MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 27-28, 2008

**MEETING SUMMARY**

**PURPOSE:** To discuss issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

**OUTCOME:** The Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

## MONDAY, OCTOBER 27, 2008

### OLD BUSINESS

Ms. Ashley Tull, NRC, provided updates on the status of the 17 recommendations and action items from ACMUI meetings held in 2008. Ms. Tull also highlighted items from the 2007 list that were updated since the last meeting or were to be discussed on the current meeting agenda.

### CESIUM CHLORIDE SUBCOMMITTEE REPORT

In response to the National Academies' *Radiation Source Use and Replacement* report published in 2007 and under direction of the Commission, the ACMUI formed a subcommittee to provide detailed information on the medical impacts. Dr. Bruce Thomadsen, ACMUI, summarized the ACMUI's report on the need for cesium-137 chloride ($^{137}$CsCl) irradiators, viable alternatives, and current security issues. The subcommittee report emphasized that irradiation facilities are essential for irradiation of blood and in research, and forced replacement of $^{137}$CsCl-based units would compel many facilities to stop irradiations due to the considerable expense. When comparing $^{137}$CsCl irradiators to x-ray technology, the ACMUI concluded that while x-ray units have been used for blood, animal, and material irradiation, the dose delivered by an x-ray unit will not produce the same biological effect as a dose delivered by a $^{137}$CsCl irradiator. Lastly, Dr. Thomadsen summarized the security enhancements that have been implemented since 2007. Background checks and fingerprints are now required for individuals with access to an irradiator; physical security has been enhanced following orders issued by the NRC; and security is also being enhanced through programs of the Departments of Energy and Homeland Security. ACMUI concluded that with the enhanced security programs in place for $^{137}$CsCl irradiators, replacement is unnecessary.

Dr. Douglas Eggli, ACMUI, added that in the state of Pennsylvania, a special exemption is needed for linear accelerators that are used on both humans and animals. This further limits the alternatives to the use of $^{137}$CsCl irradiators. Dr. Subir Nag, ACMUI, also clarified that $^{137}$CsCl should not be confused with the ceramic form of cesium-131, which is used for permanent implant brachytherapy. Mr. Robert Lewis, NRC, posed a question on the feasibility

of ceramic forms of cesium-137 for larger activities. Dr. Thomadsen, ACMUI, commented that the manufacturer indicated that production of solid forms of cesium-137 would present a hazard to production workers, and they had no interest in pursuing this option. Additionally, the subcommittee was not convinced that the solid form of cesium-137 would actually be safer. Dr. Richard Vetter, ACMUI, inquired as to whether the activity concentration of a solid cesium-137 source would be equivalent to that of $^{137}$CsCl, since a lower activity concentration may require the source to be physically larger, thereby preventing source exchange for current irradiators. Mr. Lewis confirmed that the solid form of cesium-137 would be larger than the existing $^{137}$CsCl sources. Dr. Orhan Suleiman, ACMUI, shared observations from the NRC's $^{137}$CsCl workshop, and he indicated that $^{137}$CsCl is more reliable and slightly less expensive than other alternatives. Overall, the ACMUI believed that when considering the recent advancements in security, $^{137}$CsCl irradiators offer the best technology and should not be eliminated.

Mr. Lewis informed the ACMUI that the subcommittee report on $^{137}$CsCl would be transmitted to the Commission along with other NRC recommendations.

**FINGERPRINTING SUBCOMMITTEE REPORT**

Dr. Richard Vetter, ACMUI, summarized the major points from the subcommittee report on decreasing costs and increasing efficiency for fingerprinting. The subcommittee report indicated that although licensees could request an exemption for individuals with current security clearances or use fingerprints taken for other state and federal requirements, licensees often opted not to use this process due to the burden of paperwork. Second, the subcommittee report described the process by which only one or a few individuals are allowed access to the irradiator; thereby avoiding the need to fingerprint large numbers of individuals. Dr. Vetter indicated many facilities were implementing this method; however, for some licensees this method was not practical, especially at blood banks, due to individuals' schedules and the need to have someone available at all times for irradiation. Next, the subcommittee report indicated licensees have the option to isolate the irradiator to a small room to reduce the number of people who have access, which increases the security. Also, the subcommittee researched the possibility of licensees using a "core facility" that specializes in doing irradiation; however, the subcommittee concluded both of these options were not feasible for all facilities, especially the smaller facilities, due to cost and scheduling. The subcommittee's final point was that licensees may offer fingerprinting onsite through their own security or a local law enforcement agency; however, some licensees indicated in-house fingerprinting was not an option, and individuals needed to travel 20 miles or more for fingerprinting.

Dr. Vetter also emphasized that the subcommittee discovered licensees were experiencing unclassifiable fingerprints at a rate as high as 25%; however, the subcommittee believed 10% was a more realistic rate. Mr. Chris Einberg, NRC, clarified that the NRC's Office of Administration reported that rejection rates were very high for certain licensees; however, the overall rejection rate was 7%. The high rejection rate for certain licensees is possibly attributed to lack of experience in taking fingerprints, since licensees who use local law enforcement officers, who are trained to do fingerprints, have a lower rejection rate. Mr. Jim Luehman, NRC, also clarified that the Energy Policy Act of 2005 requires all fingerprints be submitted to directly the Federal Bureau of Investigation by the NRC.

Mr. Einberg informed the ACMUI that the subcommittee report was transmitted to the Commission in the form of a Commissioner's Assistant note on August 20, 2008.

**ITEM (1):** NRC staff agreed to consider incorporating the subcommittee's recommendations in NRC's *Questions and Answers with Regards to Fingerprinting and Criminal History Records Checks* or use another appropriate method of communication to transmit the information to licensees.

**PERMANENT IMPLANT BRACHYTHERAPY RULEMAKING SUBCOMMITTEE REPORT**

Dr. Subir Nag, ACMUI, described the subcommittee's concerns with the current 10 CFR Part 35 rulemaking. The subcommittee believed the proposed rule would inappropriately deem certain events to be medical events (MEs), when in reality these events may occur in the course of a properly executed brachytherapy procedure or may be beyond the control of the authorized user (AU). Furthermore, the subcommittee expressed concerns that physicians might abandon permanent implant brachytherapy procedures rather than risk an ME. The subcommittee indicated this could have a negative impact on patient care.

The subcommittee recommendations were as follows: (1) In 10 CFR 35.3045(a)(2)(i)-(iv), NRC should delete "pre-implantation" from "pre-implantation written directive"; (2) In 10 CFR 35.3045(a)(2)(ii), NRC should clarify that the "treatment site" includes the gross tumor, the clinical target volume, plus a variable planning margin as defined by the AU; (3) If recommendation two is accepted, NRC should eliminate 10 CFR 35.3045(a)(2)(iii), since it becomes superfluous; (4) NRC should replace "activity" with "source strength" as applicable to permanent implant brachytherapy; (5) NRC should allow ACMUI to review and comment on any proposed rules before the proposed rule are published; (6) Administrations without a WD should be cited as violations, rather than being required to be reported as MEs.

**ITEM (2):** NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."

For item 2, the first recommendation passed with three opposing votes. The remaining five recommendations passed with two opposing votes.

**ITEM (3):** The ACMUI endorsed the permanent implant brachytherapy subcommittee report.

The motion passed with two opposing votes.

**YTTRIUM-90 MICROSPHERE LICENSING GUIDANCE**

Dr. Riad Salem spoke to the ACMUI on behalf of the Society of Interventional Radiology and the American Board of Radiology (ABR). Dr. Salem reviewed the evolution of yttrium-90 (Y-90) microsphere licensing guidance and raised concerns that the current guidance creates confusion and impedes the ability of interventional radiologists (IRs) to attain AU status, thereby limiting patient access to therapeutic options. Dr. Salem described the training received by IRs, which meets the training and experience requirements under 10 CFR 35.290. Dr. Salem proposed the ACMUI recommend IRs to be qualified as AUs for Y-90 microspheres under 10 CFR 35.290 based on their training and experience but with additional certification offered by the ABR based on an examination specific to the use of Y-90 microspheres. Dr. Salem outlined a proposal for a course that IRs could complete to achieve such certification. In addition to the

ABR certification for Y-90 microspheres, IRs qualifying as AUs under 10 CFR 35.290 would need to complete vendor training, as required for all AUs under NRC's current microsphere licensing guidance. Dr. Douglas Eggli, ACMUI, suggested that ACMUI set up an additional category under 10 CFR 35.390 intended for IRs to become AUs for Y-90 microspheres.

**ITEM (4):** The ACMUI formed a subcommittee to draft a set of proposed qualifications that IRs must satisfy to become AUs for Y-90 microspheres. The subcommittee includes: Dr. Bruce Thomadsen (chair), Dr. Douglas Eggli, Dr. Subir Nag, Dr. James Welsh, and Mr. Steve Mattmuller.

**ITEM (5):** ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted though the public review process instead of residing in guidance space.

The motion passed with one opposing vote from Dr. Orhan Suleiman.

**MEDICAL ISOTOPES SHORTAGES**

NRC staff sought input from the ACMUI on the recent reactor shutdowns that have caused shortages in medical isotopes, specifically molybdenum-99 (Mo-99). Dr. William Van Decker, ACMUI, stated that these shortages have a large impact on diagnostic procedures and that these impacts can be detected quickly. Dr. Van Decker added that approximately 15 to 20 million diagnostic radiopharmaceutical studies are performed each year in the United States (US). He estimated that approximately fifty percent of these diagnostic procedures are for cardiac studies, and seventy percent of the cardiac studies are performed with technetium-99m (Tc-99m). Dr. Van Decker indicated a shortage of isotopes could be tolerated only for short periods of time once in a while.

Dr. James Welsh, ACMUI, added concerns about the production of cobalt-60 (Co-60), which comes from only one reactor in the world. A shortage in Co-60 places an exceptional vulnerability on licensees who own and operate gamma knife units.

Dr. Robert Atcher, Society of Nuclear Medicine President, emphasized that approximately 20 million procedures performed each year require radiopharmaceuticals; and practitioners who use these radiopharmaceuticals are significantly impacted by the shortages. Dr. Atcher added that this is a worldwide issue, and that Tc-99m, as a diagnostic agent, probably justifies building a new reactor in the US.

Dr. Douglas Eggli, ACMUI, stated that there should be an economic incentive for individuals interested in building a reactor to produce Mo-99, and this may require a subsidy, since start-up costs are large, and the marketplace is relatively small. Dr. Eggli also stated that the vast majority of nuclear medicine procedures were performed with Tc-99m, since it is safe, effective, and can be used for many procedures. Furthermore, at this time, there is no viable substitute.

Dr. Mickey Guiberteau pointed out that the alternatives to using Tc-99m include Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans, and these alternative scans increased the cost to patients and caused delays in patient care.

Mr. Roy Brown spoke on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). Mr. Brown echoed Dr. Van Decker's estimates and informed the ACMUI that he

would be forwarding the results of a survey taken of a few thousand hospitals in the US, which would verify the information provided at the meeting.

The ACMUI also discussed the US's initiative to decrease risk by using Low-Enriched Uranium (LEU) instead of Highly-Enriched Uranium (HEU) as a target for producing Mo-99 and other radiopharmaceuticals.

**ITEM (6):** The ACMUI strongly encourages NRC to: (1) continue supporting the exportation of HEU material for Mo-99 targets used by international producers; (2) provide all possible help towards the development of US producers of Mo-99.

The motion passed unanimously.

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**TUESDAY, OCTOBER 28, 2008**

**REVISIONS TO THE NRC RADIATION PROTECTION REQUIREMENTS: POTENTIAL IMPACTS TO THE MEDICAL COMMUNITY**

Dr. Donald Cool, NRC, described NRC's proposals to potentially revise the radiation protection regulations, specifically 10 CFR Parts 20 and 50. This process was started at the direction of the Commission in 2008 following the publication of the International Commission on Radiological Protection's (ICRP) Publication 103. Dr. Cool indicated staff would submit a paper to the Commission in December 2008 with options. Dr. Cool expressed interest in exploring the impacts and implications of any proposed changes with the ACMUI.

Dr. Orhan Suleiman, ACMUI, added that the Food and Drug Administration (FDA) sometimes adopts scientific standards by reference, as opposed to incorporating or amending regulations. Dr. Cool responded that NRC cannot incorporate any documents by references that have not undergone a public comment process in accordance with the Administrative Procedures Act.

Ms. Debbie Gilley, ACMUI, stated that many Agreement States include exposure from x-ray sources and material sources in occupational dose limit calculations, so a reduction in the yearly occupational dose limit would impact many medical users. Dr. Richard Vetter, ACMUI, indicated that it is not uncommon for a few interventional radiologists to exceed the five rem limit. On the contrary, Dr. Darrell Fisher, ACMUI, stated that the scientific evidence for reducing the annual dose limit to two rem is justified and would not greatly impact most licensees. Dr. Thomadsen added that at his facility neither the interventional radiologists nor cardiologists would approach the proposed two rem limit. Mr. Douglas Pfeiffer, speaking on behalf of the American Association of Physicists (AAPM), echoed Dr. Thomadsen's observations that based on his experience, interventional radiologists would not approach the proposed two rem limit while using the two-badge system.

ACMUI agreed to facilitate stakeholder input as the NRC moves forward on this issue.

**POTENTIAL RULEMAKING AND ASSOCIATED REGULATORY ISSUE SUMMARY REGARDING MULTIPLE RADIATION SAFETY OFFICERS ON A MEDICAL USE LICENSE**

Dr. Ron Zelac, NRC explained that the NRC Office of General Counsel previously determined that multiple RSOs cannot be listed on a license, since the regulations only allow for one RSO to be named. Dr. Zelac stated that NRC staff intends to consider revising the regulations to

allow more than one RSO on a license during the upcoming rulemaking. Dr. Zelac also stated that a draft Regulatory Issue Summary (RIS) was sent the ACMUI for comment, and the same RIS would be distributed to the Agreement States for comment as well. The ACMUI agreed to provide additional comments on the draft RIS.

Mr. Ralph Lieto, ACMUI, asked for clarification on the regulation that only allows one RSO on a license prior to 2002 and indicated there is nothing in the regulations to state that more than one RSO on a license is prohibited. Mr. Lieto added that smaller hospitals with multiple modalities are reluctant to allow only one individual to assume responsibility for all modalities either due to time constraints or lack of involvement in each type of modality. Mr. Lewis responded that the NRC Office of General Counsel has the sole responsibility for interpretations and remained convinced that the Commission intended for one RSO to serve on a license. Ms. Gilley stated that it is common in the Agreement States to list more than one RSO on a license with a clear indication of which RSO is responsible for each activity.

**STATUS OF TECHNICAL BASIS FOR FOLLOW-UP TO PETITION FOR RULEMAKING 35-20 (RITENOUR PETITION)**

Dr. Ron Zelac, NRC, informed the ACMUI that the NRC issued letters to the NRC-recognized boards with the intent of receiving feedback in mid-January on the impacts of the current training and experience requirements on the medical community. NRC intends to use this information to create a technical basis to proceed with rulemaking in response to the Petition for Rulemaking (PRM) 35-20 (Ritenour Petition).

**STATUS OF COMMISSION PAPER FOR MODIFYING TRAINING AND EXPERIENCE ATTESTTATION REQUIREMENTS**

Dr. Ron Zelac, NRC, informed the ACMUI that NRC staff sent a letter to the Agreement States requesting input on the three previous recommendations made by the ACMUI with regard to preceptor attestations for 10 CFR Part 35 training and experience requirements. Dr. Zelac briefly covered the responses NRC had received from nine Agreement States, the Conference of Radiation Control Program Directors, and NRC Regional staff. Overall, the respondents supported the ACMUI's recommendations. Dr. Zelac informed the ACMUI that NRC staff would be submitting a paper to the Commission in November for approval. The paper will outline the NRC staff's recommendations based on ACMUI, Agreement State, and Regional input.

Dr. Mickey Guiberteau brought an issue to the attention of NRC staff and the ACMUI with regard to individuals who complete training and meet the NRC's training and experience requirements in 10 CFR Part 35; however, based on a new American Board of Radiology (ABR) process to be implemented in 2010, these individuals will not receive their board certificate until 15 months later when they complete an examination. This gap causes individuals who would normally qualify under the board certification pathway to be forced to use the alternate pathway to achieve AU status.

**ITEM (7):** ACMUI formed a subcommittee to develop a solution that satisfies both the training needs of the residency program and the NRC requirements for achieving AU status using the board certification pathway. The subcommittee should create a recommendation to be discussed at a future teleconference prior to the spring 2008 ACMUI meeting. The subcommittee includes: Dr. Douglas Eggli (chair), Dr. Subir Nag, Dr. William Van Decker, and Dr. Mickey Guiberteau (technical assistance).

## STATUS OF CURRENT AND FUTRE RULEMAKING

Ms. Neelam Bhalla and Mr. Ed Lohr, NRC, gave an overview of the status of the current 10 CFR Part 35 rulemaking. The public comment period for the rulemaking was extended to November 7, 2008 to allow adequate time for ACMUI and other stakeholder input. The next 10 CFR Part 35 rulemaking is expected to commence in the summer of 2009.

## POTENTIAL CHANGES TO 10 CFR PART 35

Dr. Donna-Beth Howe, NRC, gave a presentation on proposed changes to 10 CFR 30.35(b) and 10 CFR 35.40; 35.65; 35.590; 35.20(b); 35.204(b); 35.50; and 35.51 through 35.690.

**10 CFR 30.35(b)** requires a certificate of financial assurance for decommissioning of licensees authorized for the possession and use of sealed sources with a half-life greater than 120 days and in quantities exceeding 10,000 but less than 1,000,000 curies for Co-60. Most medical use licensees do not exceed these limits that require financial assurance for sealed sources unless they possess multiple gamma knife units. However, a medical use licensee with a single gamma knife unit that has not gone through a complete half life of decay that changes the sources may exceed the limit for the short period of time that the sources are exchanged or a new replacement unit is installed. The financial assurance requirements should not apply to short term (e.g. 60-day period) in which the limits are exceeded because of source exchange.

Dr. Howe recommended revising 30.35(b) to read, "Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section (except licensees that exceed these limits for 60 days due to source exchange) shall either--…"

**ITEM (8):** NRC staff should revise 10 CFR 30.35(b) to allow licensees to exceed the limits short term (e.g. 60 days) during source exchange.

The motion passed unanimously.

**10 CFR 35.40** requires the AU to date and sign the WD. 35.40(b)(6) requires a two part WD for "all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders." The two part WD includes the: 1) before implantation portion; and 2) after implantation but before completion of the procedure portion. The proposed Part 35 rulemaking clarifies that the AU needs to sign and date the additional information provided after implantation but before completion of the procedure. However, this rulemaking only applies to permanent manual brachytherapy and not all the brachytherapy modalities in 35.40(b)(6).

Dr. Howe recommend revising 10 CFR 35.40 to clarify that the AU needs to sign and date both the pre-implantation and after implantation parts of the WD for all modalities with two-part WDs.

**ITEM (9):** NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs.

The motion passed unanimously.

The ACMUI later clarified that it is possible for two different AUs to sign the before and after portions of the WD; therefore, a follow-up motion was made.

**ITEM (10):** NRC staff should revise 10 CFR 35.40 to clarify that an AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. The motion passed unanimously.

**10 CFR 35.65** authorizes medical use licensees to use byproduct material in this section for transmission sources as well as check, calibration, and reference use. All the other sources are used for quality control and quality assurance test when evaluating the function of equipment traditionally found in medical use facilities. These sources are not used to produce radiation for use on humans.

Dr. Howe recommended revising 10 CFR 35.65 to clarify that it does not apply to sources used for medical use (i.e., the intentional external administration of radiation from byproduct material to patients or human research subjects). Dr. Howe also recommended revising 10 CFR 35.590 (sealed source use for diagnostic purposes) to permit the use of transmission sources under 35.500 by AUs meeting the training and experience requirements of 35.590 or 35.290.

**ITEM (11):** NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.

The motion passed with three opposing votes.

**10 CFR 35.204(b)** permits licensees that elute Mo-99/Tc-99m generators to perform molybdenum breakthrough measurements on the first generator eluate to demonstrate compliance with the requirement that a licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of Mo-99 per megabecquerel of Tc-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m).

Dr. Howe recommended revising 35.204(b) so that licensees must measure the molybdenum breakthrough for each eluate.

**ITEM (12):** NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo-99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.

The motion passed with nine favorable votes, one opposition, and one abstention.

As a follow-up to the previous disccusion, Ms. Cindy Flannery, NRC, requested input from the ACMUI on the possibility of requiring licensees to report molybdenum breakthrough that exceeds the limits.

**ITEM (13):** NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.

The motion passed with one opposing vote.

**10 CFR 35.51, 35.190, 35.290, 35.390, 35.490, 35.590 and 35.690** require the supervising individual and the preceptor to meet the current applicable training and experience requirements of that section. The effect is that grandfathered authorized medical physicists (AMPs) and AUs may not serve as supervising individuals or preceptors.

Dr. Howe recommended revising the supervised work experience and attestation sections of the applicable regulations to allow grandfathered AMPs and AUs to be supervisors and preceptors for that particular use.

**ITEM (14):** NRC staff should approve the proposed change for "grandfathered" AUs as supervisors and preceptors for the purposes of training and experience.

The ACMUI indicated very strong support and voted in favor of the motion unanimously.

Ms. Flannery, NRC, added that NRC staff was seeking a higher opinion from the NRC Office of General Counsel on this issue, and grandfathered authorized individuals should continue to serve as preceptors and supervisors. Ms. Flannery assured ACMUI that once a final interpretation was determined, NRC staff would expeditiously pursue rulemaking, if needed.

**ITEM (15):** NRC staff should notify ACMUI when the NRC Office of General Counsel makes a determination on the availability of "grandfathered" AUs as supervisors and preceptors for the purposes of training and experience.

**MEDICAL NUCLEAR MATERIALS EVENTS**

Dr. Donna-Beth Howe, NRC, provided an update on the status of the 31 reported medical events from fiscal year 2008. Dr. Howe summarized medical events into the following categories: diagnostic (35.200); therapy (35.300); brachytherapy (35.400); high dose-rate (HDR), gamma knife, and teletherapy (35.600); Y-90 microspheres (35.1000); and other. Compared to fiscal year 2007, there was an overall decrease in medical events reported during fiscal year 2008.

Mr. Ralph Lieto, ACMUI, provided an update on the status of the 32 reported events that relate to the medical use of radioactive materials. Mr. Lieto summarized other reported events into the following categories: lost sources; leaking sealed sources; fetus/embryo doses; landfill alarms; and miscellaneous.

**ITEM (16):** The standing ACMUI medical nuclear materials events subcommittee should review events and provide an analysis to the full committee annually in the spring instead of the fall.

The motion passed with six favorable votes and five abstentions.

**INTRAOCULAR STRONTIUM-90 EYE APPLICATOR**

Dr. Jeff Heier, representing NeoVista, spoke to ACMUI about neovascular (aka wet) age-related macular degeneration (AMD) and treatment using NeoVista's intraocular strontium 90 (Sr-90) EpiRad 90$^{TM}$ device. Dr. Heier informed the ACMUI that many patients must be seen immediately and treated within a day or two. Dr. Heier added that coordination of the retina specialist with a radiation oncologist in this short time period is extremely unlikely. Dr. Heier

also described the training received by retinal surgeons. Lastly, Dr. Heier stated he believed the new intraocular device should be regulated the same way as the Sr-90 surface applicator.

Dr. Nag compared the new EpiRad 90$^{TM}$ device to iodine 125 (I-125) plaques. Dr. Heier countered that the procedures are different and the training required differs as well, since the I-125 plaques required more detailed training and delivery. Dr. Heier added that currently the EpiRad 90$^{TM}$ device is only being used with fixed dosimetry. Dr. Donna-Beth Howe, NRC, stated that NRC staff believed the training that retinal surgeons receive should differ from what ophthalmologists are required to obtain for external use of the existing eye applicator under 10 CFR 35.491. Mr. John Hendrick, NeoVista, believed that it was not necessary for a radiation oncologist to be the AU in accordance with the current NRC guidance. Rather, a retinal surgeon should be able to serve as the AU on a license.

**ITEM (17):** ACMUI believes that 10 CFR 35.491 provides adequate training and experience for the use of NeoVista's EpiRad 90$^{TM}$ device, if the training under 10 CFR 35.491 is accompanied by appropriate device specific training.

ACMUI clarified that the device should not be moved from 10 CFR 35.1000; however, the NRC guidance for the EpiRad 90$^{TM}$ device should be revised to mimic the requirements in 10 CFR 35.491.

The motion passed with seven favorable votes, one opposition, and two abstentions. Dr. Thomadsen provided clarification that he did not vote in favor of the motion only because he thought the decision was too premature.

**ITEM (18):** NRC should add a training requirement that the individual using the EpiRad 90$^{TM}$ device should be a retinal surgeon.

The motion failed with only four favorable votes, five votes in opposition, and one abstention.

## PATIENT NEEDS, CONCERNS, AND RIGHTS IN RADIATION MEDICINE

Dr. Darrell Fisher, ACMUI, provided information to the ACMUI on patients' needs, concerns, and rights in radiation medicine. Dr. Fisher described the factors that may impact patients' rights: (1) regulations that restrict or limit availability or patient access to new treatments; (2) slow processes for new drug or device approval; and (3) regulations that restrict hospitals' and physicians' ability to provide the most effective treatments. Dr. Fisher also described the role of the ACMUI patients' rights advocate, emphasizing that it is the member's responsibility to bring key issues to the attention to NRC on behalf of patients and that the member must be cognizant of the impacts of NRC actions on patient access to health care. Dr. Fisher also provided a historical summary on the evolution of federal regulations concerning patients' rights in the context of radioisotope research and the practice of medicine.

## CLOSING

Ms. Ashley Tull, NRC, briefly summarized the items proposed by ACMUI as recommendations and action items for the current meeting and suggested dates for the next ACMUI teleconference and full meetings. The teleconference was scheduled for December 18, 2008, from 1:00 pm to 3:00 pm Eastern Standard Time. Based on availability of the conference room and ACMUI members, Ms. Tull tentatively scheduled the next full ACMUI meeting for May 7-8, 2009, at NRC Headquarters.