SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
March 22, 2004

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) met on March 22, 2004, in a public teleconference session.

The ACMUI members who participated in the teleconference 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
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 teleconference. Staff from the Office of the General Counsel (OGC) also participated. Specific participating staff members are listed below:

Roger W. Broseus, PhD	NMSS/IMNS/RGB
Susan Chidakel	OGC
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Donna-Beth Howe, PhD	NMSS/IMNS/MSIB
Sami Sherbini	NMSS/IMNS/MSIB
Anita Turner, PhD	NMSS/IMNS/MSIB
Sandra Wastler	NMSS/IMNS/RGB
Angela R. Williamson	NMSS/IMNS/MSIB
Ronald E. Zelac, PhD	NMSS/IMNS/MSIB

Members of the public participated in the teleconference. Specific participating members of the public are listed below:

Carol Marcus	Society of Nuclear Medicine
Jeffrey Siegel	Society of Nuclear Medicine
Lynne Fairobent	American College of Radiology
William Uffelman	Society of Nuclear Medicine
Roshunda Drummond	American Society of Therapeutic Radiology and Oncology

Francis Yak

The meeting came to order at 1:05 p.m.

OPENING REMARKS

Thomas H. Essig, Designated Federal Officer, made opening remarks, thanking everyone for their participation. In his remarks, Mr. Essig recused the ACMUI member, Mr. Ralph Lieto, from any decision making activities, recommendations, or conclusions related to the ACMUI subcommittee's dose reconstruction effort associated with the St. Joseph Mercy Hospital case. Mr. Essig recused Mr. Lieto because Mr. Lieto currently serves as Radiation Safety Officer at St. Joseph Mercy Hospital.

TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH 10 CFR 35.300

Dr. Jeffrey Williamson, ACMUI, explained the substance of the discussion. Dr. Williamson explained that, prior to the effective date of the implementation of the revised 10 CFR 35, Medical Use of Byproduct Material, the radiation oncology certification through the American Board of Radiology (ABR) was an acceptable credential for being an authorized user (AU) of radiopharmaceuticals, for which a written directive is required. However, the revised Part 35 put in place training requirements that the ABR does not meet. Therefore, radiation oncology certification through ABR is no longer acceptable for meeting the training and experience (T&E) requirements in 10 CFR 35.

To address this issue, the ACMUI formed a T&E subcommittee. The subcommittee's specific attempt to address this issue is its proposal to place within the revised rule, a requirement for supervised clinical experience with 12 different cases, distributed in 4 different categories. This will be a common but separate requirement applying to those who are qualifying as AUs, both by virtue of board certification and alternate pathway training.

Dr. Williamson then read an excerpt of the proposed language:

"Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.300 to be a physician who:

(a) Is certified by medical specialty board whose certification process includes all of the requirements in Paragraph (b)(1) of this section, whose certification has been recognized by the Commission or an Agreement State...to be recognized, a specialty board shall require all candidates for certification to:

1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of...or a training program in nuclear medicine or a related medical specialty that includes 700 hours of training and experience as described in Paragraph (b)(1) of this section."

Dr. Williamson explained that the above basically requires completion of a 3 year residency in radiation oncology, approved by the appropriate body; or training in a nuclear medicine or related medical specialty program that includes 700 hours of T&E as described in Paragraph (b)(1). Thus, there are two groups: 1) the radiation oncology group that defines the appropriate

residency, and the nuclear medicine group that defines what constitutes a program (by reference) to the alternate T&E pathway requirements.

Dr. Williamson stated other elements of the proposed language in detail. Of particular interest was Paragraph (b)(1), the alternate training pathway, which requires 700 hours of T&E plus the listed work experience requirements. Dr. Williamson concluded by explaining that the essence of the proposed language is that the radiation oncology T&E requirements need not comply, to the letter, with everything that is in Paragraph (b)(1), but any other residency experience does.

Dr. Eggli, the nuclear medicine physician representative, asked Dr. Williamson why he is proposing that all physicians, except radiation oncologists, meet the 700 hour training requirement. Dr. Williamson responded that the structure of the boards that certify radiation oncologists do not support the requirement that the 700 hour T&E be supervised by a qualified AU. The radiation oncology boards do not require or do not have a mechanism to have a qualified AU supervise the 700 hours of T&E, as the Pt. 35 rule currently requires. Another underlying reason, is that about 40 percent of radiation oncologists have substantial practices in radionuclide therapy. They have successfully pursued this practice under regulations that do not require them to have the 700 hours of T&E. Dr. Williamson explained that he is trying to create a pathway by which graduates of those programs that have clinical experience can become AUs for 35.390 uses, without having an undue burden placed upon them.

Dr. Eggli responded that the primary practitioners in 35.390 modalities are nuclear medicine physicians. He expressed his opinion that it may not be prudent to hold nuclear medicine physicians to a higher standard than radiation oncologists. Dr. Williamson replied that he was open to that observation, but he proposed this language with the belief that the nuclear medicine community was content with its T&E requirements as currently listed. Dr. Williamson stated he had no objection to amending the nuclear medicine T&E so that it is more performance-based (i.e., less regulatorily demanding) so that its T&E requirements are parallel to that of radiation oncology's T&E requirements.

The ACMUI further discussed the specifics of the language, and agreed that the radiation oncology T&E in 35.390 should be amended in the following manner:

- A requirement for certification in radiology, along with the requirement for supervised clinical experience with 12 different cases. (Refers to Paragraph (a) of 35.390).

- Removal of the 700 hour training requirement from Paragraph (b)(1). Replace with some kind of enumeration listing the appropriate residency training.

Richard Vetter, the ACMUI's Radiation Safety Officer representative, asked a question relating to the proposed T&E's language requiring 3 years of residency in radiation oncology. Dr. Vetter wanted to know if 3 years was really needed.

After discussion between members of the ACMUI and Roshunda Drummond, American Society of Therapeutic Radiology and Oncology; William Uffelman, Society of Nuclear Medicine; and Lynne Fairobent, American College of Radiology; there was agreement that if the language was adjusted to remove "requiring 3 years of residency in radiation oncology" and replaced with language stating that the individual complete a residency program approved by the Accredidation Council for Graduate Medical Education (ACGME), this would ensure that

individuals pursuing their particular professional discipline would spent the appropriate amount of time in residency. After more discussion a recommendation was made.

The ACMUI recommended the following:

That NRC staff re-define the training requirement in 35.390(b)(1), by removing the reference to 700 hours of training, and replacing with a requirement to successfully pass the board exam by the ACGME in the areas of oncology, nuclear medicine, diagnostic radiology, or a program in a related medical specialty.

As ACMUI continued its discussion, another issue in Dr. Williamson's proposed rule language was questioned. Dr. Williamson proposed that 35.390 be amended to delete Paragraph F which requires that trainees elute generator systems. The general consensus was that training for eluting generators is more appropriate for diagnostic and imaging uses. It is not necessary training for radiation oncologists.

The ACMUI recommended the following:

To remove Paragraph F of 35.390, the requirement to elute generator systems from the 35.390 language.

However, as the ACMUI continued discussion, it was noted that nuclear medicine physicians qualifying under 35.390 may still need generator elution training. To address that issue, Dr. Vetter made the following motion.

Recommendation:

That the NRC staff amend 35.200 to add the requirement that any authorized user pursuing 35.390 qualification must have had experience in eluting generators.

DISCUSSION OF ACMUI DOSE RECONSTRUCTION SUBCOMMITTEE FINDINGS

Remarks: At the March 1, 2004 ACMUI meeting, Jeffrey F. Williamson, PhD, ACMUI member, gave a presentation on NRC's method of dose reconstruction. This presentation was 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 (DRS), chaired by Dr. Leon S. Malmud.

Mr. Essig began the discussion by re-stating the deadlines for the subcommittee's report submittal: March 30, to the full ACMUI for review, and April 9, to the NRC staff.

Dr. Malmud, Chair of the DRS, then summarized the DRS's 6 preliminary opinions of the NRC's dose reconstruction methods:

1. Dr. Jeffrey Williamson's calculations estimate the range of radiation exposure to the patient's daughter, a "member of the public, " as a best case/worst case scenario, using methodology that does not include a radiation dose contribution from the patient's urine bag, which Dr. Williamson presumed did not contribute to the daughter's radiation dose. Furthermore, Dr. Williamson acknowledged that his lowest estimate of 4 rem was still well above NRC's regulatory limit of 100 rem to members of the public.

2. Dr. Williamson's estimated dose calculation to the daughter was 4 to 9 rem. The NRC's calculations were 1.67 to 3.75 times that of Dr. Williamson's calculations.

3. The reasons for the differences in the estimated dose calculations are the result of the differences in Dr. Williamson's assumptions, versus NRC's assumptions, of the time the daughter spent near the patient, and the distance between the daughter and the patient.

4. Dr. Williamson believed that the NRC calculation that produced a radiation dose of 15 rem to the daughter was overly conservative because it assumed extended close contact between the patient and the daughter at an unrealistically close distance, and ignored the use of local shielding. More specifically:

   a) The NRC's use of Monte Carlo simulation to reconstruct the bed side measurement distance resulted in an unrealistically short distance for mean patient center-to-daughter surface distance.

   b) Had the NRC used continuous decay, this would have lowered the dose estimate by about 10 percent.

   c) Most importantly, the licensee's post-incident interviewers and dose reconstruction led to a different scenario regarding the use of body shields and daughter dwell time distribution than that derived from the NRC interview. The DRS strongly feels that these differences should have been outlined in the inspection report and used to define lower and upper exposure bounds. In other words, the NRC should have reported a range of possible doses.

5. Had the licensee promptly notified the NRC about the unwillingness of a member of the public to comply with the directions given by the licensee's RSO, it is assumed the desirable effect of better documentation of the event would have occurred.

6. A concern of the DRS is how such a similar situation in the future might be handled in a more optimal manner for both the public and the licensee.

Regarding the concern raised in Item 6, the DRS suggested that the full ACMUI recommend to NRC staff several actions as follows:

- That the NRC develop an information notice (IN) asking licensees to provide contemporaneous notification to the NRC when a member of the public does not comply with instructions, despite the best effort and advice of the licensee. The IN should

summarize all available guidance on exposure limits and licensee options when a family member insists on attending a radioactive patient.

- That the NRC develop a modification process to allow the enforcement policy to grant exemptions based on humanitarian grounds. Thus, when a licensee is unable to enforce the dose limit regulations despite a best attempt to do so, the licensee will have recourse in dealing with the issue, without unduly alarming members of the public regarding the consequences of exceeding the allowable radiation dose, when doing so is deemed not to have serious medical consequences.

Also mentioned was a suggestion made by a member of the ACMUI, Dr. Subir Nag, who is not a member of the DRS. Dr. Nag suggested that, regarding Item 6, licensees should have the option to have patients' relatives sign a form indicating that the licensee explained to them that the time they are spending in proximity to the radioactive patient is likely to cause them to receive a dose in excess of the public radiation dose limit; and that they are voluntarily exceeding the permissible limit against medical advice. In instances where the relatives refuse to sign, a note explaining the circumstances can be made in the patient's chart.

The ACMUI made a motion:

That in instances when patients' relatives refuse to follow licensees' instructions regarding radiation safety, that licensees be allowed to have the relatives in question sign a form indicating that they were instructed as to what the regulations require in relation to dose limits to members of the public, and they are nevertheless ignoring this instruction against medical advice. If the relatives in question refuse to sign the form, a note explaining this action can be placed in the patient's chart. [1]

Next, the ACMUI subcommittee Chairman referred to the March 1-2, 2004 ACMUI public meeting at NRC Headquarters, where the ACMUI stated its opinion that in instances where there is uncertainty in dose reconstruction, the NRC should present a best case/worst case scenario in its final report.

Dr. Carol Marcus, Society of Nuclear Medicine, added that although she agreed with the DRS's report to the NRC on how to "more accurately" calculate the dose to the patient's daughter's arm, she believed that the dose to the daughter's arm in this case is not indicative of the dose to the patient's trunk (i.e, whole body). Dr. Marcus stated that a trunk dose of the whole body is what is used for risk assessment. In this type of situation, there needs to be an additional calculation done that is to be used for risk assessment, because the whole body dose is what should be used for risk assessment, and it will be a lower number.

Dr. Jeffrey Siegel complimented the DRS on its work, then added that, in this case, he and Dr. Marcus went beyond the regulatory definition of total effective dose equivalent (TEDE) because, in terms of risk assessment, one needed more than a regulatory value. He stated that the daughter's trunk and arm were different distances from the patient; also, there was more attenuation of radiation to the trunk.

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[1] The ACMUI did not actually vote on this motion, but there was no expressed disagreement with this concept.

Regarding the findings of the medical consultant that the NRC hired to estimate the daughter's medical risk, the ACMUI mentioned that it believed that the consultant was not given relevant data to determine risk. They stated that whenever the NRC asks a consultant to estimate risk due to exposure, the consultant should not be given TEDE, but should be supplied with the whole body dose.

The ACMUI made a few more remarks regarding the DRS's draft report. However, the subcommittee did not submit the report to the ACMUI for a final vote. Toward that effort, the subcommittee Chair, Dr. Malmud, summarized the tasks that still needed to be done:

- Point out that a major discrepancy exists between St. Joseph Mercy Hospital's calculation and the NRC's calculation of the patient's dose;

- When the NRC asks consultants to review medical risk, the NRC should ensure the risk is evaluated based upon whole body exposure rather than using the TEDE.

The DRS committed to editing and reviewing the report further, and then submitting it to the full ACMUI for a final vote.

This discussion begins on Page 69 of the meeting transcript.

The meeting adjourned at 3:00 p.m.