TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

JULY 21, 2008

MEETING SUMMARY

PURPOSE: To discuss issues related to the permanent implant brachytherapy rulemaking, the resolution of the Ritenour petition, and proctoring for the yttrium-90 (Y-90) microsphere licensing guidance.

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.

OPENING COMMENTS

Mr. Robert Lewis, NRC, provided a brief overview of the goals for the meeting and discussed current NRC projects of interest to the ACMUI. These projects included: NRC correspondence with the American College of Radiology (ACR), progression of NRC work on cesium (Cs-137) chloride issues, NRC staff transmittal of ACMUI's subcommittee report on fingerprinting to the Commission; and NRC's publishing of the resolution to the Petition for Rulemaking (PRM) 35-18 (Crane Petition) and related guidance.

PERMANENT IMPLANT BRACHYTHERAPY RULEMAKING

Dr. Subir Nag, ACMUI, outlined his concerns with regard to the wording of the proposed rulemaking in which any seed more than three centimeters outside the treatment area would prompt a Medical Event (ME). Dr. Nag disagreed with the proposed wording, since there are many reasons in the normal course of a procedure that a few seeds may be more than three centimeters away. Dr. Nag suggested that an allowance be made for a certain number or percentage of seeds to be more than three centimeters from the treatment area. Dr. Nag also raised a concern about the possibility of ambiguity in NRC's interpretation of the treatment area, not only for prostate treatments, but for other permanent implant brachytherapy treatments as well.

Drs. Thomadsen and Welsh supported Dr. Nag's comments. Mr. Lewis outlined the possible pathways forward. After considerable discussion on the technicalities of permanent implant brachytherapy, the enhanced participatory rulemaking process, and procedures for submitting and withdrawing Commission papers, Mr. Lieto made the following recommendations, and Dr. Richard Vetter seconded:

ITEM (1): NRC staff should not withdraw the paper currently before the Commission on permanent implant brachytherapy rulemaking.

ITEM (2): ACMUI should provide comments to clarify their position on the permanent implant brachytherapy rulemaking during the regular comment period.

ITEM (3): NRC staff should send information back to the ACMUI for a second review, once NRC staff has interpreted and incorporated the ACMUI's original comments.

The motions passed with one opposing vote from Dr. Nag.

ITEM (4): Dr. Leon Malmud, ACMUI Chairman, requested ACMUI form a subcommittee, which includes: Mr. Lieto, Dr. Nag (chair), Dr. Thomadsen, and Dr. Vetter, and Dr. Welsh. The charge of the subcommittee is to create a document that establishes a standard for medical events in permanent implant brachytherapy, which is both practical and in the interest of public safety and welfare.

Dr. Nag also made the following recommendation, which was seconded by Dr. Welsh, at the conclusion of the permanent implant brachytherapy rulemaking discussion.

ITEM (5): If a recommendation is made by the ACMUI for rulemaking, NRC staff should resend the draft rulemaking to ACMUI, which incorporates the ACMUI comments, before proceeding to final rulemaking.

The motion passed unanimously.

RITENOUR PETITION

Mr. Ed Lohr, NRC, gave an overview of the *Federal Register* notice, which provided NRC's response to the Petition for Rulemaking 35-20 (Ritenour/AAPM Petition). Mr. Lohr explained that in order for NRC to proceed with rulemaking, a technical basis must be provided from NRC's medical group. Dr. Ronald Zelac, NRC, clarified that NRC medical staff would solicit information from the community to provide the justification needed in the technical basis.

Dr. Gerald White from the American Association of Physicist in Medicine (AAPM) expressed a concern with the boards being able to determine which individuals would benefit from the potential rulemaking. Dr. Zelac reiterated that NRC is seeking specific data and not generalities or suggestions.

Dr. Zelac also responded to a question from Mr. Steve Mattmuller, ACMUI, to clarify that NRC would solicit information from all of the boards and not just the boards certifying medical physicists.

Ms. Melissa Martin, AAPM, asked when NRC expected to mail letters. Ms. Cindy Flannery, NRC, responded that NRC would request information and hoped to receive responses before the end of the year.

Mr. Lieto suggested that this issue be added to the October ACMUI agenda. Dr. Malmud supported this request. Mr. Lieto also asked that other groups, such as the academies and colleges, be solicited for information for the technical basis.

Y-90 MICROSPHERE GUIDANCE

Dr. Malmud, ACMUI Chair, opened the discussion by explaining that there are not currently enough physician proctors to oversee all trainees throughout the United States for yttrium 90 (Y-90) microsphere brachytherapy; therefore, ACMUI was being asked 1) if it is acceptable for a non-physician to proctor new trainees and 2) for input as to the types of other individuals that can fill this role, if it is determined that non-physicians can serve as a proctor.

Mr. Ken Thurston of Sirtex Medical described Sirtex's model for proctoring cases, which typically includes proctoring by a physician for at least three cases. Mr. Thurston went on to explain that in selected circumstances for sites that have shown to be very capable, a non-physician proctor may be used to proctor the third case. Mr. Thurston recommended this model to the ACMUI.

Mr. Tom Burnett of MDS Nordion described how a non-physician, full-time MDS Nordion employee with extensive training proctors cases for their new licensees. Mr. Burnett also explained that the model is very well received by the new licensees and that MDS Nordion continues to proctor more than the first three cases, if necessary.

Dr. Nag added that both catheter placement and radiation safety issues should be covered by proctors. Dr. Nag stated that the medical aspects should be proctored by a medical doctor and that the radiation safety aspects could be handled by a manufacturer's representative.

Ms. Debbie Gilley, ACMUI, inquired as to how the Agreement States are to implement the guidance with respect to individuals completing three simulated cases to become an Authorized User (AU)I and later completing the proctored cases. Ms. Tull clarified that the guidance would address this issue and that the licensee would be responsible for notifying the regulatory body that the three proctored cases were complete. Ms. Gilley was concerned that ME may occur during the proctored cases. Dr. Donna-Beth Howe indicated that MEs have occurred during the first patient treatments. Mr. Thurston added that if this type of issue were to occur, Sirtex would increase the number of proctored cases for that particular licensee.

Dr. Nag made a motion that was subsequently withdrawn, since it could have required multiple individuals to be onsite for proctoring cases. Dr. Nag's specific concern was that the proctoring individual posses the knowledge, skill, and training in the placement of the catheter, the calculation of the dose, the methodology of injection, and radiation safety procedures. Dr. Riad Salem representing MDS Nordion opposed Dr. Nag's suggestion, and Dr. Vetter also expressed concerns with Dr. Nag's new wording.

Dr. Malmud made the following recommendation, and Dr. Vetter seconded:

ITEM (6): NRC staff should accept proctoring models from both manufacturers, since they incorporate the concerns with regard to radiation safety and clinical expertise.

The motion on the floor passed with two oppositions from Ms. Gilley and Mr. Lieto. Ms. Gilley explained that she was concerned about documentation in the Agreement States and was not inclined to add an individual to a license who had not received all of their training, including the proctored cases.