MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 24, 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, OCTOBER 24, 2006 (CLOSED SESSION[1])

ETHICS BRIEFING

Mr. Szabo, Office of General Counsel provided the ACMUI its required annual ethics briefing.

AMENDMENTS TO THE ACMUI'S BYLAWS

Ms. Flannery, NRC, presented proposed amendments to the ACMUI bylaws and the proposed changes were approved.

The following motion was made by the ACMUI during this presentation:

MOTION: ACMUI approve the proposed changes to the ACMUI bylaws.

REVISED SELF-EVALUATION QUESTIONS

Ms. MacIntosh, NRC, presented to the Committee the revised self-evaluation questions.

[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."

The following actions items were recommended by the ACMUI during the closed session:

ACTION : The NRC staff should establish a system for evaluating proposed agenda items with a response back to the Committee member as to why a proposed topic was denied.

ACTION: The NRC staff should check on whether ACMUI members can access Informs on-line or whether editable PDF file of Financial Disclosure form can be obtained for the Committee members.

ACTION: The NRC staff should provide a copy of the Nuclear Material Safety and Safeguards (NMSS) reorganization slides to the ACMUI.

ACTION : The NRC should consider listing the ACMUI on the main NRC web page and add ACMUI to the Federal and State Materials and Environmental Management Programs (FSME) organization chart.

ACTION: The NRC should amend future ACMUI agenda to add a standing agenda item that allows the ACMUI a period of time to discuss emerging medical issues.

TUESDAY, OCTOBER 24, 2006 (OPEN SESSION)

NARM LEGISLATION UPDATE

Ms. Chang, NRC, made a presentation to inform the Committee of the activities associated with the NARM legislation that have occurred since last ACMUI meeting. These activities included the receipt of Staff Request Memorandum (SECY-06-0069), the Commission briefing with the stakeholders, publication of proposed rule in *Federal Register*(FRN Volume 79, No. 145), and the public meeting that was held in Las Vegas on August 22, 2006.

Ms. Chang explained that NRC had received 39 comments during the public comment period for the proposed rule. Four of those comments were from Federal Agencies and fourteen were associated with the Agreement States. The remaining comments were from individuals, professionals societies, universities, medical communities, and industries. The comments were in the area of compatibility designations; definition of discrete sources, regulations for items containing Ra-226; old contaminated sites; clarification on licensing practices, specific values of the DAC for N -13 and O -15; grandfathering of Authorized Users, Authorized Nuclear Pharmacists, Radiation Safety Officers; clarification on non-commercial distribution; decommissioning of accelerators, equipments, and facilities; financial assurance for decommissioning; fee categories; waver termination and transition plan.

The speaker also informed the ACMUI that the next steps are to address public comments, revise regulatory requirements, prepare a Federal Register Notice (FRN), send the draft FRN to the States and ACMUI for review and comment, and initiate the office concurrence process. The goal is to submit the Commission paper and the rulemaking package to the Executive Director for Operations on December 22, 2006.

The following actions were recommended by the ACMUI during this presentation:

ACTION: The NRC staff should send the draft final NARM rule to ACMUI for review at the same time that it is sent to Agreement States.

ACTION: The NRC staff should consider workshops regarding NARM implementation for licensees.

REVISIONS TO NUREG 1556 VOLUME 9, 13, and 21

Dr. Donna - Beth Howe, NRC made a presentation to update ACMUI on changes to NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance about Material Licenses: Program Specific Guidance about Medical Licenses". The changes include: 1) revision of sample licenses, 2) addition of SI units, 3) an update to the Agreement State map, 4) addition of information about sensitive information, 5) incorporation of the changes in 10 CFR Part 35, 6) removal of all references to subpart J, and 7) addition of accelerator produced radioactive materials and Ra-226. NRC will publish the final guidance after incorporation of the changes in the regulations due to the NARM rulemaking.

Mr. Duane White, NRC, provided information to the Committee regarding the changes to NUREG 1556, Volume 13, " Consolidated Guidance about Material Licenses: Program Specific Guidance about Commercial Radiopharmacy Licenses" and the new NUREG 1556 Volume 21, Consolidated Guidance about Material Licenses: Program Specific Guidance about Possession of Licenses for Production of Radioactive Materials Using an Accelerator". The revision to Volume 13 include: 1) adding accelerator produced materials such as positron emission tomography (PET) radionuclides, 2) referring radiopharmacies, which use an accelerator to produce radioactive materials, to the new NUREG 1556 Volume 21, 3) providing some radiation safety recommendations for handling high energy photon-emitting radionuclides (e.g. pocket dosimeters), and 4) ensuring applicants are aware that discrete sources of Ra-226 now need to be identified and licensed by NRC.

NUREG 1556 Volume 21 addresses: 1) listing accelerator produced activation products to as radioactive materials, 2) radiation safety training for individuals who perform maintenance and repair on the accelerator, 3) requiring a detail description of the facility's layout, which would include method used to transfer radioactive material from the accelerator to other areas of the facility or to another licensee, and 4) raising awareness that discrete sources of Ra-226 now need to be identified and licensed by NRC.

The following action items and motion were recommended by the Committee during this presentation:

ACTION : The NRC staff should provide the three NARM-related guidance documents (NUREG 1556 Volumes 9,13, and 21) to ACMUI for review and comments.

ACTION : NRC should allow the Regions some flexibility from meeting their normal METRICS requirements in reviewing amendments requests that are NARM related. This action will assures NRC that some of the items will not fall through the cracks.

MOTION: NRC staff should follow-up with the ACMUI via e-mail regarding ACMUI's

proposed rewording of the statements in NUREG 1556, Volume 21 as presented in paragraph two of Mr. White's third slide.

PETITIONS FOR RULEMAKING

Petition Submitted by Mr. Peter Crane

Ms. Neelam Bhalla, NRC, updated the ACMUI on a petition regarding release of I-131 patients. The petition was filed by Peter Crane on September 21, 2005. A notice was published in Federal Register on December 21,2005 and comment period ended on March, 6, 2006. The petition review board is expected to make a determination on how to respond to the petition by December 20, 2006. The speaker informed the Committee that NRC has received 48 comments from patients, physicians, medical physicists, radiation safety officers, and professional organizations. Fourteen of the comments supported the petition and 31 opposed.

The petitioner requested to change 10 CFR 35.75 to reflect the NRC's patient release criteria prior to 1997. This criteria required the measured dose for release of I-131 patient to be less than 5 mrem per hour at a distance of one meter from the patient. Mr. Crane claimed that NRC has allowed for reduction of exposure to hospital employees at the expense of elevated exposure to family members. At the end, the speaker stated that a working group is reviewing the petition to determine whether there is a need to amend the current regulations.

Petition Submitted by William Stein III, PhD

Mr. James Firth, NRC, updated the ACMUI on the petition that was submitted by William Stein III, MD. The petition requested NRC to establish training and experience requirements for Authorized Users limited to parenteral administrations requiring a written directive of the following:

^{153}Sm-lexidronam (Quadramet),

^{131}I-tositumomab (Bexxar), and

^{90}Y-ibritumomab tiuxetan (Zevalin)

In addition to that request the petitioner requests that NRC recognizes the following adequate training and experience for the limited Authorized User status:

80 hours of classroom and laboratory training
Supervised work experience, and Written attestation.

NRC has received 23 comments from Agreement States, Organizations, and physicians.

The following motion was made by the ACMUI during this presentation:

Motion: That ACMUI opposed the petition as submitted by Dr. William Stein.

A Request for Petition for Rulemaking Submitted by Dr. E. Russell Ritenour

Dr. Ron Zelac, NRC, advised the Committee on the status of a request for petition for rulemaking

from the American Association of Physicists in Medicine. The petition was dated September 10, 2006 and will be noticed in the *Federal Register.* The comment period will end 75 days after the date noticed in the *Federal Register*. Resolution is anticipated approximately 1 year from the date noticed in the *Federal Register* or sooner.

Dr. Zelac explained to the Committee that the Dr. Riteneour requested NRC to revise 10 CFR 35.57 to "grandfather" as Authorized Medical Physicists all medical physicists certified by either the American Board of Radiology or the American Board of Medical Physicists on or before October 24, 2005, for the modalities that they practiced as of October 24, 2005. In addition the Dr Riteneour request that 10 CFR 35.57 be revised to "grandfather" as Radiation Safety Officers (RSO) all individuals certified by boards named for Radiation Safety Officer (RSO) training and experience requirements in the former 10 CFR 35 Subpart J who have relevant work experience, providing appropriate preceptor statements are submitted.

STAFF ACTIONS for AUTHORIZED MEDICAL PHYSICIST (AMP) and RADIATION SAFETY OFFICER (RSO) RECOGNITION

Ron Zelac, PhD, NRC, explained to the ACMUI the staff actions for recognizing amps and RSO. The speaker listed the available pathways to authorized (recognized) status as: 1) the certification pathway (10 CFR 35.50(a) and (c); 35.51(a)), 2) the "grandfather" provision pathway (35.57(a)), 3) the notification provision pathway (35.2 and 35.14); for AMP only, not for RSO), and 4) the alternate pathway (35.50(b); 35.51(b)).

Dr. Zelac explained why authorization of medical physicists MP as AMPS is a concern. Specifically, Dr. Zelac stated: 1) MP are not "grandfathered" if not listed on licenses or permits by April 29, 2005, 2) that some Agreement States currently don't list MP on licenses; all list RSO, but typically only one per license, and 3) the certification pathways are now time restricted in NRC states and will become so in Agreement States, in 2008.

The speaker described to the ACMUI what NRC is doing to reduce the impact of this issue as follows: 1) encouraging MP to get listed on licenses or permits Agreement States, to list MP whenever licensing actions occur, 2) encouraging Boards, to broaden recognition times, 3) encouraging Boards, to identify, upon request, diplomates from non-recognized years who meet current requirements for certification pathways to AMP, 4) issuance of All-Agreement States Letter (encouraging listing of MP on licenses), 5) issuing a Regulatory Issue Summary (RIS) (encouraging MP to request being listed), 6) providing copies of the RIS to MP professional organizations and Boards (suggesting that members and diplomates be notified of the RIS), 7) developing revised simplified NRC Forms 313A (for possible use by individuals applying for AMP or RSO status via the certification or alternate pathways), and 8) continuing discussions with Boards (about broadening recognition times and identifying earlier diplomates whose documented training and experience satisfy current requirements).

At the end the speaker added that the NRC staff has prepared a summary information paper on the results of the staff's action to identify problems in authorizing MP under 10 CFR Part 35 that should be with the Commission soon.

The following action item was recommended by the Committee during this presentation:

ACTION : The NRC staff should provide the ACMUI a copy of the pre-decisional paper

to the Commission regarding a summary on the results of staff actions to identify problems in authorizing medical physicists under 10 CFR Part 35 for review and comment.

AMERICAN ASSOCIATION of PHYSICISTS in MEDICINE (AAPM)

Gerald White, PhD, AAPM, made a statement on behalf of AAPM. Dr. White's concern was the issue with the NRC recognition of the boards for their certification process before 2005. The other concern was the certificates that are no longer offered by boards. He expressed concerns about physicists who move from one jurisdiction to another as these regulations changes from one state to another. Dr. White requests a uniform national criteria for authorized medical physicists and RSO. The commenter believes that alternate pathway is more cumbersome and there are a great number of physicists who desire to be listed on a license and have not submitted applications because they do not feel to meet the criteria. Also the commenter believes that the burden should not fall on the boards to evaluate individual applications for years prior to the effective date.

STATUS OF SPECIALTY BOARD

Ms. Cindy Flannery, NRC, summarized the status of specialty boards recognition in as shown in the following table:

Specialty Board:	Status:
Board of Pharmaceutical Specialties	Approved for 35.55
American Board of Nuclear Medicine	Approved for 35.190, 35.290, 35.390
American Board of Health Physics	Approved for 35.50
American Board of Science in Nuclear Medicine	Approved for 35.50
American Board of Radiology (Radiation Oncology)	Approved for 35.390, 35.490, 35.690
American Board of Radiology (Diagnostic Radiology)	Approved for 35.290, 35.392
American Board of Radiology (Radiologic Physics)	Approved for 35.50, 35.51
American Osteopathic Board of Radiology (Rad. Onc.)	Approved for 35.390, 35.490, 35.690
American Osteopathic Board of Radiology (Diag.Rad.)	Approved for 35.290, 35.392
American Osteopathic Board of Nuclear Medicine	Approved for 35.290
American Board of Medical Physicists	Awaiting input

Ms. Flannery explained to the Committee that NRC is discussing options with various specialty boards that are interested in recognizing diplomates certified prior to the effective dates, summarized as below:

American Board of Radiology (ABR) – Radiation Oncology recognized under 10 CFR 35.490 and 35.690 (Effective date of June, 2007). ABR modified their certification process to meet the requirements for recognition under 10 CFR 35.390 only. Since ABR did not need to revise their certification process for recognition under 35.490 and 35.690, ABR is determining an earlier effective date for recognition under 10 CFR 35.490 and 35.690.

The ABR is considering appending the certificates (or providing a letter) for diplomates who met NRC's current T&E requirements at the time of certification. This will be done on a case-by-case basis at the request of the diplomate. This method is under consideration for the following specialties:

American Board of Radiology – Diagnostic Radiology (Effective date of June, 2006)

American Board of Radiology – Radiologic Physics (Effective date of June, 2007)

American Board of Radiology – Radiation Oncology (35.390) (Effective date of June, 2007)

ATTESTATION FOR RADIATION SAFETY OFFICER (RSO)

Ken Brown, MD, American Society for Nuclear Cardiology (ASNC), opened up a discussion on perceptor requirements for authorized users seeking to serve as RSO. Dr. Brown expressed his concern regarding the new requirement in 10 CFR Part 35 that an authorized user (AU) must obtain written attestation, signed by a preceptor RSO, stating that he or she has the necessary radiation safety experience should that AU also wish to serve as the RSO on their license.

A second concern of ASNC revolves around the practicality of having AUs obtain a perceptor statement from an RSO. The statement required for board eligibility or the statement required for those individuals applying on the basis of training and experience criteria is adequate documentation for this purpose.

The speaker believed the result of this additional preceptorship requirement would be limiting patient access to nuclear diagnostic imaging – particularly in small facilities in suburban or rural areas where it is just not feasible or financially possible to employ a full time RSO. Should this requirement continue, it is likely that the patients will have to wait longer or travel farther to receive these critical diagnostic services.

Finally, ASNC believes that this additional mandate possibly resulted from clerical error between the December 9, 2003 proposed rule and the drafting of the March 30, 2005 final rule.

The following motion was made by the ACMUI during this presentation:

> **MOTION: The attestation requirements for all RSO pathways should be deleted from the regulations.**

INTERIM INVENTORY and NATIONAL SEALED SOURCE TRACKING

Interim Inventory

Mr. William Ward, NRC, updated the Committee of the development on interim inventory of the radioactive sources. The speaker explained that the reason for doing an interim inventory is that NRC has interest in tracking International Atomic Energy Agency (IAEA) category 1 and 2. IAEA Code of Conduct recommends establishment of a national register. After the IAEA issued a Code of Conduct, NRC and Department of Energy (DOE) adopted the IAEA list. NRC develops the Interim Inventory with annual updates until replaced by National Source Tracking System (NSTS). The inventory provides "snapshot" of high-risk sources, includes NRC and Agreement State licensees, and includes IAEA Category 1 and 2 sources. The database has been used to: 1) locate sources following Gulf hurricanes, and 2) issue advisories and orders for enhanced control measures by licensees. Database will be used to inform the NSTS design parameters and provide baseline data.

The speaker also provided the ACMUI with additional information regarding the inventory that NRC performed in 2004 and 2005. With regard to 2006 and 2007 inventories, Mr. Ward explained that: 1) the inventory process for 2006 was similar to that of 2005, however, the data are not analyzed yet, 2) during the 2006 inventory, NRC contacted 3,122 licensees and reviewed 17,389 reports, and 3) the response rate was 97.4%. For 2007, the inventory will include: 1) category 3.5 which is $1/10^{th}$ of category 3 and is 1/100 of category 2, as directed by the Commission, 2) generally licensed devices, and 3) a significantly higher number of sources as compared to 2006.

National Source Tracking System

Mr. Paul Goldberg, NRC, gave an overview and the following reasons for the development of the NSTS: 1) Joint NRC/DOE report on Radiological Dispersal Devices recommends development of a NSTS, 2) IAEA Code of Conduct on Safety and Security of Radioactive Sources recommends establishment of a national register, 3) work underway before 9/11/2001, and 4) Energy Policy Act of 2005 codified requirement for rule and placed requirements on system.

The NSTS will have two phases: 1) interim inventory now provides database on sources – short term solution; gathered valuable data to locate sources, permit implementation of security measures and provide baseline data for NSTS, and 2) introduction of the NSTS.

The speaker added that an interim inventory will be performed annually until NSTS is in place. Requirements for design were guided by a working group consisted of NRC, DOE, and Agreement State representatives. The design was approved by a Screening Committee, with NRC, DOE, and Agreement State membership, and an interagency Committee comprised of representatives from NRC, DOE, Agreement States, and ten other Federal agencies.

The speaker also explained to the Committee that the NSTS will include sealed sources from NRC and Agreement States licensees; and DOE facilities. Special nuclear materials will not be included except Pu-239/Be and Pu-238 sources. Toward the end, the presenter provided the schedule to the Committee.

STATUS OF MEDICAL EVENTS

Dr. 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 33 recent medical events for 2006 listed according to the type of use. Dr. Howe then provided an overview of the specific medical events.

Mr. Lieto, ACMUI, made his presentation to inform the Committee of the other medical events involving or related to medical uses of radioactive materials. Mr. Lieto provided an overview of 42 other medical events from October 2005 to October 2006.

The Committee suggested the following action item:

> **ACTION: The NRC should send a strong message to the licensees on the air kerma source strength versus activity.**

PATIENT RELEASE

Ms. Cindy Flannery, NRC, summarized a collaborative effort with Agency Healthcare Research and Quality (AHRQ) on information collection related to patient release. The driver behind this initiative was an AHRQ *Federal Register* Notice issued by AHRQ expressing its intent to perform this study (71 FR 2550). Several NRC stakeholders responded to this FRN. Comments focused on the fact that NRC should be engaged and that this topic falls under NRC jurisdiction. Consequently, AHRQ and NRC began a dialogue concerning the study, and NRC agreed to collaborate.

Patients who have been administrated or have implants are released in accordance with 10 CFR 35.75, and medical facilities are not required to provide patients with information that could be presented to law enforcement personnel. Many patients who are stopped at security checkpoints are not aware that they have received a procedure involving radioactive materials and, therefore, sometimes can not adequately communicate with the law enforcement or personnel at these security checkpoints.

In 2003, NRC issued an Information Notice (IN) to urge medical facilities to provide the patients with information or documentation to present to law enforcement or security personnel at these security checkpoints. NRC has recently issued a temporary instruction (TI). This TI is intended to give direction to the inspectors of the medical facilities on gathering information in addition to what is collected during the inspections. Ultimately, the data will be used and evaluated by AHRQ or CDC and an article will be published in a peer review journal.

ADMINISTRATIVE CLOSING

Mohammad Saba, NRC, reviewed the motions and action items arising from the meeting and discussed proposal dates for the Spring 2007 meeting. The ACMUI and the staff agreed on April 24-25 for the Spring meeting. In addition, the Committee has also requested to meet with the Commission in the Spring of 2007 at the same time. Therefore, the date of the next ACMUI meeting is considered tentative, until such time as the date for Commission Meeting is set by the Office of the Secretary. The meeting was adjourned at 5:24 p.m.