MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

June 28, 2005

TELECONFERENCE MEETING SUMMARY

PRINCIPLES TO ASSIST IN DRAFTING CRITERIA TO CAPTURE MEDICAL EVENTS INVOLVING PERMANENT IMPLANT BRACHYTHERAPY

This was a teleconference meeting of the ACMUI. During this meeting, Jeffrey F. Williamson, PhD, Chairman of the ACMUI's Medical Events Subcommittee (MESC), led the discussion of the product which resulted from the MESC's efforts. The purpose of this teleconference meeting was to forward, to the ACMUI for a vote, a set of principles intended to assist the NRC staff in drafting language that will capture medical events resulting from permanent implant brachytherapy. Furthermore, the meeting was held so that the MESC could forward, to the ACMUI, recommendations on communicating risks associated with medical events. Members of the MESC are Jeffrey F. Williamson, PhD, Therapy Physicist, Chair, MESC; Ralph P. Lieto, Medical Physicist; Subir Nag, MD, Radiation Oncologist; and David A. Diamond, MD, Radiation Oncologist.

During the meeting, the MESC referred to its document dated June 21, 2005, entitled "Medical Events Subcommittee Meeting Summary and Draft Recommendations to the ACMUI." In this document, the MESC articulated two sets of principles. The first set of principles were related to the new rule definition. The second set of principles articulated associated risks. The MESC believed that both sets of principles will assist the NRC staff in creating a medical event rule that will be more risk-informed and will more accurately capture medical events resulting from permanent implant brachytherapy procedures.

The MESC briefly discussed each principle with the ACMUI. After minor refinements, the MESC made motions on the principles and forwarded the motions, as stated below, to the ACMUI for a vote.

Motions:

- Principle B1: For all permanent implants, medical events should be defined in terms of the total source strength implanted in the treatment site, not in terms of absorbed dose.

  Motion for Principle B1 carried unanimously.

- Principle B2: Any implant in which the total source strength implanted in the treatment site deviates from the written directive by more than 20 percent, in either direction, should be classified as a medical event.

  Motion for Principle B2 carried unanimously.

- Principle B3: The revised criteria designed to capture events where the wrong area was treated should distinguish between two scenarios: 1) Tissue or organs immediately adjacent to the treatment site, and 2) organs that are distant from the treatment site. For permanent implants, tissues that are more than 3 cm from the treatment site boundary can be considered "distant"[1] because the dose has fallen to subtherapeutic levels (1-5% of the prescribed dose). The following are sub-principles that should be considered along with Principle B3:

    - Subprinciple B3a: Medical events should include those events in which sources that exceed 20% of the total source strength that is documented in the pre-implantation written directive are implanted in tissue or organs adjacent to the treatment site.

    - Subprinciple B3b: For erroneous implantation of radioactive seeds in an organ distant from the intended treatment site, such implants should be classified as medical events if: 1) seeds are actually implanted in a distant organ; 2) the excess dose of a distant organ exceeds 50 rem; and 3) the excess dose to the organ is at least 50% greater than the dose that would have been delivered had the seeds been implanted in the correct tissue volume.

    - Subprinciple B3c: The medical event criterion that defines medical events for capturing both adjacent and distant wrong-site implants should exclude instances in which seeds were correctly implanted, but subsequently migrated from the implantation site. Note: the staff should be mindful that a seed can occasionally migrate a large distance from the site in which it was correctly implanted. Therefore, it may be difficult to distinguish between true medical events resulting from wrong site implantations and instances of seed migration.

    Motion for Principle B3 carried unanimously.

- Principle B4: Given a source strength-based medical event criterion of 20% in either direction, it is reasonable to require that the authorized user complete any revision to the written directive for permanent implants before the patient is released from licensee control.

    Motion for Principle B4 carried unanimously.

[1] The MESC suggested that the definition of "distant organ" is an organ whose closest boundary to the treatment site receives less than 5 percent of the dose.

- Principle B5: In addition to incorporating the activity-based medical event pathway into Part 35, the MESC recommends retaining a limited dose-based medical event criterion. An implant is a medical event if the dose calculations used to determine the total source strength documented in the written directive are in error by more than 20% in either direction.

  Motion for Principle B5 carried unanimously.

RISKS ASSOCIATED WITH MEDICAL EVENTS

Dr. Williamson led the discussion on methods to communicate risks associated with medical events. Dr. Williamson stated his belief that, because of the manner in which the medical event rule is currently written, the regulated community views the reporting of medical events as a punitive requirement. Dr. Williamson suggested that the way to adjust this perception would be for the NRC to review the manner in which it defines medical events; review the enforcement procedures that are associated with the investigation of medical events; and reframe the Agency's response so that it is similar to the "industry standard."

With respect to the MESC document's characterization of risk associated with medical events, Thomas Essig, Designated Federal Official for the ACMUI, suggested two refinements. First, Mr. Essig suggested that the characterization of the NRC's response to medical events be amended. The MESC document stated that the NRC routinely responds to medical events by conducting "reactive inspections using investigation teams". Mr. Essig clarified that this appears to refer to an Incident Investigation Team (IIT), which is the Agency's highest level of response, and is conducted only in rare instances when severe patient harm has occurred (e.g., the Indiana-Pennsylvania event where a patient died from radiation exposure). The MESC accepted this refinement.

The second refinement Mr. Essig suggested involved the statement that NRC's response to medical events is similar to NRC's response to "reactor disasters." Mr. Essig's contention was that such a comparison was neither accurate nor appropriate. However, Dr. Williamson stated his belief that the public's perception is that NRC responds to medical events in a manner that is similar to the way the Agency responds to nuclear reactor accidents. Nevertheless, Dr. Williamson agreed to amend the MESC document, to state that NRC's response to medical events is comparable to its response to "reactor events" rather than "reactor accidents." Mr. Essig agreed to accept this characterization, since it may reflect the public's perception. The MESC then discussed principles it formulated to communicate its perception of risk associated with medical events.

Following is the set of principles, associated with risk, the MESC formulated. After discussing these principles with the ACMUI and making minor refinements, the MESC forwarded the motions, as stated below, to the ACMUI for a vote.

Motions:

- Principle C2: The role of the 10 CFR 35.3045 medical event reporting rule as a technical quality performance indicator should be decoupled from its use as a potential patient harm index. To this end, the patient reporting requirement 35.3045(e) should be amended to require informing the patient and/or friends and relatives only if the licensee determines that the medical event may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decisions. [2]

  Motion for Principle C2 carried unanimously.

- Principle C3: The NRC staff should strive to make the medical event reporting and subsequent enforcement processes more like the regulated community's own Quality Assurance (QA) practice of follow up and process review that occurs following detection of a delivery error or potential error. This should be done given that:

  - Subprinciple C3a: Making an error is not grounds for disciplinary action;

  - Subprinciple C3b: Institutional QA findings and deliberations are not discoverable and can not be used to increase its liability;

  - Subprinciple C3c: Error reports are input to a systematic effort for improving planning, delivery, safety, QA, and documentation processes.

  Motion for Principle C3 carried unanimously.

- Principle C4: NRC can make medical event reporting more like the industry standard by considering the following:

  - Subprinciple C4a: To the extent possible, NRC's medical event reporting and follow up procedures should be designed so as to not increase licensee liability. Keeping medical event reports, or at a minimum, the licensee's identity out of the public record is probably the single most useful improvement NRC could make in this regard.

  - Subprinciple C4b: NRC is encouraged to develop a more graded medical event inspection response process that ties the intensity and immediacy of its inspection response to risk to the individual patient and public health implications of the event. For example, for relatively minor medical events, where public health and safety is not in question, NRC could

[2] Ronald Zelac, PhD, NRC, clarified that the Commission's past position regarding the requirement to report medical events to patients was to ensure that patients are aware of instances in which they have been identified in NRC's records as a person who was involved in a medical event. If potential for harm or actual patient harm occurred, this also would necessarily be included in the report.

minimize reactive inspections of licensees, pending a satisfactory investigation and quality-improvement response on the part of the licensee. Thus, the MESC recommends that NRC manage minor medical events much like recordable events in the former 10 CFR 35.

- Subprinciple C4c: NRC should change the 24 hour Operations Center reporting procedure. Medical events that the licensee has determined have not harmed the patient, could not potentially harm the patient, or are not materially relevant to the patient's future medical treatment decisions, need not be reported orally to the Operations Center in 24 hours. Instead, licensees should be allowed to report these types of medical events in a written report within 7 days.

Motion for Principle C4 carried unanimously.

PROCESSING THE PRINCIPLES

The ACMUI expressed interest in reviewing the principles before staff submits them to the Commission, to ensure the principles are properly characterized. Toward that end, the ACMUI made a motion.

Motion:

That the ACMUI be provided an opportunity to review and comment on the draft Commission paper whereby the NRC staff will communicate to the Commission its opinion as to whether the staff should use these principles as guidance to draft a rule to capture medical events involving permanent implant brachytherapy, and/or to make the medical event rule more risk-informed.

Motion carried unanimously.

The meeting was adjourned at 2:53 p.m.

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Motion carried unanimously.

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