SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
May 20-21, 2003

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 May 20-21, 2003.

ACMUI members present at the meeting were:

| | |
|---|---|
| Manuel Cerqueira, MD | Nuclear cardiologist, ACMUI Chairman |
| Jeffrey A. Brinker, MD | Interventional cardiologist (designee) |
| David A. Diamond, MD | Radiation oncologist |
| Douglas F. Eggli, MD | Nuclear medicine physician |
| Nekita Hobson | Patients' rights advocate |
| Ralph Lieto | Medical physicist |
| Leon Malmud, MD | Healthcare administrator |
| 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 |

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. Specific participating staff members are listed below:

| | |
|---|---|
| Robert Ayres | NMSS/IMNS/MSIB |
| Roger Broseus | NMSS/IMNS/RGB |
| Charles Cox | NMSS/IMNS/MSIB |
| Thomas H. Essig | NMSS/IMNS/MSIB, Designated Federal Officer |
| Donna-Beth Howe | NMSS/IMNS/MSIB |
| Michael Markley | NMSS/IMNS/MSIB |
| Charles L. Miller | NMSS/IMNS |
| Linda Psyk | NMSS/IMNS/MSIB |
| Roberto Torres | NMSS/IMNS/MSIB |
| Anthony Tse | NMSS/IMNS/RGB |
| Angela Williamson | NMSS/IMNS/MSIB |
| Ronald Zelac | NMSS/IMNS/MSIB |

Invited guests present at the meeting:

Ryan T. Coles, Government Accounting Office
William R. Hendee, American College of Radiology
Jeffry Siegel, Society of Nuclear Medicine
Prabhakar Tripuraneni, American Society of Therapeutic Radiology and Oncology

The meeting came to order at 1:04 p.m.

**OPENING REMARKS**

Thomas H. Essig, Designated Federal Officer, introduced each ACMUI member and welcomed all present to the meeting.

**SOCIETY OF NUCLEAR MEDICINE LICENSING GUIDE**

Thomas Essig, NRC, gave a brief presentation on this agenda topic.

Mr. Essig began by explaining that this agenda topic's title is a bit of a misnomer. He explained that the guide is not a licensing guide per se, but is actually a guide for the medical use of byproduct material in a diagnostic setting.

Next, Mr. Essig outlined the genesis of this guide. He noted that the Society of Nuclear Medicine (SNM) developed this guide to assist the diagnostic regulated community in implementing the new 10 CFR Part 35 (Part 35). SNM reviewed and commented on NRC's licensing guide, NUREG 1556, Volume 9 (Consolidated Guidance About Materials Licenses: Program-Specific Guidance Aboujt Medical Use Licenses). Nonetheless, SNM volunteered to create its own version of Volume 9, because they believed that the NUREG was difficult to use due to its extensive detail.

Mr. Essig explained that as SNM developed its guidance, it gave the guidance to NRC to review, and eventually, NRC entered into a licensing agreement with SNM so that this guidance could be published on NRC's website as a service to licensees. This diagnostic guidance is not a substitute for NRC's regulations, but is one acceptable method of assisting licensees in implementing the regulations; therefore; it can be considered an adjunct to NUREG 1556, Volume 9. Mr. Essig further explained that the Agency stated its position on SNM's diagnostic guidance in a Regulatory Issues Summary, dated November 27, 2002.

Regarding licensees who choose to use SNM's diagnostic guidance, the ACMUI asked Mr. Essig to clarify whether it will have the same level of recognition as NRC's guidance if licensees use the SNM guidance and then need to defend their actions because they followed the guidance's recommendations. Mr. Essig explained that since NRC recognizes the guidance as one acceptable method of implementing Part 35, it carries an equivalent level of recognition as the NRC guidance document.

This presentation begins on page 6 of the meeting transcript.

**UPDATE: REVIEW OF DOMESTIC REGULATION OF NUCLEAR MATERIAL**

Mr. Ryan T. Coles of the U.S. Government Accounting Office (GAO), initially made a presentation on this topic at the October 28, 2002 meeting. He returned to give the ACMUI an update.

Mr. Coles began by explaining that the GAO was in the process of completing its investigation into the accountability of radiation sources (an effort that was undertaken at the request of Senator Daniel Akaka, Chairman of the Subcommittee on International Security, Proliferation,

and Federal Services; Senate Committee on Governmental Affairs). As such, he had no findings that he could share with the ACMUI. However, was able to update the ACMUI on three items: 1) a status update on GAO's three separate efforts in which they are reviewing materials regulation and security; 2) a description of GAO's objectives, scope, and methodology used to review the domestic regulation of nuclear material; and 3) a synopsis of a report GAO has already released, regarding the U.S. Department of Energy's (DOE) source recovery program.

Regarding GAO's review of domestic regulation and security, Mr. Coles explained that the final report will be issued most likely in late July/early August. He explained that as this effort began, GAO structured it so that the findings will be an educational tool to teach Congress how radioactive materials are regulated in the United States. Questions GAO attempted to answer are: What is the scope of radioactive material use in the United States, specifically, how many licensees exist? How many radioactive sources are in use? What are the typical uses of these sources? What kinds of radiation-related incidents are occurring (such as lost/abandoned sources, misadministrations, and malfunctioning devices) and what are licensees' reporting requirements? Mr. Coles further explained that GAO is attempting to get a grasp on the effectiveness of Federal and State controls over this material, as well as what efforts have been initiated to safeguard this material since the terrorist attacks of September 11, 2001.

To answer these questions, Mr. Coles explained that GAO issued a survey to 32 Agreement States, all of the non-Agreement States, all four NRC regions, and to Puerto Rico. Furthermore, GAO visited and interviewed several State and local officials, as well as some licensees. During its visits, GAO reviewed a cross section of radioactive material programs (e.g., academic, research, and industrial programs). Moreover, GAO had extensive discussion with several Federal agencies besides the NRC (the U.S. Department of Transportation, the U.S. Environmental Protection Agency, the U.S. Federal Emergency Management Agency, the DOE, and the U.S. Department of Justice).

Mr. Coles concluded his presentation by giving a synopsis of GAO's findings on DOE's source recovery program. He explained that DOE appeared to not give the mission to collect Greater Than Class C sources sufficient attention. He explained that DOE's environmental management office does not believe that this mission is an appropriate one for DOE to conduct, and that in the nearly 20 years in which it has been tasked with this mission, no progress toward ultimate disposal of this material has been made.

After thanking Mr. Coles for his update, ACMUI advised him on the outcome of one of the briefings NRC staff gave them earlier during the closed session portion of the meeting. This briefing involved staff's efforts regarding the implementation of NRC's Interim Compensatory Measures (ICM) to safeguard sources. The ACMUI expressed their belief that the Agency's ICMs reflected a logical and well-thought out approach to safeguarding sources, and they hoped that any recommendations included in the GAO's report on the domestic regulation of radioactive material will also be as well-thought out. The ACMUI believed that GAO's report may provide the basis for new legislation. If so, the ACMUI emphasized the need to include accurate and common sense information and recommendations in the report, otherwise, legislators could use it to develop laws that will adversely impact the practice of medicine.

This presentation begins on page 11 of the meeting transcript.

**TRAINING, EDUCATION, BOARD CERTIFICATION AND THE NEW PART 35**

William Hendee, Ph.D, American College of Radiology (ACR) led the discussion on this topic. Dr. Hendee began by relaying the experience he had with three NRC staff members in a meeting earlier in the day. He explained that he met with Roger Broseus, Patricia Holahan, and Sandra Wastler, (NRC/NMSS) in which he laid out ACR's concerns. Dr. Hendee found the discussion "excellent, open, and frank", and he thanked Dr. Broseus, Dr. Holahan, and Ms. Wastler for their willingness to work with him to address ACR's concerns.

Next, Dr. Hendee expounded on three issues of concern to ACR regarding the proposed training and experience (T&E) to be applied as an acceptable method of recognition to gain authorized user status in Part 35.

The first issue involves the default pathways to gain NRC recognition for the various categories of users [Authorized User (AU); Authorized Medical Physicist (AMP); Authorized Nuclear Pharmacist (ANP); or Radiation Safety Officer (RSO)]. According to Dr. Hendee, the pathway in the proposed T&E language that allows for recognition via didactic instruction and supervised practical training is vague, with respect to how it applies to boards. He explained that this pathway does not specify whether a board must require its candidates to obtain a specific number of hours of this instruction/supervision. Dr. Hendee believes that, consequently, the language in the proposed rulemaking makes it difficult to ascertain whether NRC views board certification as assurance that candidates have met the specific hours of didactic instruction and training that NRC considers essential. To address this issue, Dr. Hendee stated that ACR recommends that the NRC recognize the certification process of well-established boards (such as the American Board of Radiology (ABR)) as sufficient to certify users. Dr. Hendee believes NRC should allow these boards to define the education, training, and experience that is most appropriate to delivering quality care within the medical specialty for which they offer certification.

Dr. Hendee's second concern related to the appropriate person to attest to satisfactory completion of training. The proposed T&E rule language requires that this person be an experienced preceptor AU (or AMP, ANP, etc.). However, Dr. Hendee believed that the more appropriate person to provide this attestation is the program director. He stated that the AU would be an acceptable preceptor in non-accredited training programs, but in cases where the program is accredited, the program director would be the best person to attest to satisfactory completion of training. According to Dr. Hendee, this is true because the program director is the person responsible for the training in accredited programs.

Dr. Hendee's third concern involved certification examinations as a measure of competency. Regarding this concern, Dr. Hendee recommended that any reference to successful passing of board examinations as a measure of competence be removed. His rationale was that the passing of board examinations illustrates the mastery of a body of knowledge, but it does not evaluate competence in a clinical setting.

Dr. Hendee concluded his discussion by announcing a position statement and a comment. The position statement was that the ACR supported the listing of certain NRC-recognized boards on

the NRC website. The comment was that ACR strongly objects to the omission of the ABR as one of those NRC-recognized boards. Dr. Hendee believes that the ABR should be included because, as he stated, there are many present RSOs with oversight responsibilities in diagnostic nuclear medicine programs who are certified by the ABR. Furthermore, according to Dr. Hendee, diagnostic uses of source material constitute the greatest use of this material (in the medical arena), so the omission of the ABR as a recognized board will create a shortage of RSOs to oversee the safety program of most licensees. Moreover, certification by the ABR meets or exceeds that of the other three certification boards the ACMUI recommends. Those boards are the American Board of Health Physics in Comprehensive Health Physics; the American Board of Medical Physics in Medical Health Physics, and the American Board of Science in Nuclear Medicine and Radiation Protection.

The ACMUI had extensive discourse with Dr. Hendee regarding his concerns. With respect to Dr. Hendee's concern about board certification and the T&E rule language, the ACMUI explained that the T&E language was not intended to make boards require a specific number of hours of didactic training as part of the certification process. ACMUI underscored that the only pathway intended to prescribe hours of training was the alternate training pathway to certification, not the default board certification pathway.

Regarding Dr. Hendee's opinion on the appropriate person to attest satisfactory completion of training, ACMUI assured Dr. Hendee that they recommended that the program director be the party that attests to this training. Nonetheless, the Commission believed that the party best suited to this task was a preceptor AU who is listed on an NRC or Agreement State license.

Regarding the third concern, certification examinations as a measure of competency, ACMUI explained that a tremendous number of program directors felt uncomfortable attesting to competence, and that these individuals stated that the certification boards were the party responsible for attesting to competence. In response, Dr. Hendee then suggested that the ACMUI define "competence." If "competence" is the mastery of a body of knowledge, then Dr. Hendee agrees that the boards should attest to competence. However, if competence can be demonstrated only through one's performance in clinical practice, then program directors should attest to competence. Following that suggestion, there was some discussion as to which way the word "competence" should be defined in this context. Dr. Patricia Holahan, NRC, clarified that the Commission has allowed for the word "competence" to be defined as sufficient attestation to demonstrate that the candidate has knowledge to fulfill the duties of the position for which certification is sought. ACMUI asked Dr. Hendee if that was an acceptable way to define competence, and Dr. Hendee agreed it was.

Regarding Dr. Hendee's comment on the omission of ABR as a recognized board for RSO status, the ACMUI believed that the essence of the problem is in the language in the T&E, which asserts that a user can serve as the RSO only in programs where the use of source material is similar to the use for which the RSO has certification. Mr. Hendee responded that a way to address this would be to allow a person certified as an AMP to function as the RSO over research and diagnostic applications, if that person has had some basic education in the safe handling of unsealed sources. The ACMUI agreed to that proposition.

This presentation begins on Page 23 of the meeting transcript.

**DISCUSSION: NRC LICENSING TIME LINES, PROPOSAL FOR MONTHLY/BI-MONTHLY TELECONFERENCES**

Thomas Essig, NRC, briefed the ACMUI on this agenda topic. This was a discussion to create a course of action that staff can use to keep ACMUI meaningfully involved and updated, in a timely manner, on issues where they can contribute.

Action suggested was staff use of periodic, public teleconference calls with the ACMUI. However, as Mr. Essig explained, there are several points to consider regarding teleconferences. One consideration is the increased time consumption for both NRC staff and the ACMUI. NRC staff would have to expend a significant amount of time preparing for these calls by coordinating staff and ACMUI schedules. The schedule of teleconference meetings would require listing in the Federal Register several months in advance to allow for public participation. Furthermore, because of advanced meeting announcements, there would be no flexibility to revise meeting dates to accommodate changes in participants' schedules. A possible consequence of that restriction would be that the committee's business would be impaired during some meetings, because of an insufficient number of participants needed to reach a quorum.

Yet another concern, as explained by Mr. Essig, would be the increased cost to the Agency. The Agency would experience increased costs for meeting-related activities, to include meeting preparation, participation, and follow-up actions, where required. Mr. Essig explained that these costs have not been factored into the Fiscal Year 2004 budget, although it is possible that savings from a reduced effort elsewhere could finance increased effort in this area.

Nontheless, ACMUI and staff agreed that teleconferences are necessary, so that important issues are not inadvertently forgotten. During the closed session meeting, ACMUI and staff agreed that a reasonable approach would be to schedule at least one teleconference in the period between the semi-annual meetings. Toward that end, the ACMUI made a recommendation during the closed session meeting.

***Recommendation:***

**Approximately 2 weeks after distribution of the staff response to ACMUI recommendations, a conference involving the ACMUI and staff be held to review and prioritize items of discord.**

This discussion begins on Page 58 of the meeting transcript. The recommendation is on Page 66 of the May 20, 2003, closed session transcript of the meeting. (Accessible to NRC employees only, in ADAMS under ML031700405).

**T&E RULEMAKING, STATUS, AND DISCUSSION**

Roger Broseus, NRC, made a presentation on this topic. Dr. Broseus explained that the Commission approved, in Staff Requirements Memorandum 02-0194, the ACMUI's T&E recommendations. Those recommendations included a suggestion that the NRC list boards it recognizes in 10 CFR Part 35. That suggestion notwithstanding, the Commission approved

the ACMUI's T&E recommendations with a caveat suggested by staff. This caveat was that the approved boards be listed on the NRC website rather than directly in the rule.

Regarding evidence of authorized users' competence, Dr. Broseus affirmed that the proposed rule should require that candidate AUs satisfactorily demonstrate to preceptors a mastery of a body of knowledge, rather than have the preceptor attest to the candidate's clinical "competence."

Dr. Broseus then outlined small, detailed changes that staff made to the ACMUI's recommendations. The changes were numerous, and they involved formatting revisions to increase clarity, ensure that items are cross-referenced properly, and remove redundancy in the language. Next, Dr. Broseus informed the ACMUI there was one area where staff still needs advice, and that is whether the Royal College of Physicians and Surgeons of Canada (RCPSC) should be added to the list of approved boards that will eventually be posted to the NRC website. (Later, ACMUI clarified that RCPSC is actually an accreditation program, not a board).

Dr. Broseus continued to outline other modifications that staff made to the ACMUI's T&E recommendations. However, these changes involved extensive re-wording and re-formatting, such that ACMUI had difficulty comprehending them. Therefore, ACMUI suggested that staff perform redline/strikeout edits to the T&E in its original form, so that the modifications can be clearly seen. Staff responded that simple redline/strikeout changes would be difficult to insert, because of the reformatting of the language. To address this issue, staff suggested that they meet with ACMUI to go over the document thoroughly to get a grasp on all the changes. The ACMUI agreed that the best way to do so would be via conference calls some time soon. Staff informed the ACMUI that the goal was to get the proposed rule up to the Commission by the end of July (2003).

**Follow-up: On June 20, 2003, staff concurred on the draft memorandum, "REVIEW AND CONCURRENCE: PROPOSED RULE ON RECOGNITION OF SPECIALTY BOARDS." Staff forwarded the draft memorandum to the ACMUI for review. Staff discussed the ACMUI's comments on the draft memorandum during the July 17, 2003, teleconference, which was closed to the public. This meeting was announced in the Federal Register (68 FR 41665).**

This discussion begins on Page 64 of the meeting transcript.

## SEALED SOURCE MODEL NUMBERS AS LICENSE CONDITIONS

Donna-Beth Howe, NRC, provided a briefing on this subject. Dr. Howe began by reminding the ACMUI that, at their October 28, 2002, meeting, they made a recommendation to staff to initiate rulemaking that would modify 10 CFR Part 30.32(g)(1) to allow more generic listing of interstitial seeds and sources on NRC licenses. (The ACMUI made this recommendation because licensees are required to list, by manufacturer and model number, all of their individual sources, or in the case of multiple sources in a single device, they must list each device. The ACMUI said this requirement is overly burdensome because device names and/or model numbers change frequently, resulting in ceaseless license amendments). Dr. Howe noted that staff evaluated this recommendation but decided to not adopt it because of the likelihood that such a change may ultimately result in reduced source accountability (For more discussion of this topic, see "Update: Recommendations from Fall 2002 Meeting" in these minutes). Dr. Howe

emphasized that both staff and the Commission are very concerned, particularly in this post-September 11 environment, about licensees maintaining adequate control and security over radioactive sources.

Dr. Howe then reminded ACMUI of alternative methods they may employ to reduce the burden of needing to update their licenses every time there is a change in the device name or model number. One alternative is to identify the sources or devices by manufacturer and model number as they are registered with the Commission in the Sealed Source and Device Registry (SSDR). The other is for licensees to provide the information that is contained in 10 CFR 32.210, Registration of Product Information.

The ACMUI believed that the options are still overly burdensome, and suggested that better alternatives could be developed. They stated that the number of seed models has increased dramatically, so a requirement to list every radioactive seed by manufacturer and model number, rather than generically, seriously restricts licensees' ability to negotiate for the most economically priced seeds. The ACMUI further stated that device model numbers change, but the seeds within them do not change substantially, so in terms of radiation safety, it does not matter whether the licensee is using Model A, B, or C. Therefore, a generic statement to describe the seed, such as "encapsulated radioactive iodine" rather than "Theragenics, Model XYZ" would suffice. ACMUI reiterated that public health and safety would not be compromised.

In response, an NRC staff member, Ronald Zelac, Ph.D., pointed out another consideration. He explained that another reason for listing sources on licenses by manufacturer and model number was to protect the public health by giving the Agency an opportunity to ensure that the source to be used was registered in the SSDR. The ACMUI replied that the revised Part 35 requires licensees to use only those sources that are in the SSDR; therefore, NRC verification that licensees are using only these sources is unnecessary. The ACMUI believes that NRC should assume that licensees will use only the SSDR-registered sources, then should apply the Agency's performance-based regulation philosophy to address those licensees who do not follow this requirement.

As the discussion ensued, the ACMUI and the staff reached an impasse regarding the need to list sources by model number and manufacturer, to protect the public health and safety. Therefore, the ACMUI made the following recommendation:

***Recommendation:***

***Whereas the ACMUI sees no conceivable patient or public health hazard from listing interstitial brachytherapy sources generically on license applications, NRC should develop a strategy for eliminating this requirement for this narrow class of sources.***

This discussion begins on Page 92 of the meeting transcript.

**NATIONAL MATERIALS PROGRAM PILOT PROJECT ON OPERATING EXPERIENCE EVALUATION**

Michael Markley, NRC, gave a presentation on this subject. Mr. Markley began by introducing members of the pilot project working group. They were Debbie Gilley, Florida; Cynthia Taylor, Region 2, NRC; and Marsha Howard, Ohio. Ms. Gilley participated via telephone, and Ms.

Taylor was present in the audience. Ms. Howard was not present.

Mr. Markley then explained that the working group had already developed its charter and was approaching the ACMUI to get their input early in the process of the working group's efforts. Next, Mr. Markley outlined the working group's efforts. He explained that the group hoped to use licensees' common operating experience information to conduct trending. This effort is not an evaluation of Agreement State performance, but rather an attempt to use their operating experience to make better resource allocation and regulatory decisions. Mr. Markley explained that the group, ultimately, is seeking to develop a data evaluation process that would produce similar outcomes, regardless whether the Agreement States or the NRC was using the process.

Later in his presentation, Mr. Markley emphasized the need for effective communications as part of this effort. He noted that both the NRC and the Agreement States perform many positive deeds, but do not necessarily share results of outcomes with each other. He emphasized the necessity that the NRC and the Agreement States create efficiencies and reduce burden by sharing information.

ACMUI was supportive of the Working Group's philosophy. Furthermore, ACMUI suggested, and Mr. Markley agreed, that it would be useful for NRC to share any insights gained from this exercise with the regulated community as well.

This presentation begins on Page 115 of the meeting transcript.

**CONTENT AND STATUS OF DIRECT FINAL RULE**

Anthony Tse, NRC, gave a presentation on the Direct Final Rule (DFR) to clarify and amend 10 CFR Part 35.

Dr. Tse began by informing the ACMUI that this rule was published (in the Federal Register) in April 2003 for public comment. However, the NRC has received no comments to date, and if no significant adverse comments are received by May 21, 2003, then the rule will automatically become effective July 7, 2003. Note: No adverse comments were received, so the rule became effective July 7, 2003.

Dr. Tse then explained the necessity of the DFR: Shortly after the revised Part 35 was published, staff became aware of an unintended restriction within the rule, as well as inconsistencies in the rule application. Furthermore, certain areas needed clarification and correction. Dr. Tse then outlined the affected areas. The major areas he outlined were:

- The retraction of a restriction that requires that training of ophthalmic uses of Strontium- 90 be done only at major medical institutions. Staff believed this training can appropriately be performed by an authorized user in a private medical clinic or ophthalmic office as well.

- Correction to the title "National Institute of Science and Technology." The organization is correctly entitled "National Institute of Standards and Technology."

- The addition to the record-keeping section of the rule that refers to calibrations of brachytherapy sources (§35.2432). This section was amended to add that calibration can

be done by the licensee or by the manufacturer or by calibration laboratories. This was added so that the language is consistent with the language in the section that outlines calibration requirements (§35.432).

The ACMUI understood the changes and made no substantive comments or suggestions.

This presentation begins on Page 130 of the meeting transcript.

**HEALTH AND HUMAN SERVICES DATABASE OF REGULATORY ACTIONS: STATUS AND DISCUSSION**

Linda Psyk, NRC, gave a presentation on this topic.

Ms. Psyk provided an overview: 1) the purpose of the database; 2) what the NRC reports to the database and how it reports to the database; 3) the NRC's internal guidance document (Management Directive 8.6) that outlines the procedure the Agency uses to identify what needs to be reported and how; and, 4) a discussion of the Agreement States' reporting responsibilities.

Ms. Psyk then explained that the Health Insurance Portability Database is a database that contains information on certain adverse actions applied against health care practitioners, providers, and suppliers. This confidential database was created as a result of the Health Insurance Portability and Accountability Act of 1996, a law designed to address health care fraud in the United States. Ms. Psyk emphasized that the general public cannot access the database.

Next, Ms. Psyk stated that entities and persons who are reported to the database are notified. The reported entities/persons are given access to the database, so that they can view the information it contains about them. In addition to reported persons who can review their own information, certain other interested parties also have access to the database. These parties include State and Federal agencies; health plan providers (i.e., insurance or programs that provide health benefits); and other health practitioners, providers, and suppliers.

Ms. Psyk outlined the three criteria any reportable action must meet:

1. The negative action or finding must be final.
2. The negative action/finding must be publicly available.
3. The negative action/finding must directly affect health care.

Ms. Psyk then provided examples of actions the NRC reported to the database. One example included a hospital that received a Notice of Violation, with a civil penalty, for failure to obtain the AU's signature on a written directive before administration of a therapy dose of Iodine - 131. Ms. Psyk explained that NRC reported this licensee to the database because the licensee's actions could have directly affected health care.

The ACMUI expressed concern with this action. They believed this illustrates a scenario in which a licensee's failure to perform a technicality could result in punitive action. The ACMUI stated that, in an instance similar to this, a patient may ingest the therapeutic dose three

seconds before the physician signed the written directive. Furthermore, the ACMUI was not convinced of the database's confidentiality. Instead, ACMUI believed this information would find its way into the public domain, and possibly increase physician liability and result in litigation.

Ms. Psyk, along with Sally Merchant from NRC's Office of Enforcement, restated this example to demonstrate the grievous nature of this particular licensee's action. They emphasized that the Agency does not intend to use technicalities in rule applications, in order to locate licensees to report to the database.

Ms. Psyk then briefly explained that Agreement States must report all their affected licensees to the database as well. To remind them of the requirement, NRC plans to forward an Agreement States letter once Management Directive 8.6 is finalized.

Ms. Psyk concluded her presentation by explaining that NRC must submit any reportable actions starting from 1996, since that was the year the requirement to report came into effect.

This presentation begins on Page 135 of the meeting transcript.

**DISCUSSION: WRITTEN DIRECTIVES FOR BRACHYTHERAPY NOT ASSOCIATED WITH PERMANENT IMPLANTS**

Ronald E. Zelac, NRC, gave a presentation on this subject.

Dr. Zelac explained that this presentation is being provided in response to an apparent ACMUI concern that the written directive requirements concerning low and medium dose rate brachytherapy are inappropriate. The specific concern is that the written directives are only applicable to high dose rate brachytherapy and permanent radioactive source implants, but are not applicable to low, medium, and pulsed rate doses of brachytherapy, nor to temporary radioactive source implants.

Dr. Zelac then briefly outlined the written directives requirements in the rule for low, medium, and pulsed rate doses of brachytherapy as described in 10 CFR 35.40(b)(6). The requirements state that an AU must date and sign a written directive that includes the treatment site, radionuclide, and dose before implantation. After implantation, but before completion of the procedure, the AU must state the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose).

Next, Dr. Zelac explained the changes in the new Part 35 as compared to the previous rule. The first change is that the number of total sources used must be entered after implantation rather than before implantation. The second change is that the listing of individual source strengths is no longer required. The third and final change is that the treatment site and the dose need to be entered into the written directive before implantation, besides being verified afterward. Dr. Zelac informed the ACMUI that these changes were implemented to make brachytherapy requirements consistent with other sealed source therapy requirements. Furthermore, these changes were based upon previous ACMUI comments.

ACMUI stated that the requirement to have a written directive that specifies the treatment site,

radionuclide, and dose before the implantation of the radioactive seed is appropriate for implanting permanent seeds, but inappropriate for the implantation of temporary seeds. The reason this requirement is inappropriate for temporary seed implantation is because, with temporary implants, one must put in a number of seeds, then calculate the volume of tissue being treated. Since volume and dose are interrelated, the amount of calculated volume will determine whether the dose needs to be increased or decreased (i.e., more seeds need to be added or seeds need to be removed).

In response, Dr. Zelac noted that the AU has flexibility to modify the written directive based on findings associated with the treatment. ACMUI concurred.

In conclusion, the ACMUI agreed that the rule, as written, is adequate and flexible enough to address both temporary and permanent radioactive seed implantation.

This presentation begins on Page 152 of the meeting transcript.

**DOWNLOADING PART 35 FROM THE NRC WEBPAGE**

In this extremely brief presentation, Tom Essig, NRC, distributed a set of instructions entitled "Saving Part 35 to Disk from NRC's Website." These instructions show how to download 10 CFR Part 35, in its entirety, from the NRC website. Previously, Part 35 was downloadable by section only. The ACMUI believed that the "section only" accessibility was burdensome to print, and requested that Part 35 be made available as one unit on its website. In response, NRC staff put a full text version of Part 35 on the 10 CFR Part 35 webpage, so that the public now has the choice to view/print sections of Part 35 or view/print Part 35 in its entirety. The ACMUI was pleased with this result.

This presentation begins on Page 163 of the meeting transcript.

**SOCIETY OF NUCLEAR MEDICINE'S SUGGESTED GUIDANCE FOR THERAPY APPLICATIONS**

Dr. Jeffry Siegel, SNM, presented this topic to the committee.

Dr. Siegel began by explaining that SNM developed some diagnostic nuclear medicine guidance. (For more information on the purpose and history of this guidance, see the agenda topic entitled "Society of Nuclear Medicine Licensing Guide" as summarized earlier in these minutes.) Now, SNM has developed some therapy guidance.

Dr. Siegel stated that he met with Chairman Meserve, NRC, in December 2001, and it was "agreed upon" that new guidance to address therapeutic uses of nuclear medicine was needed. Therefore, SNM and the American College of Nuclear Physicians drafted some therapy nuclear medicine guidance. Dr. Siegel explained that, although NRC has guidance in the form of NUREG 1556, SNM believes its draft guidance is easier for the regulated community to follow. Dr. Siegel then requested that the ACMUI review the guidance and comment on it, and explained that SNM's hope was that ACMUI would ultimately endorse the the SNM's therapy guidance to the NRC.

**On July 30, 2003, SNM met with Commissioner McGaffigan to discuss this issue. SNM informed him that that they will get letters support on the therapy guidance from these other organizations, such as the American Collage of Radiology, and the American Society of Therapuetic Radiology and Oncology. Commissioner McGaffigan then indicated his support of NRC staff review of SNM's therapy guidance.**

This presentation begins on Page 163 of the meeting transcript.

The above-entitled matter went off the record at 4:55 p.m., and the committee reconvened at 5:08 p.m. to discuss miscellaneous matters related to the Commission briefing, to be held May 28, 2003. The ACMUI adjourned for the day at 6:45 p.m.

**May 21, 2003 Meeting**

The meeting convened at 8:08 a.m.

**REVIEW OF "COMPLICATED" LICENSING ISSUES SINCE 10/24/02**

Donna-Beth Howe, NRC, briefed the ACMUI on this topic.

During this agenda topic, Dr. Howe outlined the Agency's handling of non-routine licensing issues. The issues involved calibration of Strontium-90 eye applicators; intravascular brachytherapy (IVB) using the Novoste system; recentness of training; and radiation doses to family members.

Regarding a Strontium-90 eye applicator case, Dr. Howe explained that the licensee requested that a physicist who performs service for him be allowed to perform decay corrections for the eye applicators. The problem was that the regulation requires that the person who performs these decay corrections be an AMP, and this person was not an AMP. Dr. Howe then reminded ACMUI that this was a case that was brought to them for recommendation, and, based on their recommendation, the individual was granted authority to perform the decay corrections, although the person was not granted AMP recognition.

In the IVB case, Dr. Howe explained that the licensee requested they be allowed to use their AMP as a consultant, who would communicate with them via telephone or fax, since he moved several hours away. After review of this licensee's license, staff decided to not grant an exemption. Staff learned that the licensee had many complicated issues associated with its use of IVB, and because staff considered consulting on this type of action to be an activity in which the AMP must be intimately involved in the treatment planning and subsequent verification, remote consulting was not acceptable.

In the recentness of training case, Dr. Howe stated that an individual wanted to be recognized as an AU, and that he was board-certified, but failed to meet the regulatory requirement that the the AU's training and experience be within the past 7 years. Staff denied this request based on failure to meet the recentness of training stipulation, despite this physician's board certification (which was 26 years ago). Dr. Howe further stated that, in matters where the individual obtains continuing training and experience, NRC, not the licensee, has the authority to determine if this training and experience is adequate.

In the final case, Dr. Howe spoke about a request to allow a family member to receive a dose of up to 2 rem while caring for a young child undergoing treatment using byproduct material. She stated that the staff agreed, but that the Commission stated emphatically that these types of requests must be considered individually. However, if staff gets repeated requests of this nature, rulemaking may be considered, to increase the allowable dose that members of the public may receive during special cases such as this one.

The ACMUI made numerous comments on the specifics of each case. Generally, they agreed with staff's handling of the issues.

This presentation begins on page 4 of the transcript.

**PHYSICAL PRESENCE REQUIREMENTS DURING STEREOTACTIC RADIOSURGERY TREATMENTS**

Robert Ayres, NRC, gave a presentation on this subject. In this presentation, Dr. Ayres underscored the physical presence requirements that licensees must meet while delivering gamma stereotactic radiosurgery (GSR) treatments. The purpose of his presentation was to provide illustrative examples of the type of exemption requests the Agency will either honor or deny.

Dr. Ayres explained that 10 CFR 35.615(f)(3) requires that the AU and the AMP be physically present throughout all patient treatments involving GSR. He stated that since this rule became effective on October 24, 2002, the NRC has received three requests for exemptions to the physical presence requirement in §35.615(f)(3), and one was granted while the other two were denied.

Dr. Ayres then explained the two criteria the Agency uses to either grant or deny an exemption request. First, the licensee must provide a justification for the exemption. Second, the licensee must outline an equivalent level of protection that will be used to ensure health and safety are not compromised.

Next, Dr. Ayres outlined the exemption request that was granted. In this request, the licensee proposed that an adequately trained neurosurgeon be substituted to fill the physical presence requirement of the AU after the AU (and AMP) initiated the treatment. The licensee explained that the AMP would be present throughout the entire treatment, and the AU would be in close enough proximity to the treatment such that (s)he could respond quickly to an emergency. The licensee further explained that this exemption was needed so that the AU could be used maximally in the Radiation Oncology Department, while not diminishing patients' access to GSR treatments.

The staff granted this request because the licensee provided an equivalent level of health and safety assurance by substituting the neurosurgeon for the AU on average for not more than 50 percent of the treatment time; having the AU immediately available in the event of an emergency; and requiring the AMP to be present throughout the procedure.

In one of the requests that was denied, the licensee proposed several exemptions:

- That the AU, accompanied by a neurosurgeon trained in the use of GSRs, be present at the treatment as an alternative to the requirement that the AU and the AMP be physically present throughout GSR treatment;

- That during some treatments, the neurosurgeon be physically present instead of the AU, while the AU is present at the control console.

- That they have the flexibility to interchange the presence of these individuals so that some combination of either the AU, neurosurgeon, or AMP be physically present at the treatment site while the other(s) are present in the central treatment planning room.

The staff denied this request based on the Agency position that an AU and AMP must be physically present throughout all GSR treatments. Furthermore, the licensee's alternative physical presence scenarios do not ensure that two individuals with the necessary knowledge and experience will be available to respond effectively to emergencies. Finally, the licensee provided no substantive need for this exemption.

There was extensive discussion with the staff, in which the ACMUI commented on specifics of the requests. Basically, they questioned the staff's decision to deny the requests that were denied (particularly the one outlined above). Dr. Ayres explained that in the cases where exemptions were denied, the licensee, in some respects, did not provide enough detailed information to determine the safety of the proposed alternative and that - combined with the reasons already stated - factored into the decision to deny the exemption requests. One ACMUI member agreed with Dr. Ayres on that point. Furthermore, Dr. Prabhakar Tripuraneni, ASTRO, addressed the committee and agreed strongly with Dr. Ayres that it is critically important that the AU and the AMP be present during GSR treatments. He explained that setting the coordinates to treat the diseased area involves a lot of numbers, and mistakes that are not readily apparent can be easily made. Therefore, it is critical that adequately trained professionals are present during treatment to ensure treatment is accurate, or to respond to emergencies.

Dr. Tripuraneni commended the staff in its decision to deny the exemptions, particularly in the case outlined above. However, Dr. Tripuraneni did not agree with the staff's decision to grant the exemption it granted, because he believed it was done too much for the convenience of the radiation oncologist. Nonetheless, Dr. Tripuraneni conceded that there may be extenuating circumstances for granting the exemption.

As this extensive discussion continued, the ACMUI stated that they would greatly appreciate being consulted on matters such as exemption requests. ACMUI expressed a belief that even in cases where the rule seems clear it is still subject to interpretation. Furthermore, ACMUI noted that NRC staff may be able to approve more exemption requests if staff would more actively engage the licensee to get additional information that would aid the staff in making a more informed decision.

In response, Charles Miller, Director, IMNS, stated that the ACMUI's stance on the need for staff to discuss licensee-related matters with them more often is worth considering. He quantified that stance, however, by adding that NRC has deadlines to respond to these applications, and frequent consultation with ACMUI could adversely affect those deadlines. He

further explained that NRC has limited resources (time, money, etc.) to engage licensees who submit inadequate applications for exemptions. Nevertheless, in the interest of public service, he would get advice from staff on how staff could help improve the application process so that licensees are more likely to submit better applications. Likewise, he would get staff input as to how ACMUI can be more involved in these decisions. ACMUI was receptive to these proposals.

**ACTION ITEMS:**

**Charles Miller, Director IMNS, will:**

- **Get staff input on how to improve the application process so that licensees are more likely to submit quality applications.**
- **Get staff input as to how ACMUI can be more involved in these decisions.**

This presentation begins on page 33 of the transcript.

## DISCUSSION: THE LISTING OF CERTAIN PRACTITIONERS IN 10 CFR 35.1000

**Background note: This discussion involves a brachytherapy device known as TheraSpheres® microspheres. Theraspheres are microscopic glass beads that deliver radiation therapy to inoperable liver cancer. Theraspheres administration is a type of therapy treatment for cancer that is handled by radiation oncology specialists. However, nuclear medicine specialists have a role in evaluating candidates for the procedure, as well as assessing the procedure's success. TheraSpheres are manufactured by MDS Nordion**.

Leon S. Malmud, MD, ACMUI, led the discussion on this subject.

In this discussion, Dr. Malmud outlined how the Theraspheres approval process has unintentionally curtailed nuclear medicine physicians' ability to administer them.

Dr. Malmud explained that when the manufacturer introduced Theraspheres, it did so representing it as a therapy device. Accordingly, when NRC reviewed the use of Theraspheres, Dr. Malmud explained that NRC apparently viewed them as therapy devices; and consequently, hospitals view the use of Theraspheres as a radiotherapy technique, rather than a nuclear medicine technique.

Dr. Malmud's stance is centered around the method of introducing Theraspheres to the patient. Theraspheres administration is a type of therapy — generally the purview of radiation oncologists. However, Theraspheres are injected into patients (i.e., administered as radiopharmaceuticals) — generally the purview of nuclear medicine physicians. According to Dr. Malmud, the currently accepted view that Theraspheres are strictly therapy devices has resulted in denying professionals with the greatest amount of radiopharmaceutical injection experience an appropriate level of involvement in Theraspheres administration. These professionals are nuclear medicine physicians.

To prevent recurrence of this type of situation, Dr. Malmud suggested that NRC review not only the type of administration involved in radiation treatments, but also the method of delivery.

Next, Dr. Malmud explained what he believed are the practical problems associated with this issue. Theraspheres are not readily accessible to nuclear medicine physicians listed on broad scope licenses, according to Dr. Malmud; therefore, broad scope licensees require amendments to get access to Theraspheres. Also, licensees with specific licenses must apply for Theraspheres use. These requirements create delays in the delivery of this new therapy to patients. Another committee member, Dr. Vetter, clarified that a broad scope licensee would not require an amendment since they have the authority to determine who may administer material; however, a limited scope licensee would require an amendment.

The ACMUI as a whole acknowledged that, due to the numerous components of Theraspheres delivery and numerous types of professionals involved in its delivery, turf wars amongst physicians have appeared. A way to alleviate this issue would be to determine the following: Who has specific purview over certain aspects of treatment delivery? What aspect of treatment requires the services of a particular type of physician? What aspect of treatment can be delivered by any physician who simply receives additional training to deliver it?

The nuclear medicine physician of the committee, Dr. Douglas Eggli, believed that for strategic marketing reasons and not medical reasons, Theraspheres were marketed as therapy devices. Furthermore, because there are many more limited scope licensees than broad scope licensees, Theraspheres cannot be rapidly approved at most institutions that have well-qualified nuclear medicine physicians that could administer it. Dr. Eggli suggested that this be corrected in the rule rather than by exemption, since this is a widespread issue.

Because Theraspheres are registered in the SSDR, ACMUI asked staff to verify that Theraspheres meet the definition of sealed sources. Donna-Beth Howe, NRC, replied that as glass-encapsulated sources entered into the patient as permanent implants, they do. Furthermore, staff determined that radiation oncologists are the most appropriate physicians to deliver them after staff reviewed the required training and experience necessary for delivery of therapy sources. Additionally, Dr. Howe explained that staff recognizes that newer products may cross boundaries in terms of classification, so staff has flexibility, in guidance space, to allow a product such as Theraspheres to be classified in multiple categories. (For detailed discussion on NRC's rationale for classifying Theraspheres as therapy devices, see agenda topic "10 CFR 35.1000 Licensing Guide" in these minutes).

The ACMUI, in general, agreed that Theraspheres should not be strictly categorized as either a radiation therapy or nuclear medicine application, but that institutions should have the flexibility to view it either way. ACMUI agreed that further discussion and a possible recommendation later in the day during the 10 CFR 35.1000 subcommittee meeting was warranted.

This presentation begins on page 102 of the transcript.

**INTERPRETATION OF 10 CFR 35.61(b)**

Ronald E. Zelac, NRC, led the discussion on this topic. Dr. Zelac explained what 10 CFR 36.61(b) requires. This section, Calibration of survey instruments", requires that the exposure rate, as read on the instrument when it is measuring a radiation field, may not differ by more than plus or minus 20 percent from the exposure rate that was calculated during calibration of the instrument. If they differ by more than 20 percent, then the instrument is not calibrated to

detect radiation fields accurately, and may not be used.

Dr. Zelac noted that all Federal agencies are required to use national performance standards when they are available and they apply to a particular activity the agency is regulating. The national standard for instrument calibration is the American National Standards Institute N323A, better known as ANSI Standard N323A. ANSI N323A explicitly states that instruments that are used to measure radiation fields must give measurements that do not differ by more than 20 percent from the calculated exposure.

Next, Dr. Zelac explained that in practice, instrument probe calibrations are usually performed with a high energy source although the energies that will be measured are not necessarily high energies. He further explained that many energy-dependent instrument probes that are calibrated with high energy sources are able to respond within the plus or minus 20 percent allowance when they are used to measure lower energies. However, specialized probes, such as probes designed specifically to detect low energies, will give inaccurate readings if calibrated with a high energy source, because they are designed to detect low energies. Dr. Zelac stated that licensees who own such specialized instrument probes should calibrate them with lower energy sources. The special calibration requirement for these types of instrument probes is neither onerous nor cost-prohibitive, according to Dr. Zelac.

One ACMUI member disagreed that the need to calibrate certain instrument probes in a certain manner, as Dr. Zelac outlined, is not a problem. He contended that those licensees who must measure fields of various energies yet possess only the type of instrument probe that is suited to measuring high energies, must purchase additional probes to measure lower energies. Therefore, licensees in this situation should be given the more cost-effective alternative to use the manufacturer's energy response curve to mathematically calculate what the actual exposure is at the lower energies they measure.

Dr. Zelac responded that licensees cannot do this, because 10 CFR Part 35 does not allow licensees to use the manufacturer's energy response curve to extrapolate measurements of energies the instrument is not specifically designed to detect (nor does Part 35 allow them to use any other type of correction chart for this purpose). Dr. Zelac restated his earlier position -- that if one has an instrument probe suited to measuring a broad range of energies, then calibration with a high energy source will leave the probe sufficiently sensitive to detect lower energies as well.

Some ACMUI members, as well as members of the general public, informed staff that they still believe that licensees should be allowed to use correction charts of some sort to measure energies that an instrument's probe is not specifically designed to measure. They underscored their position by the fact that Part 35 allowed the use of correction charts before it was revised.

**ACTION ITEM: Dr. Zelac informed ACMUI that staff will re-discuss this issue and provide the ACMUI feedback at the next public meeting.**

This presentation begins on page 132 of the transcript.

**REVIEW OF MEDICAL AREA OPERATING EXPERIENCE AND ENFORCEMENT ACTIONS: ONE YEAR AND SINCE 10/24/02**

Roberto Torres, NRC, gave the ACMUI a presentation on this topic. The purpose of Mr. Torres's presentation was to provide ACMUI with a snapshot of the type and severity of events that have occurred since the new 10 CFR Part 35 has been promulgated. The ACMUI requested this briefing in an effort to ascertain how effective the revised regulations are at protecting public health and safety.

Mr. Torres began by explaining that, since the rule has been promulgated for such a short period of time, it is too early to determine with any precision whether the updated rule has improved safety across the population of medical licensees. Nonetheless, he outlined select events data on misadministrations and medical events, that was collected in 2000 and 2001 (before the new rule was promulgated) and compared that to the misadministration/medical event data that were collected through April 2003.

As Mr. Torres continued, he supplied details on the various causes of the events, and associated NRC responses. The events data generally showed a trending toward human error as the cause, either by omission or commission of activities. The data also showed a trending toward fewer events as the years progressed. The data showing trending toward fewer events, is not statistically significant, however.

Jeffry Siegel, SNM, commented on the low numbers of events involving diagnostic nuclear medicine. Dr. Siegel implied that diagnostic procedures may not need regulatory oversight, since events within that area are low. In response, Angela Williamson, NRC, acknowledged that the record of safety for diagnostic nuclear medicine procedures is good, but noted that the Agency must keep track of these events (as well as others) because it is required to report these numbers to Congress.

Toward the end of the presentation, the ACMUI suggested that when the NRC presents these types of numbers to them, to put the data in perspective by presenting it as a ratio to the estimated numbers of procedures given, and further quantify the data by factoring in relative risk as well as the absolute number of adverse events or severity violations.

Charles Miller, NRC, informed the ACMUI that before the Agency can justify expending the necessary resources to present data in this manner, the ACMUI would need to explain its value in assisting them in their advisory role to staff. Dr. Miller further explained that expenditure of staff effort for this purpose must assist the ACMUI in providing NRC with information that can be used to help frame the future regulatory structure. As discussion ensued, ACMUI stated that they believed that they could use this information to help staff frame future regulatory structure, and that the professional medical societies they are affiliated with tend to collect data of this nature. ACMUI suggested that staff approach them individually to get these data.

This presentation begins on page 153 of the transcript.

**UPDATE: RECOMMENDATIONS FROM FALL 2002 MEETING**

Angela R. Williamson, NRC, gave this update. During this presentation, Ms. Williamson

outlined the staff's response to several recommendations the ACMUI made at the October 28, 2002 meeting.

A recommendation that generated a lot of discussion involved the listing, by serial and model number, of interstitial radioactive seeds in licenses. (See the summary of the agenda topic "Sealed Source Model Numbers as License Conditions" for related discussion of this topic.) The ACMUI believed that this requirement was overly burdensome since manufacturers often change model and serial numbers, resulting in the need to amend licenses to reflect the changes. ACMUI recommended that staff initiate a rulemaking to allow licensees to list their seeds generically, so that amendments are not necessary when manufacturers change model/serial numbers.

Ms. Williamson explained that, although staff fully understood the rationale to change the rule to allow for generic listing of radioactive seeds, staff did not believe it was wise from either a safety or regulatory standpoint to do so. Ms. Williamson explained that staff believed that a relaxation of the requirement to list seeds by model/serial number will ultimately reduce accountability; and thereby, undermine the Agency's ability to protect public health and safety. She furthermore explained that such a move in a politically sensitive environment where the threat of terrorism is ever-present is not prudent public policy.

One ACMUI member replied that generic listing of radioactive seeds would not lead to reduced source accountability, and that political sensitivity and public perception are not good enough reasons to resist changing the rule. He argued that in a performance-based, less prescriptive environment, the rule should be relaxed, and that the argument surrounding public perception of hazards can be applied to resist any attempt to change any rule. However, the ACMUI Chairman, stated that NRC staff seem to be aware of the arguments supporting the generic listing of radioactive seeds on licenses. He indicated that he agreed that the public perception of reduced accountability is a valid factor to consider.

Another ACMUI member underscored the need to not reduce source accountability; nevertheless, the burden of listing seeds and sources by model/serial number should be reduced. He reminded everyone that NRC staff and the ACMUI agreed, in previous discussion, that it is necessary that staff go back and revisit this issue to come up with an alternative to rulemaking that would reduce the licensee burden of listing interstitial seeds by model/serial number on licenses.

The other recommendations briefly discussed were:

- That the Chairman, ACMUI, contact the NRC Chairman to inquire about the status of the ACMUI Subcommittee recommendations to amend the revised 10 CFR Part 35's T&E;
- That ACMUI formation of a standing subcommittee to review 10 CFR 35.1000 licensing guidance;
- That NRC staff initiate replacement members for the approaching nuclear cardiologist, patient advocate, and state government representative vacancies.

Ms. Williamson briefly expounded on the other recommendations, explaining that staff implemented those that required staff action. ACMUI understood and offered no further suggestions regarding staff's action, nor any substantive comments.

This presentation begins on page 197 of the transcript.

**10 CFR PART 35 QUESTION AND ANSWER PROCESS**

Ronald E. Zelac, NRC, briefed the ACMUI on this topic.

Dr. Zelac informed the ACMUI that the NRC staff is developing answers to frequently asked questions regarding the revised Part 35. These questions and answers (Q&As) are being posted to the Agency's website.

Next, Dr. Zelac explained that the questions come from various avenues: from staff during internal training; from the public during public workshops on the revised Part 35; from telephone calls, e-mails, and letters to staff from stakeholders; and finally, questions are generated from implementation issues that staff becomes aware of as the rule is being applied.

Dr. Zelac then gave a general outline showing how staff processes questions. He explained that the Part 35 Implementation Working Group, consisting of Headquarters and regional staff, meets regularly to discuss questions and propose solutions. Once the group decides it has answered a batch of questions satisfactorily, they are put in a paper and circulated throughout the Agency for comment. The Q&As are then adjusted as necessary and forwarded to the Office of the General Counsel (OGC). After OGC input, IMNS reviews them once more before posting them to the NRC website.

The ACMUI praised this effort and wanted to know how they can assist staff in making this resource widely known. Dr. Zelac informed them that NUREG 1556 Vol. 9 mentions that Q&As are available on the website. Additionally, anyone who visits the website can easily locate the Q&As. Dr. Zelac then stated that he is open to suggestions for ways to make the Q&As more widely known. The ACMUI suggested that the staff contact professional societies.

This presentation begins on page 191 of the transcript.

**10 CFR 35.1000 LICENSING GUIDANCE**

Donna-Beth Howe and Robert Ayres, NRC, made presentations on this topic.

Dr. Howe ultimately explained where the guidance stands on issues presently identified under §35.1000 of 10 CFR; but first, she explained the relationship between NRC and the U.S. Food and Drug Administration (FDA). Dr. Howe stated that the NRC and the FDA work closely, sharing information. NRC staff participates on some of FDA's advisory committees, and this interaction is a primary means of informing the NRC of new technologies.

Dr. Howe next explained the process NRC uses to categorize new technologies in Part 35. First, the technology is reviewed for its standard characteristics, its unique characteristics, and unique safety problems. Next, staff reviews definitions within the rule to see if the new technology fits nicely into a pre-existing definition. Following that, staff reviews an internal document that shows how it regulates different materials, and will look to see how well the new technology fits into that process. If the product does not fit nicely into how NRC regulates similar products, Dr. Howe explained, then staff usually must develop guidance. Dr. Howe

then explained the rationale used to classify microspheres.

NRC regards microspheres as devices. The ACMUI mentioned during an earlier presentation ("The Listing of Certain Practitioners in 35.1000") that manufacturers were driven by marketing interests to market microspheres as devices, although they are more appropriately categorized as radiopharmaceuticals. However, as Dr. Howe explained, the Agency believes microspheres are most appropriately categorized as devices, because they do not meet the FDA's definition of a radiopharmaceutical. Unlike pharmaceuticals, microspheres do not interact pharmacologically, physiologically, or biochemically within the body. Dr. Howe also stated that although microspheres are injected, they are not injected using syringes or intravenous drips, which is yet another argument to not classify them as radiopharmaceuticals.

Next, Dr. Howe explained the unique safety issues involving Theraspheres microspheres. Two conditions must be met in order to deliver microspheres satisfactorily. First, the microspheres must be adequately suspended in the source vial. Second, the delivery device must function properly. The safety issues, as Dr. Howe explained, are that the product is not always in adequate suspension, and the delivery system does not always perform properly. Yet another safety problem is shunting. Shunting occurs when the microspheres are delivered to the target organ (the liver); yet, too many of them end up migrating into the major vasculature of the body and carried to an unintended organ, usually the lung. Any of these problems can result in improper dosages and/or spillage.

Dr. Howe then explained the Agency's actions to address, specifically, the problem of shunting. Because some shunting appears to be inevitable with Theraspheres microspheres, NRC had to develop criteria to preclude the possibility that every procedure winds up being a medical event. Therefore, NRC decided that, as long as the dose shunted to unintended organs does not meet a certain threshold, it is the physician's medical decision to define the level of acceptable shunting for every patient.

Next, Dr. Howe briefly explained the safety issues with the SirSpheres® brand of microspheres. Sirspheres have a different delivery system than do Theraspheres. Also, because Sirspheres have a much smaller specific gravity than do Theraspheres, they stay suspended better. However, backflow of Sirspheres is common, which means that they end up migrating to unintended places. It appears that only so many of the spheres can be delivered to the target organ (liver), so that backflow is inevitable. To address this issue, Dr. Howe explained that the NRC's Sirspheres guidance recommends that the AU record in the written directive the patient-specific dosages that state the acceptable dose of spheres that can be delivered to unintended sites.

Dr. Howe also spoke about issues with a particular liquid brachytherapy treatment. Like the Theraspheres and Sirspheres microspheres, this item, named Iotrex, is a device and not a radiopharmaceutical. This device is a balloon in which liquid radioiodine is placed. The balloon is then placed in a catheter that is inserted into the patient's body. One of the problems with this device is that the radioiodine can become disassociated with the molecule it is attached to, and seep through the catheter membrane to be absorbed by unintended parts of the body. Another problem is that if the licensee mistakenly leaves too much radiopaque dye in the balloon, the dye will absorb too much of the radioiodine so that the patient doesn't receive the proper dose.

Dr. Howe noted that a certain amount of seepage into undesired areas is inevitable. Using the strict definition of leaking sources, a leaking source would occur every time this procedure is administered. To prevent this occurrence, NRC has drafted guidance that explains that for this device, a failure of the catheter to contain the source is considered leakage, not the inevitable seepage of some small volume of radioiodine. Further, to address the issue with radiopaque dye remaining in the balloon and causing underdoses, NRC's licensing guidance encourages licensees to follow the manufacturer's instructions, and Dr. Howe briefly explained what this entails.

Regarding the microspheres discussion, a small number of ACMUI members believed that customizing a written directive for each patient may impinge on the practice of medicine. However, most other ACMUI members' responses to that proposal were positive. With respect to either therapy, they believed that the freedom to craft a written directive that is patient-specific in terms of dose delivered is a useful, flexible tool that will eliminate "excessive" medical event cases. Regarding the liquid brachytherapy discussion, after the staff provided a few more clarifying comments, the ACMUI's consensus was that staff's actions were appropriate.

Dr. Ayres centered his presentation around IVB issues. He began by explaining that NRC requires that IVB procedures are conducted under the supervision of the AU, who must consult with the AMP and the interventional cardiologist during the treatment planning phase. Dr. Ayres further explained that in clinical practice, IVB procedures are far broader in scope than the procedure that FDA approved (which is the use of IVB to treat a condition called in-stent restenosis). However, licensees may conduct these broader uses of IVB, due to the NRC's requirement that the AU and AMP be present during IVB procedures. The presence of these professionals allows licensees to safely conduct IVB procedures for other than the FDA-approved use.

Next, Dr. Ayres provided information regarding medical events associated with IVB use. He noted that over the years, he has collected about 100 medical events involving IVB. This number is far above what NRC has seen with almost any other modality. Furthermore, NRC is aware of other issues - that cause medical events and are associated with IVB - that are reportable to the FDA. These issues contribute to failure of the device to work as intended. Dr. Ayres explained that these combined factors contributed to the need for certain NRC requirements, such as the requirement that the AMP perform an independent measurement of source output during IVB, and the requirement that licensees have written emergency procedures.

Dr. Ayres then briefly outlined the guidance that NRC has posted to its website for licensees to use to assist them in obtaining licensing for the Novoste Beta-Cath; Cordis Checkmate, and Guidant Galileo IVB systems.

ACMUI and Dr. Ayres discussed in detail the specifics of each IVB system with respect to licensing, regulatory requirements, and problems unique to each system. The discussion concluded with no recommendations or general consensus forwarded to the staff. ACMUI offered no substantive comments regarding Dr. Howe's presentation.

These presentations begin on page 205 of the transcript.

**10 CFR 35.1000 SUBCOMMITTEE WORKING MEETING**

Ruth McBurney, the ACMUI's state government representative, and Chair of the 10 CFR 35.1000 Subcommittee, led the discussion on this topic. This was a working meeting where members of the public had an opportunity to provide the ACMUI with information they believed the subcommittee should consider as it develops recommendations for 10 CFR 35.1000 licensing guidance.

The first item discussed was microspheres. Ms. McBurney stated the unique nature of microspheres: that their physical properties and behavior in the body has led them to be officially considered sealed sources (and therefore therapy devices that would come under the auspices of radiation oncology), but their drug-like properties makes it possible for them to be licensed as radiopharmaceuticals (which would bring them under the auspices of nuclear medicine). This dual view of microspheres' applicability has created physician training issues.

Several ACMUI members, as well as NRC staff, believed that a team should administer microspheres, because of the complexity of the procedure and types of problems that could arise. Dr. Hevezi, representing ASTRO, also agreed that the team approach is appropriate; however, what group of professionals should comprise the team? One ACMUI member believed the AU should always be a team member and should determine who the others are for each case. Dr. Donna-Beth Howe, NRC, suggested that the way to determine the team members would be for the ACMUI to identify the task being performed. Once it is clear what the different types of tasks are, NRC will be able to identify the appropriate professional who should be available to oversee that task. The ACMUI agreed.

Later on, the discussion focused on physician training issues. The general question was: If a physician team member does not quite meet the level of training in 10 CFR 35.390 that is needed to administer certain Theraspheres or Sirspheres therapies, what further training is needed? Dr. Robert Ayres, NRC, suggested that the ACMUI assist the NRC staff in writing Information Notices that will notify licensees about training-related issues. Regarding which professionals should administer the Sirspheres therapy treatments, the general committee and NRC consensus was that this is best accomplished by professional medical societies. Lynne Fairobent, representing ACR; and William Uffelman, representing SNM; suggested that ACR, SNM and ASTRO meet to draft some recommended training. Ms. McBurney asked them to get a consensus on recommended training and correspond with her by e-mail on the result.

Regarding Gliasite IVB, the subcommittee indicated they believed it should be moved from §35.1000 to §35.400 , the uses of manual brachytherapy section. However, Dr. Howe explained that it doesn't fit entirely within §35.400. The discussion continued at length. Although neither the ACMUI nor members of the public communicated that they believe there must be changes to the licensing guidance regarding the written directive, there was no discernable agreement on what other changes may be needed.

The meeting adjourned at 5:01 p.m.