MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 25-26, 2005

**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 more 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. 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.

**TUESDAY, OCTOBER 25, 2005**

**ADMINISTRATIVE ISSUES (CLOSED SESSION)**

Thomas Essig, Designated Federal Official, NRC, led the discussion during this topic. Mr. Essig informed the ACMUI of several administrative issues necessary to the conduct of the ACMUI's business. One of these issues was the self-evaluation. The Commission requires that the ACMUI perform a self-evaluation every two years. The ACMUI performed its last self-evaluation in the Spring of 2005. Of the 12 ACMUI members, 7 responded to the self-evaluation.

It was noted that the ACMUI Chairman, Leon Malmud, MD, was to meet with Commissioner Merrifield at 9:00 a.m. on October 25, 2005, to discuss the results of the ACMUI self-evaluation. It was anticipated that Commissioner Merrifield would query the ACMUI Chair as to why more ACMUI members did not respond to the self-evaluation.

The ACMUI stated that the percentage of responses could be increased if the staff would send out e-mail notifications, specifying which ACMUI members have not responded, and requesting responses from those members.

**The ACMUI made the following recommendation:**

**That, as a means to remind the ACMUI to submit responses to the self-evaluation, the NRC staff should e-mail the entire ACMUI the names of those members who have not responded to the self-evaluation, no later than one week prior to the deadline for response. The self-evaluation should be attached to the e-mail.**

The ACMUI also stated that it would be helpful if questions pertaining to the staff's assistance to the ACMUI could be included on the ACMUI self-evaluation. With regard to that proposal, the ACMUI made the following recommendation:

**That the NRC staff add a question to the ACMUI self-evaluation that allows the ACMUI to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists.**

After discussion of the self-evaluation, the ACMUI stated that there was considerable concern among stakeholders regarding the new training and experience (T&E) requirements in 10 CFR Part 35, which stakeholders in medical specialty boards regard as an intrusion on specialty boards. The NRC staff stated that discussion of concerns about T&E requirements is an item that must be discussed during the open session, as it does not meet the criteria for discussion during the closed session.

## STATUS OF BOARD APPLICATIONS

NRC staff consisting of Cynthia Flannery, CHP; Donna-Beth Howe, PhD; Ronald Zelac, PhD; and Mohammad Saba presented this topic to the ACMUI. The NRC staff has updated the requirements that certifying boards must meet so that their certification processes are recognized by the NRC as viable processes for certifying Authorized Users (AUs) under 10 CFR Part 35. This presentation was given to inform the ACMUI of the status of the boards who submitted their processes to the NRC for review against the updated requirements.

Ms. Flannery explained that staff mailed letters of notification to 12 boards, asking them to submit their certifying processes for NRC review. (These letters were mailed to recommend that they get their certification processes reviewed, and if necessary, adjusted, by the October 24, 2005, deadline, after which the new requirements for certification would be effective). Nine of the 12 boards responded between July and August 2005. These boards are now listed under one of several categories:

- **Approved**. The boards' certifying processes were reviewed and approved, and the board was listed on the NRC website.
- **Approvable**. The board's certification process generally meets criteria for approval, but the NRC staff is waiting for the board to respond with the date in which the board will fully meet the staff's criteria for approval.
- **Under Review**. The staff has contacted the board for additional information, has received the information, and continues to review the information.
- **Awaiting Input**. NRC staff is waiting for requested additional information.

One ACMUI member expressed concerned that any board that applied for recognition after the October 24, 2005, deadline would not be recognized as a viable body for certifying AUs, He stated that this is unacceptable, because it creates a situation whereby individuals are forced to gain recognition as AUs via the T&E pathway rather than the board certification pathway. The NRC staff responded by stating that while persons applying for recognition in certain specialties will need to gain AU status via the T&E pathway, it is expected that many boards will be able to demonstrate that their certifying processes met NRC requirements before the October 24, 2005, deadline. Staff explained that it is premature to determine that most boards will not have their certifying processes approved.

**The ACMUI made the following recommendation:**

**That NRC staff provide a more detailed explanation of the reason for any case in which a board certified individual is not recognized by the NRC, because the board's certifying process does not meet NRC's requirements.**

The ACMUI clarified that the point of this motion is to better understand why certain subgroups of board certified individuals will not be able to gain recognition under NRC's new requirements.

The ACMUI asked the staff if it would recognize individuals who have been granted recognition under a state license. Staff responded by stating that NRC requires authorized users to be licensed in the United States. NRC does not accept state licensure as a mechanism for recognition. Rather, recognition is granted based on a candidate's ability to meet the NRC's regulations.

As extensive discussion ensued, the ACMUI stated its concern that certain individuals, who the ACMUI believes may be otherwise qualified, may be inappropriately denied recognition, which would have a detrimental effective on patient care.

**ACTION ITEM: That the NRC staff provide a report to the ACMUI on the actual number of board certified individuals who have been denied recognition as AUs. The report should include a rationale for excluding these individuals.**

The ACMUI explained that such a report would help everyone understand the nature and the magnitude of this issue, which will enable the ACMUI and the NRC staff to respond appropriately to stakeholders' perception that persons are being inappropriately disqualified.

**UNAUTHORIZED INJECTIONS OF RADIOPHARMACEUTICALS**

Douglas F. Eggli, MD, of the Milton S. Hershey Medical Center, presented this subject to the ACMUI. This was an exploration of a case history at Milton S. Hershey, whereby individuals injected themselves with radiopharmaceuticals for the purpose of acquiring unauthorized imaging studies on themselves. The purpose of the presentation was to suggest what other licensees might do to prevent such abuses of radioactive material, and to seek recommendations on how to prevent these abuses.

Several incidents of unauthorized self-injections occurred at Milton Hershey in 1997, 2002 and 2004. The incidents in 2002 and 2004 were substantiated.

Dr. Eggli stated that as part of Hershey's corrective actions, Hershey has instituted the following:

- Written directives are required for diagnostic administrations on all staff members.
- Technologists who perform injections must review the written directive.
- Technologists must discuss the written directive with the AU.
- New employee training and annual staff training now emphasizes this incident, and associated consequences with unauthorized injections.

Dr. Eggli remarked that it is easy for technologists to make this sort of activity invisible, as these incidents were not detected either by Hershey Medical Center, nor by several routine NRC inspections; but rather, were eventually uncovered as a result of a nuclear medicine technologist reporting an incident to Hershey staff. Dr. Eggli asked how to prevent this type of incident, when knowledgeable persons are intent on willfully violating NRC requirements?

The ACMUI expressed two general concerns: 1) that there appears to be nothing a licensee can do to prevent the illegal actions of a person intent on deliberately violating rules, and 2) that it appears to be unfair to penalize an organization for the deliberate misconduct of its employees.

NRC staff agreed that there is probably little a licensee can do to prevent willful, deliberate illegal actions of one if its employees. Nevertheless, licensees are responsible for determining the integrity of the people they hire, and are therefore responsible for their actions.

**The ACMUI made the following recommendation: The ACMUI goes on the record to register its support and commendation to Milton S. Hershey for its handling of this case.**

**REVISION OF NRC FORM 313A**

Sandra Gabriel, NRC, presented draft changes to NRC Form 313A, which applicants complete to gain recognition as AUs, authorized medical physicists, (AMP) authorized nuclear pharmacists (ANP), and radiation safety officers (RSO) on NRC licenses.

Ms. Gabriel explained that as the revision to 10 CFR Part 35, effective in 2002, promulgated a somewhat more complex set of T&E requirements, this resulted in an increased challenge to licensees' abilities to effectively communicate their T&E on the present Form 313A. Therefore, staff found it necessary to revise Form 313A so that licensees more clearly understand what sections to complete, and how to complete them correctly. Ms. Gabriel stated that, in conjunction with updating Form 313A, staff is also updating Appendix D to NUREG 1556, Volume 9, "Consolidated Guidance About Materials Licenses, Program Specific Guidance About Medical Use Licenses." NUREG 1556, Volume 9, instructs applicants on the use of Form 313A.

After commending staff on this effort, the ACMUI provided some specific feedback on ways to improve the draft Form 313A. The staff made note of this feedback and informed the ACMUI that the staff will submit a revised Form 313A, along with NUREG 1556 Volume 9, Appendix D, for public comment. Concurrent with the collection of public comments, the staff will submit Form 313A to the Office of Management and Budget (OMB), who must grant clearance for Form 313A, making it official. The staff hopes to obtain OMB clearance within 6 months.

**STATUS OF GUIDANCE ON REDUCING DOSES TO MEMBERS OF THE PUBLIC**

Sami Sherbini, PhD, NRC, made a presentation to inform the ACMUI of the status of this guidance, which will instruct licensees on the procedure to allow members of the public to receive radiation doses in excess of the limits in NRC's regulations when caring for sick relatives who are hospitalized. Staff took action to create this guidance, based on comments the ACMUI made at the October 2004 ACMUI public meeting.

Most of the comments received were favorable, and staff incorporated most portions of the comments. Dr. Sherbini provided an overview of the nature of the comments and the staff's disposition of them. Below is an abbreviated list of comments and the NRC staff response:

Comment: That this guidance gives licensees an unacceptable alternative to adequate monitoring of visitors, which will prevent excessive dose.

Response: Staff addressed this comment by interjecting language in the guidance that states this may not always be a justifiable alternative, therefore, licensees should explore other means of providing control of doses.

Comment: Be consistent with the use of radiation terminology. In other words, either use the new international units (e.g., Sievert) or the conventional units (e.g., rem).

Response: NRC policy is to use both old and new units. This is necessary, in part, since certain instruments are still calibrated using the old units.

Comment: Remove instructions on performing retrospective dose reconstruction (as the instructions are not exhaustive).

Response: The intent of the guidance was to suggest what kind of data should be collected to perform retrospective dose reconstruction, not to provide an exhaustive description on the performance of dose reconstruction. Staff clarified this intent by stating what kind of data is necessary to perform dose reconstruction, but giving no information on how to perform dose reconstruction.

Dr. Sherbini mentioned the importance of licensee control of radiation doses - that licensees have a level of awareness in which they can control doses to visitors. Some ACMUI members objected to this position, stating that licensees do not have absolute control of visitors, who can elect to be overexposed despite instructions and safeguards from licensees. Dr. Sherbini clarified his point by stating that "control" in this context is not meant to hold licensees accountable for visitors who ignore safeguards and instructions. Rather, "control" in this context means licensees should have a level of awareness that allows them to take appropriate action to discourage visitors - who are not aware they are being exposed - from getting overdosed. In cases where it is evident that the visitor will exceed the dose limit, the licensee can use this guidance to request an exemption to the regulations.

The ACMUI and a member of the public continued to object to this principle, stating that licensees cannot predict visitors' behavior, and therefore, are not able to prospectively ascertain when a visitor is likely to exceed the dose limit. However, one ACMUI member agreed with the staff, in that there is a distinction between responsibility for a visitor's behavior versus responsibility to make a reasonable effort to ensure that the visitor is following instructions. The NRC staff and the ACMUI agreed that the use of the term "licensee control" may lead to confusion, because it seems to imply that licensees' responsibility relates to visitors' behavior, rather than to the assurance that licensees be proactively aware of whether visitors are following instructions. Dr. Sherbini agreed to remove that term from the guidance. The ACMUI further encouraged the NRC staff to be sensitive to the fact that there is a human relational and

emotional element associated with this issue. Physicians have this element to consider, and cannot view this issue strictly as scientists applying dosimetry and physics.

**RIS ON CAREGIVER DOSE LIMITS**

Sami Sherbini, PhD, NRC, made a presentation to inform the ACMUI about the Regulatory Issue Summary the staff is preparing as guidance to rapidly grant exemptions from regulatory limits for certain caregivers of inpatients who have been administered radioactive material.

Dr. Sherbini explained that input from the NRC regions will be used to prepare the guidance. The NRC Headquarters (HQ) staff is seeking regional input since the NRC regions will be responsible for implementing the guidance. The HQ staff has received input from 2 of the regions. Once the HQ staff receives all regional input, the HQ staff will submit the guidance for comment. Following comment resolution, the staff will issue the guidance, hopefully by the end of next year.

The ACMUI asked for assurance that this exemption to the NRC limit on doses to the public would be granted, without NRC verification of the licensee's assertion that there is a need to grant this exemption. Dr. Sherbini explained that this system of granting exemption to the limit on public doses will be pre-configured so that exemptions may be granted rapidly. Dr. Sherbini further explained that the purpose of this action was to enable licensees to gain this exemption expediently. Therefore, the NRC will not arbitrarily deny such requests.

**ELECTRONIC SIGNATURES ON WRITTEN DIRECTIVES**

Donna-Beth Howe, PhD, NRC, gave this presentation. The NRC staff encountered a licensee, during an inspection, who utilizes a completely electronic system to generate and authenticate its written directives. Dr. Howe gave this presentation to seek ACMUI insights on the acceptability of electronic signatures on written directives.

Dr. Howe explained that written directives must be dated and signed by the AU before the administration of radioactive material. The AU does not have to generate the written directive, but the AU must date and sign it. Likewise, any revisions to the written directive must be signed and dated by the AU. Written directives must contain all the minimum, necessary information.

If the electronic written directive is printed on paper and signed by hand, it is no longer an electronic record. It would be inspected as any other printed record. However, if the written directive is not printed and signed by hand, it will be regarded as an electronic record. It must be inspectable by the NRC as an electronic record.

The NRC staff is using 3 sources of data collection to compose regulations/guidance on electronic written directives. The first is an American National Standards Institute guidance document that the health care industry uses to authenticate electronic signatures. The second is data collected on the licensees' software, to get a better understanding of the capabilities of the software. The third is data obtained by the NRC staff during a demonstration of the method of electronic audit on the licensees' software. Based on these sources, the NRC will determine if this particular licensee's electronic signature on its written directives is valid, in accordance with current regulatory requirements.

Two ACMUI members stated that they produce electronic written directives that they sign and authenticate by means of a personal password, and stated that this system worked well at their institutions.

**WEDNESDAY, OCTOBER 26, 2005**

**DISCUSSION OF CONGRESSIONAL ENERGY BILL - NRC REGULATION OF ACCELERATOR PRODUCED ISOTOPES**

This presentation was given so that the NRC staff and outside stakeholders could share their perspectives on NRC's new jurisdiction over naturally-occurring accelerator produced radioactive material (NARM) under the Energy Policy Act of 2005. Three individuals presented this topic: Richard Blanton, NRC; Roy Brown, Senior Director of Federal Affairs, Council on Radionuclides and Radiopharmaceuticals (CORAR); and Terrence Beven, MD, Society of Nuclear Medicine (SNM).

Mr. Blanton gave an overview of the Energy Policy Act and current efforts of the NRC staff to implement the Act. He stated that the Energy Policy Act gave the NRC regulatory authority and jurisdiction over certain types of NARM. Although the Act gives the NRC regulatory authority over certain types of NARM, the Act does not give the NRC authority over the accelerators themselves. To implement the provisions of the Act, the NRC has initiated two efforts: the formation of a rulemaking working group and the formation of a task force.

There are several important provisions of the Act:

- **Continuing Regulatory Authority of States.** During the period while NRC is formulating a rule to regulate NARM, the Commission has granted a waiver that allows current State regulatory programs to continue regulating NARM through August 7, 2009.

- **Availability of Radiopharmaceuticals.** The NRC must consider the impact of its regulations on the availability of radiopharmaceuticals to physicians and patients.

- **Stakeholder Input.** The NRC must involve key stakeholders in the development of its NARM regulations. Toward this end, the NRC will hold a public meeting November 9th with key stakeholders.

- **Deadline for Rule.** The Act requires that final NRC regulations be in place by February 7, 2007 (i.e., 18 months after the effective date of the Act).

The ACMUI had several concerns and questions about the effect of the Act on medical stakeholders. An abbreviated list of the questions follow, along with staff responses:

Question: Will each section of 10 CFR Part 35 be revised, or will a new Part for the medical use of NARM be created?

Response: As the NRC develops NARM regulations, appropriate changes will be made to 10 CFR Part 35.

Question: Can certain accelerator-produced radioisotopes be exempted from regulation, due to their extremely short half-lives and corresponding low safety significance?

Response: The Act allows for any possible regulatory scheme deemed necessary for the NRC to safely and effectively regulate NARM.

Question: What is the intent behind the NRC's regulation of NARM?

Response: The NRC requested this regulatory authority. Due to associated national security concerns, the NRC staff believed it prudent that the NRC regulate NARM.

Furthermore, the Health Physics Society (HPS) and the Organization of Agreement States (OAS) jointly approached Congress with the concern that NARM and byproduct material with similar security risks were regulated under different regulatory schemes, because regulatory authority was split between the Agreement States and the NRC. The HPS and the OAS supported the regulation of NARM and byproduct material under one regulatory authority, to eliminate this disparity.

**ACTION ITEM: NRC staff will distribute Section 651 of the Energy Policy Act to the ACMUI.**

**ACTION ITEM: The ACMUI will supply a representative to participate in the November 9, 2005, stakeholder discussion of the Energy Policy Act.**

Roy Brown, Senior Director of Federal Affairs, CORAR, spoke to the ACMUI. Mr. Brown stated that CORAR is the North American trade association for the manufacturers and distributors of radionuclides and radiopharmaceuticals. All major manufacturers, such as Nordion and Mallinckrodt, are members of CORAR. CORAR strongly supports the Energy Policy Act because of inconsistencies in the regulation of accelerator-produced material in the Agreement States. Below is an abbreviated list of issues CORAR faces under the current dual NRC/ Agreement State regulatory scheme:

- Issues with licensing new radiopharmaceuticals. Specifically, it is necessary to gain each state's individual approval, based on each particular State's regulations. Also, NRC-licensed states lack expertise in approving new radiopharmaceuticals. This results in significant delay of the availability of new radiopharmaceuticals to some States.

- Issues with non-uniformity in Agreement States' regulations. For example, an RSO may be transferred by his employer to a State that does not recognize his qualification as an RSO.

- Issues with labeling requirements. For example, some
- States only recognize standard international (SI) units, whereas other States recognize both SI units and conventional units.

CORAR believes that the regulations should be uniform from State to State, and should focus on generally accepted safety and protection standards. The ACMUI agreed with the basic premise of CORAR's position. However, it was noted by both the ACMUI and the NRC staff that uniformity of regulations would be difficult to accomplish, since the States have much latitude in their regulatory approach and would likely object to uniform regulations. The ACMUI strongly suggested that CORAR present its concerns at the November 9, 2005, meeting on the Energy Policy Act.

The final speaker on this topic was Terrence Beven, MD, SNM. Dr. Beven stated the following SNM recommendations: 1) that the NRC exempt, from regulation, NARM with short half-lives and low safety significance (i.e., certain PET[1] radiopharmaceuticals); and 2) that a full threat assessment of each medically-used isotope be included in the NARM regulations. The SNM believed these actions will address concerns of delayed availability of NARM for patient care.

The ACMUI stated that it saw no reason to exempt PET radiopharmaceuticals from regulation, simply because of its half-life and relative safety significance. Rather, this material should be treated like any other radioactive material, in that an exempt quantity and concentration should be established. Furthermore, medical applications of PET radiopharmaceuticals can require large doses, and PET should be regulated since it gives off the highest exposure of all radiopharmaceuticals. Nevertheless, NARM regulations should not inappropriately inhibit delivery of radiopharmaceuticals to patients. Dr. Beven was encouraged to present SNM's concerns at the November 9, 2005, meeting on the Energy Policy Act.

**RECOGNITION OF FOREIGN -TRAINED PHYSICIANS AND PHYSICISTS AS AUs and AMPs**

Cynthia Flannery, CHP, NRC, gave this presentation to the ACMUI, to seek ACMUI insights on the acceptability of recognizing foreign-trained physicians and physicists who seek recognition as AUs and AMPs via the T&E pathway in 10 CFR Part 35.

Ms. Flannery briefly outlined the requirements for recognition of a physicist as an AMP under the T&E pathway in 10 CFR Part 35: a master's or doctor's degree; one year of full-time training in medical physics; one year of full-time work experience under the supervision of a preceptor AMP; and a preceptor AMP's written attestation that T&E was obtained.

The NRC staff presented 3 questions regarding foreign-trained persons:

1. May the NRC or a broad scope licensee accept foreign degrees? The NRC staff has not identified any prohibition against acceptance of foreign degrees.

2. May the NRC or a broad scope licensee accept a foreign degree not specifically mentioned in 10 CFR Part 35, if that degree can be shown to be equivalent? The NRC staff has not identified any prohibition against acceptance of a foreign degree not specifically mentioned in 10 CFR Part 35.

[1] Positiron Emission Tomography

3. May the NRC or a broad scope licensee rely on the preceptor statement from a foreign preceptor? The NRC staff has not identified any prohibition against acceptance of a preceptor statement from a foreign preceptor. However, the definition of an AU in 10 CFR 35.2 states that the individual must be licensed in the United States (U.S.)

The NRC staff noted that broad scope licensees have the authority to grant recognition without seeking NRC approval. The staff is seeking ACMUI input as to the appropriateness of granting this same authority to the NRC regions.

Regarding the issue of the acceptability of foreign preceptor AUs, the ACMUI stated this is really no issue, since any foreign-trained physician would be required to undergo extensive retraining in the U.S. before approved as a licensed physician in the U.S. The ACMUI clarified that the person's basic medical degree would be recognized, but the physician would be required to undergo extensive retraining in the specialty the physician practices. An exception would be physicians trained in Canada. Such physicians would not be required to undergo extensive retraining. Therefore, these individuals may need review and approval against Part 35.

The ACMUI was concerned with the NRC regional staff granting recognition, since the regional staff does not have specialists able to adequately judge the credentials of foreign-trained physicists. The staff acknowledged this point, but also noted that the majority of these cases are not reviewed by the ACMUI anyway, since the majority of these cases occur in the Agreement States who have broad scope licensees able to grant this authority without ACMUI review. The staff further noted that foreign-trained physicists approved for AMP status by broad scope licensees are able to gain recognition in states regulated by the NRC, since the NRC is required to recognize these individuals if they are listed on a license. These individuals would also not undergo ACMUI review.

The ACMUI does not foresee issues with regions approving physicists as AMPs without the ACMUI's involvement, provided that guidelines are established to assure uniformity of decision making.

**STATUS OF MEDICAL EVENTS**

Donna-Beth Howe, PhD, NRC presented the ACMUI with a list medical events, to seek insights on how the occurrence of these events may be prevented or reduced. Dr. Howe began with a comparison of medical events in fiscal year (FY) 2004 versus FY 2005:

- The number of medical events in FY 2004 was 35, compared with 40 medical events in FY 2005.

- For uses under 10 CFR 35.600, all medical events in FY 2005 were associated with the high dose rate remote afterloader device.

- A significant number of medical events occurred under 10 CFR 35.1000 uses in FY 2005. These events were associated with brachytherapy treatments involving the Novoste[2] device.

[2] Novoste no longer manufactures the device.

- There was an increase, in FY 2005, of medical events involving microspheres.

- In FY 2005, a licensee did not promptly identify a series of medical events. The initial identification of the medical events resulted from patients experiencing adverse consequences, and bringing this to the attention of the licensee.

Dr. Howe then provided an overview of the specific medical events. One event, involving patient treatment with a gamma stereotactic radiosurgery (GSR) unit, generated much discussion. In this event, the patient shifted his body during the GSR treatment, and this shift resulted in the movement of the headframe and a dose to an unintended site. The NRC staff believed it was a medical event. The ACMUI strongly believed the patient, by virtue of movement, intervened in the treatment, and this intervention - not licensee actions - caused the wrong area. Therefore, this particular case did not constitute a medical event.

The ACMUI agreed with the staff's conclusion on the other medical events, but did not offer any suggestions on how they may have been reduced or prevented.

**REVIEW OF THE MEDICAL EVENTS DEFINITION COMMISSION PAPER**

Ronald Zelac, PhD, NRC, presented this topic to the ACMUI. During this presentation, Dr. Zelac informed the ACMUI of the status of the draft Commission paper the NRC staff prepared, to forward to the Commission recommendations on redefining the medical event criteria in 10 CFR Part 35.

The ACMUI made several recommendations to the staff concerning redefining the medical events criteria definition in 10 CFR Part 35. The draft paper forwards the staff's endorsement of most of these recommendations. However, the staff did not accept several of the ACMUI's specific recommendations for improving public understanding of the risks associated with medical events. The recommendations and the reasons for non-acceptance follows.

**ACMUI Recommendation:** Amend the patient reporting requirement under 10 CFR 35.3045(e) so that patients/relatives are informed only if the licensee determines that the medical event may have, or potentially may have, harmed the patient; or the medical event is materially relevant to the patient's future medical decisions.

**Staff Position:** The Commission has repeatedly stated and endorsed its position that patients or human research subjects have a right to be informed when they are involved in a medical event.

**ACMUI Recommendation:** Medical event reporting and follow-up procedures should be designed so as not to increase licensee liability. Specifically, NRC should refrain from making public the licensee's identity.

**Staff Position:** This approach is counter to NRC's policy of openness in the conduct of its business.

**ACMUI Recommendation:** With respect to responding to medical events (i.e, follow-up NRC inspection of medical events), the NRC should develop a more graded and risk-informed process that ties the immediacy of response to patient risk and public health implications.

**Staff Position:** The NRC's response to medical events is already graded and risk informed. Furthermore, the staff believes follow-up inspections are the most efficient approach for ensuring the timely availability of information necessary to complete assessments of medical events.

**ACMUI Recommendation:** NRC should change the 24-hour telephone reporting procedure to its Operations Center. Specifically, medical events that have not harmed the patient, have little potential for harming the patient, and are not materially relevant to the patient's future medical treatment decisions, as determined by the licensee, should be reported to the NRC by means of written notification within seven days of discovery.

**Staff Position:** Not all medical events are associated with serious consequences. However, staff believes that a requirement that allows for different reporting periods depending on the initial assessment of the event by the licensee would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day.

The NRC continues to believe that licensees should promptly notify the NRC of medical events because the circumstances of medical events need to be evaluated as soon as possible to determine if any immediate follow-up action or corrective actions are necessary. The telephone notification allows the NRC to promptly take any necessary action based on the circumstances.

**The ACMUI made the following recommendation: That the NRC staff does not make available to the general public, information regarding a medical event until such time that the event is confirmed.**

**GUIDANCE ON I-125 SEEDS AS MARKERS FOR BREAST CANCER TUMORS**

Robert Gallaghar, State of Massachusetts, provided this follow up discussion to the ACMUI. At the October 2004 ACMUI public meeting, Mr. Gallaghar first presented the issue of the off-label use of I-125 seeds as markers for breast cancer tumors. After receiving ACMUI input, Mr. Gallaghar returned to present the status of the guidance that is being developed.

Mr. Gallaghar gave a brief overview of the procedure to be followed to utilize I-125 seeds as markers: radioactive seed localization (RSL). After the brief description of RSL, Mr. Gallaghar defined key elements of the RSL guidance. Following is an abbreviated list of these elements:

- Location of use. This includes facility diagrams where the I-125 seeds will be stored, implanted into the patient, explanted from the patient, removed from the tissue sample, and stored for decay.

- AU identification. AUs, meeting the criteria in 10 CFR 35, must be identified, and their training must be submitted.

- Safety procedures and instructions should be submitted. This includes radiation safety survey procedures, source accountability procedures, verification of source activity procedures, and identification of persons who must be present during the use of I-125 seeds.

- Licensees will need to obtain a license amendment in instances where the conditions of use extend beyond those stated in the Sealed Source and Device (SS&D) registry.

The current draft RSL guidance has already received OAS approval. It has been sent to the Agreement State directors and to the NRC for comment. The comment period will end on November 15, 2005.

The ACMUI believed the draft guidance document unnecessarily requests submittal of facility diagrams, and that this request is unwarranted, given the low activity of the I-125 seeds. The ACMUI suggested that the precautions for the use of these seeds be comparable to current survey and inventory precautions, which the ACMUI believed was more critical to safety.

Another concern of the ACMUI was the need to obtain a license amendment where the conditions of use extend beyond those stated in the SS&D registry. The ACMUI suggested that as an alternative, the NRC staff should revise the SS&D registry to allow for interstitial use of these sources. The NRC staff responded by stating that manufacturers specify the manner in which sources should be used. However, if the staff receives an application from a manufacturer to amend the use of the source on the registration certificate, the staff can accommodate that request fairly easily.

The ACMUI stated that the guidance is generally good, although somewhat overly prescriptive and burdensome considering the risks involved.

**ADMINISTRATIVE CLOSING**

Angela McIntosh, NRC, lead the discussion on this topic. During this discussion, the NRC staff and the ACMUI reviewed the recommendations and action items arising from this meeting, and discussed proposed meeting dates for the Spring 2006 meeting. The ACMUI and NRC staff agreed to explore the week of April 18, 2006, and to later confirm a set of dates for that week.

The meeting was adjourned at 4:35 p.m.

**ADMINISTRATIVE CLOSING**

Angela McIntosh, NRC, led the discussion on this topic. During this discussion, the NRC staff and the ACMUI reviewed the recommendations and action items arising from this meeting, and discussed proposed meeting dates for the Spring 2006 meeting. The ACMUI and NRC staff agreed to explore the week of April 18, 2006, and to later confirm a set of dates for that week.

The meeting was adjourned at 4:35 p.m.

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