However, since neither of the ACMUI radiation oncology representatives were present, the committee could not get their input. The ACMUI therefore, decided to discuss this issue with the NRC staff in a teleconference, in which the ACMUI's oncologist representatives can participate.

This discussion begins on Page 104 of the meeting transcript.

PROPOSED CHANGES TO 10 CFR PART 35

Donna-Beth Howe, NRC, presented this topic to the ACMUI.

Dr. Howe began by reminding the ACMUI that at the November 2003 meeting, she had brought to the committee's attention, 10 issues related to 10 CFR Part 35 implementation. Staff believes these issues require rulemaking.

Since that time, staff has identified additional issues. Some are relatively minor, involving changes to the rule. Others are a bit more involved. Below is a summary of the recommended changes.

Section	Suggested Change	ACMUI Reaction
32.74(a)	Revise to add “transmission sources” to the text in 32.74(a)	A motion for approval to add “transmission sources.”
32.74(a)	Revise to add “§35.1000" to the list of regulatory sections in §32.74(a).	A motion for approval to add “§35.1000" to the list of regulatory sections. [1]
35.12(d)	Revise to specifically include “Subpart M”	The ACMUI agreed with the idea conceptually, but withheld supporting the suggested revision until staff makes the intent of the changes more clear. [1]
35.12(d)	Revise to specifically include appropriate radiation safety requirements in Subparts D through H	Same as above.
35.41(b)(4)	Revise to add “§35.1000"	The ACMUI supported this suggestion.
36.610(d)	This section discusses the requirement for initial training. Revise to add a new section that discusses the need for vendor training, and distinguishes vendor training from initial training.	The ACMUI agreed with the idea conceptually, but withheld supporting the suggested revision until staff can verbalize the changes such that the licensee has the flexibility to require vendor training when the licensee believes doing so is necessary.
35.26	Revise to §35.26 to permit changes based upon the §35.1000 guidance posted to the NRC website.	The ACMUI supported this suggestion.
35.2026	This is the section that describes the records a licensee must keep. Suggest revision to include a requirement that licensees keep a copy of the old and new procedures; and keep a copy of the appropriate 35.1000 guidance upon which the licensee is basing his or her changes.	The ACMUI supported this suggestion.

[1]As Dr. Howe discussed these suggested changes with the ACMUI, Charles Miller, NRC, clarified that these changes were preliminary. Therefore, the staff was searching for ACMUI’s conceptual agreement on these suggested changes, and not necessarily motions to approve specific wording. This motion, therefore, will not be carried into the record as a formal motion at this time.

This presentation begins on Page 231 of the meeting transcript.

NEXT MEETING DATE, AGENDA TOPICS, MEETING SUMMARY

The ACMUI tentatively scheduled the Fall 2004 meeting for October 13-14. The ACMUI also scheduled two teleconference calls: March 22, 2004; and May 13, 2004, with May 20 as a back up date to the May 13 date. These dates were proposed to discuss issues related to T&E and the NRC's method of dose reconstruction.

This presentation begins on Page 260 of the meeting transcript.

The meeting adjourned at 5:08 p.m.

*See previous concurrence.

OFC	MSIB		MSIB		MISB		IMNS		NMSS	
NAME	AWilliamson*		RTorres*		TEssig*		CMiller*		MVirgilio	
DATE	03/29/04		03/29/04		03/29/04		4/23/04		/	/04