MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

April 25-26, 2006

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's 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.

TUESDAY, APRIL 25, 2006 (CLOSED SESSION[1])

AMENDMENTS TO THE ACMUI'S BYLAWS

Ms. Flannery, NRC, discussed the proposed amendments to the ACMUI's bylaws and the committee gave its comments.

TRAINING AND EXPERIENCE REQUIREMENTS IN RESIDENCY PROGRAMS

Thomas Essig, Designated Federal Officer, NRC, lead the discussion on the minimum number of hours of training and experience required in residency training program.

[1] These sessions were closed pursuant to 5 U.S.C. 552b(c)(2), (6) and (9)(B) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute."

TUESDAY, APRIL 25, 2006 (OPEN SESSION)

Regulatory Information Summary (RIS) ON VISITOR DOSE LIMITS

Sami Sherbini, PhD, NRC, made a presentation to inform ACMUI of the status of the draft RIS on rapidly granting exemptions from NRC regulations to allow members of the public to receive radiation dose in excess of the limits when caring for sick relatives who are hospitalized. The draft RIS had been distributed for review and comments by the Regions, the Agreement States, and ACMUI. The target date for publication is June, 2006. Dr. Sherbini provided the ACMUI with an overview of the nature of the comments and the staff's disposition of them. Dr. Sherbini also sought the ACMUI's advice on the situations of pregnant women or minors acting as caregivers who may exceed the public dose limit. ACMUI discussed this issue and advised the NRC staff that pregnant women and minors should not be considered a separate case, but that the exemption should be all inclusive.

ACMUI MOTION: To allow an exemption for exceeding the public limit dose limit to the family members who are care givers to hospitalized patients criteria or aspects considered in allowing exemption. The elements of exemption should include:

- **It is the responsibility of the licensee;**
- **The licensee will give the regional office contemporaneous notification of this exception;**
- **Informed consent will be required;**
- **There will be an discouragement of pregnant woman and minors from excessive exposure;**
- **Standard safety precautions will be in place;**
- **A dosimeter will be used to measure the exposure of the parties.**

UPDATE ON PROPOSAL REGULATIONS TO INCLUDE DISCRETE RADIUM SOURCES AND ACCELERATOR -PRODUCED RADIOACTIVE MATERIAL IN 10 CFR35

Ms. Lydia Chang, NRC, made a presentation to update ACMUI in the proposed regulation including the following topics: Energy Policy Act (EPAct) of 2005, waiver, rulemaking approach, rulemaking strategy, current status/schedule, draft proposed rule summary, implementation considerations, and next steps.

Ms. Chang explained that EPAct was signed into law on August 8, 2005. Within Section 651(e) of the EPAct, the definition of by-product material was amended. It also amends Section 274 (b) of the Atomic Energy Act to include the newly added byproduct material for agreement with the States. The EPAct allows the Commission to grant waivers allowing current programs to continue for the newly added byproduct materials (NARM). Waiver was published on August 31, 2005 (70 FR 51581).

The working group that developed the proposed rule included representatives from the NRC Headquarters, Regions, and Agreement States. Our rulemaking strategy is to use existing NRC regulatory frame work and use the suggested state regulation for control of radiation. It is proposed to regulate all accelerator-produced material and not activated material from non-production accelerators (radiation therapy LINAC).

Ms. Chang explained to the committee that the draft proposal rule package was posted on the NRC

website, on April 6, 2006, and the final rule that the EPAct requires that the final rule be issued by February 7, 2007. Only minor changes are incorporated in Part 32.72 and Part 35. Effective dates for the new rules will be 60 days from the date of publication of the final rule for the Federal facilities. License amendments shall be submitted within six months from the effective date or waver termination. New license applications shall be submitted within one year from the effective date or waver termination. The NRC is required to prepare and publish a transition plan to facilitate orderly transition of regulatory authority for ARM. Waiver is in effect through August 7, 2009. The NRC plans to include waiver termination process in the transition plan.

The Commission paper was submitted to the Commission in late March. The Commission is expected to make a decision in the proposed rulemaking after a Commission briefing on May 15, 2006. Once the Commission provides the staff directions, the staff will revise the proposed rule and published it in the *Federal Register* for a 45-day public comment period. A public meeting will be planned during the public comment period.

COUNCIL ON RADIONUCLIDES & RADIOPHARMACEUTICAL'S (CORAR's) ASSESSMENT OF THE NEW NRC PROPOSED REGULATION TO IMPLEMENT THE ENERGY POLICY ACT OF 2005

Mr. Brown, CORAR, highlighted the positive aspects of the rulemaking as follows: 1) the NRC's classification of accelerators into three different categories seems a workable solution, 2) the rulemaking does not make any distinction of how this material is produced, 3) NRC grandfathers the previously qualified authorized users (AU), Radiation Safety Officer (RSO), and authorized nuclear pharmacists (ANP), and 4) the NRC waiver that runs through 2009 will help the manufacturers and distributors of radionuclides to continue operation until new rule takes effect.

Mr. Brown's main concerns were as follows:

- Non-uniformity of the regulations, specifically:
  - lack of strict adherence to the Council of Radiation Control Program Director's (CRCPD) Suggested State Regulations among States;
  - need for a higher level of compatibility for new or existing Regulations (category B);
  - differing approaches to level of detail as approved in Sealed Source / Device Registry
  - no plan to address State - specific product approval and labeling requirements; and,
  - no plan to get ARM pharmaceuticals into the States any faster than current process.
- The new fee in part 170 will negatively impact facilities located in non-agreement States that will now be under NRC's jurisdiction;
- Special provisions could be developed for decommissioning lower energy Postion Emission Tomography (PET) cyclotrons which are typically self shielded.

Mr. Brown suggested that the rulemaking: 1) have a higher level of compatibility, 2) provide more clarification on how the NRC intends to regulate incidentally-produced materials on accelerators, and 3) NRC should promote the use of suggested state regulations for more uniformity in implementation of the rule.

PART 35 TRAINING AND EXPERIENCE

Ms. Flannery, NRC, presented to the ACMUI members the status of applications submitted for NRC recognition by various Specialty Boards. She added that nine boards have submitted

applications for recognition of their certification process, and six of these nine boards are currently recognized. The American Board of Radiology (ABR) is in various stages of the review process. Currently, only the Radiation Oncology specialty of the ABR is recognized by NRC. For the ABR Radiologic Physics and the American Board of Medical Physics (ABMP) cases, NRC review process will continue when the NRC receives the supplemental information that was requested from the boards.

ACMUI RECOMMENDATION: The Committee suggested that the NRC staff send two letters to the American Board of Radiology (ABR), one to Radiation Oncology, and one to Diagnostic Radiology, requesting the Board determine whether earlier effective dates can be used for recognition of their certification processes. The staff will provide the draft of these letters to Dr. Malmud, Dr. Diamond, and Dr. Eggli for review before they are submitted to the board.

TRAINING AND EXPERIENCE RULE CHANGE FOR AN AUTHORIZED USER SEEKING RSO STATUS

Ronald Zelac, PhD, NRC, explained the training and experience for the authorized users seeking RSO status and the rationale behind it. He added that there are the following pathways that one can follow in order to satisfy those training and experience requirements:1) 35.50(a)(1) is the health physics certification pathway, 2) 35.50(a)(2) is the diagnostic medical physicists certification pathway, 3) 35.50(b) is the alternative pathway, 4) 35.50(c)(1) is the pathway for therapeutic medical physicists who are essentially named on a license as an AMP, 5) 35.50(c)(2) is for authorized user, authorized nuclear pharmacist and authorized medical physicist. Dr. Zelac added that a perceptor statement is required from the individuals regardless of the training pathway chosen.

Dr. Zelac stated that prior to January, 2006, a problem in implementation was identified. It listed the various training and experience pathways: 35.50(a)(1), 35.50(a)(2), 35.50(b), and 35.50(c)(1), but did not list 35.50(c)(2). The new rule is corrected by simply adding (c)(2) to the list of training and experience pathways in the precentor section 35.50(d). This rule change eliminates the unintended requirements for an authorized user seeking approval as the RSO to also have completed the training and experience requirements for one of the other four pathways.

ACMUI RECOMMENDATION: The ACMUI recommended the NRC staff to send the information on this issue to Agreement States either by an article in the NMSS Licensee Newsletter or an Information Notice.

American Association of Physicists in Medicine (AAPM) Statement:

Dr. White explained that the AAPM understands the Commission desires a change in the board recognition, and the AAPM understands that the Commission desires to provide a mechanism by which the boards were grandfathered. But the AAPM does not believe that the Commission had in mind that there would be a class of previous diplomates who were unable to use their certificates to become qualified in the future.

The speaker quotes from an NRC statement that says, “If an individual holds certification from a board for which the NRC or agreement state withdraws recognition, the certification will be considered valid if it was granted during the time interval that the board certification process was

recognized." The AAPM would like the committee to consider that spirit in applying this process to medical physicists who were previously certified.

Lastly, the AAPM would like the NRC to follow some of the Agreement State's procedures that overcome these obstacles.

TRAINING AND EXPERIENCE FOR USE OF MICROSPHERES THERAPY

David Diamond, MD, ACMUI and Douglas F. Eggli, MD, ACMUI, provided their points of view with regard to licensing guidance currently posted on NRC's website on the training and experience requirements for Y-90 microspheres. Dr. Nag also gave a presentation on this subject from the viewpoint of Radiomobilization Brachytherapy Oncology Consortium (RBOC) committee and as a user of Y-90 micospheres.

Dr. Diamond described the microsphere device as a medical device and the manufacturer specifically opted to go through the FDA device, not drug pathway for approval. Physically, these are encapsulated sealed sources but it is problematic to place them under the manual brachytherapy because the number of individual sources can not be counted. This device is currently regulated under 35.1000, and current NRC guidance specifically recognizes 35.490, manual brachytherapy AU's with specific vendor training as authorized for this purpose.

Dr. Diamond explained that the question for the committee is whether the guidance be modified to allow nuclear medicine AU's to use the modality. He recommended that both nuclear medicine AU's, radiation oncology AU's and diagnostic radiologists with 35.390 AU status have the technical training and experience to safely handle and administer hepatic microspheres.

Dr. Eggli stated that his conclusion is going to be exactly the same as Dr. Diamond's. He added that therapeutic microspheres have features that are similar to both sealed sources and unsealed sources. They are regulated in the 10 CFR 35.1000. They are registered as brachytherapy sources and are either sealed in glass beads or resins. The difference is the sources do not have serial numbers and they are too numerous to count. The sources behave like large particles and have been used in nuclear medicine for years. Spills are handled like unsealed sources. Dosimetry uses nuclear medicine techniques and the administration is similar to the intra-arterial administration of Microaggregated Albumin (MAA), which has been used for evaluating chemotherapy to the liver and hepatic carcinoma for a long time.

The bottom line in training issues is that any experienced physician trained for 35.300 and 35.400 uses can be safely trained to handle therapeutic microspheres. Toward that end, Dr. Eggli raised the question of whether three cases are enough to be considered adequately trained. He suggested to increase the experience required for independent use.

Sabir Nag, MD, ACMUI, also gave an overview of the Radioembolization Brachytherapy Oncology committee's recommendations on Y-90 microspheres safety issues as follows: 1) the patient should be rendered by multi-disciplinary teams and not by single individuals, 2) nuclear medicine physicians, radiation oncologist, and interventional radiologists are qualified to use Y-90 microspheres.

Society of Interventional Radiology (SIR) Statement:

Dr. Salem stated that he had successfully performed over 850 infusions of Y-90 micosphere

therapy as an authorized user. He requested the NRC recognize interventional radiologists as qualified authorized users for Y-90.

He stated that the interventional radiologists are certified by the ABR, which includes 960 hours of nuclear medicine training during residency and a didactic physics training. He added that interventional radiologists have been the forefront of Y-90 research.

At the end, he concluded that he believed that the interventional radiologists have enough training and experience to be recognized as authorized users for Y-90 microspheres therapy.

ACMUI MOTION: The ACMUI recommended that the NRC staff revise current guidance to permit 35.390 physicians as authorized users for Y-90 microspheres. The elements of recommendation are:

- **Multi-speciality team approach;**
- **Qualification for Y-90 micispheres is minimum of three cases.**

The ACMUI defined the technical experience making up the team should include:

- **catheter placement;**
- **particle therapy;**
- **dosimetry calculations;**
- **training in 35.300 or 35.400;**
- **expertise in oncology;**
- **safe handling of unsealed sources;**
- **pharmacology (resin leaks).**

PROPOSED BREAST BRACHYTHERAPY USING I-125 SEEDS

Mr. Curter presented the new option in the treatment of accelerated partial breast by using I-125 seeds. He described that his device contains 8-12 catheters that can hold low dose sources with a maximum activity of 300 millicurie total. The intended use of the device involves implanting the I-125 sources and removing them days later. The intent is to market the device as an outpatient treatment procedure, i.e., the patient would go home with this device capped. Issues associated with the device's use as an outpatient procedure are: identification on the patient as containing radioactive sources in the event the patient were in an accident; education of the patient so they know that they need to have this device removed in a specific time frame; and shielding for these patients in some cases.

The discussion included the availability of a number of existing surgical garments that can be used with a number of shielding materials, e.g., Demon., lead, and bismuth. When incorporated into the surgical garments, the shielding materials appeared to be lightweight and are not excessive or bulky. The company also focused on the importance of patient education and physician training be part of this introduction. Preliminary data was discussed on radiation measurements at specific distances and using specific shielding materials because the breast tissue provides too little shielding. The data was based on using as much as 300 millicurie of iodine. The resulting dose from the surface, or five millimeter depth without shielding was described as high. With bismuth or Demon., the dose was reduced significantly. At a meter those dose rates dropped off significantly

and could be shielded effectively to zero.

ACMUI RECOMMENDATION: The committee recommends that these patients be released with the shields in place and follow instructions and requirements of part 35.75.

WEDNESDAY, APRIL 26, 2006 (OPEN SESSION)

ACMUI REVIEW OF MEDICAL EVENTS INVOLVING I-131

Douglas F. Eggli, Chair of the I-131 Event Review Subcommittee, provided the NRC staff with the Subcommittee's advice and insights regarding the cause of medical events where diagnostic administrations were intended, but therapeutic administrations occurred.

Dr. Eggli reviewed each I-131 incident, where a low dose was converted into a higher dose administration to identify common threads.

Dr. Eggli finally summarized three points based on Subcommittee's review of these incidents:

- Require the technologist to verify the dosage against a written directive when the technologist knows the dose in a written directive range;
- Positive patient identification should be a practice applied to outpatient clinics;
- Communication links between authorized users and individuals administering materials need to be strengthened.

ACMUI RECOMMENDATION: To remind the licensees that they have an obligation under current regulations to verify any dose of greater than 30 FCi against a written directive, and strongly recommend an effective positive approach to identify patients. The committee recommends encouraging free communication between the authorized user and administering technologist. Also the possibility of communication by Information Notice (IN) was discussed in the meeting and subsequent dissemination to professional organizations to more effectively reach the affected parties.

STATUS OF MEDICAL EVENTS

Donna-Beth Howe, PhD, NRC, provided a list of medical events to the ACMUI to seek insights on the occurrence of these events and how they may be prevented or reduced. Dr. Howe presented the summary of 12 recent medical events for the past six months listed according to the type of use. Dr. Howe then provided an overview of the specific medical events.

POTENTIAL CHANGES TO 10 CFR 35

Donna-Beth Howe, PhD, NRC, presented the potential changes to 10 CFR 35 to the ACMUI and sought its approval of the recommendations. The ACMUI discussed each item and with minor adjustments voted to accept the recommended potential changes as follows:

ACMUI RECOMMENDATION: Revise 10 CFR 32.72(b)(5) to read:
(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties and the written attestation(s), signed by a preceptor..."

ACMUI RECOMMENDATION: Revise 10 CFR 35.2 to read:
"Medium dose-rate remote after loader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

ACMUI RECOMMENDATION: Revise 10 CFR 35.12(d) to clarify either a license application or amendment requires submission of the information required in 10 CFR 35.12(b) regardless of the format used to submit it.

ACMUI RECOMMENDATION: Revise the definition in 10 CFR 35.2 to read:
Radiation Safety Officer means an individual who--
(1) Meets the requirements in §35.57 or §§ 35.50 and 35.59;
(2) and is identified as a Radiation Safety Officer on–
(I) A specific medical use license issued by the Commission or Agreement State;
(ii) or a medical use permit issued by a Commission master material licensee.

ACMUI RECOMMENDATION: Revise 10 CFR 35.50(c)(2) to read:
"Will be identified as an authorized user, authorized medical physicist, or authorized nuclear pharmacist on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities."

ACMUI RECOMMENDATION: Revise 10 CFR 35.65 by replacing the phrase "...,not exceeding 1.11 GB (30 FCi) each" be replaced with "not exceeding either 1.11 GB (30 FCi) each or a total activity of 1.11 GB (30 FCi) when used as a simultaneous aggregate..."

ACMUI RECOMMENDATION: Revise 10 CFR 35.92 to read:
"A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage without regard to its radioactivity if it...."

Because of time restriction, the committee members deferred the remaining items for discussion during the ACMUI teleconference on May 23, 2006.

COMMISSION BRIEFING PREPARATION

Thomas Essig, Designated Federal Officer, stated that the Commission briefing will be on May 15, 2006 and the first panel will talk about the three different sections of the statute, but Section 651 is of most interest to this committee.

Mr. Lieto discussed the draft presentation for the briefing to the Commission. A large portion of the presentation is based on the summary report of comments on the proposed rule that Ms. Schwarz put together. The first two slides dealt with accelerator produced radioactive material comments that the ACMUI is endorsing the proposed categorization of the particle accelerators. Also, the ACMUI agreed not to regulate the medical therapy Linear Accelerators in terms of the incidental that would be produced. In addition, the draft emphasizes high compatibility for the training and experience requirements in the area of PET and radio-pharmacies. Mr. Lieto asked for any comments from the committee members.

The committee asked Ms. Schwarz to brief the Commission instead of Mr. Lieto because majority of the briefing issues were related to the use of radiopharmaceuticals.

ADMINISTRATIVE CLOSING

Mohammad Saba, NRC, reviewed the recommendations and action items arising from the meeting and discussed proposal dates for the Fall 2006 meeting. The ACMUI and the staff agreed on October 24-25 for the Fall meeting. In addition the ACMUI and the NRC staff agreed to hold a teleconference meeting on May 23, 2006, 2:30 p.m. through 5:00 p.m. to vote on the ACMUI's bylaws and continue discussion on "Potential Changes to 10 CFR 35.50," an unfinished item from this meeting.

The meeting was adjourned at 12:02 p.m.

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