MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

June 12-13, 2007

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 a better understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

TUESDAY, JUNE 12, 2007

NARM RULE

Ms. Lydia Chang, NRC, gave a presentation to inform the Committee of the activities associated with NARM legislation that have occurred since the last ACMUI meeting. These activities included issuing a Commission Paper (SECY-07-0062) for the Draft Final Rule on April 3, 2007 and receiving approval in an affirmation session and a Staff Requirements Memorandum (SRM) on May 14, 2007.

Ms. Chang provided details on the revised definition of discrete source and described exempt, general license and specific licensing requirements for items containing radium 226. Ms. Chang gave an overview of the specific provisions of 10 CFR Part 35 for Positron Emission Tomography (PET) radionuclides and briefly discussed implementation considerations, such as waiver termination and licenses for NARM. Lastly, Ms. Chang informed the Committee that the next steps are to revise the Draft Final Rule; forward the Final Rule to the Office of Management and Budget for review and approval; and publish the Final Rule in the *Federal Register*.

NARM TRANSITION PLAN

Mr. Andrew Mauer, NRC, gave a presentation to update the Committee on NRC's efforts to publish and implement the transition plan to facilitate an orderly transition of regulatory authority for NARM. Mr. Mauer explained that the Commission-issued waivers will be terminated in phases. Mr. Mauer also stated that NRC staff expects to publish the transition plan within 60 days of the publication of the NARM Final Rule.

Mr. Mauer reviewed the details of the NARM transition plan for Agreement States and non-Agreement States and closed by stating that there will be continued communication with stakeholders to ensure a successful transition.

NARM GUIDANCE

Mr. Duane White and Dr. Donna-Beth Howe, NRC, gave presentations to the Committee about NARM guidance activities that have occurred since the last ACMUI meeting. Mr. White described revisions to NUREG-1556, Volume 13, Revision 1, "Program-Specific Guidance about Commercial Radiopharmacy Licenses," which includes recommendations for radiation safety measures for handling high energy photon-emitting radionuclides and guidance for PET radiopharmacy facilities and equipment. Mr. White also stated NRC included information in NUREG-1556, Volume 13, Revision 1, to raise awareness that discrete sources of radium 226 need to be identified and licensed by NRC.

Mr. White also presented information on NUREG-1556, Volume 21, "Program-Specific Guidance about Possession Licenses for Production of Radioactive Material Using an Accelerator." Mr. White stated NUREG-1556, Volume 21, was provided to ACMUI for comment in November 2006, and the ACMUI comments are now incorporated. The main topics Mr. White reviewed in NUREG-1556, Volume 21, include: separate materials licenses for production activities; listing experienced individuals, not "Authorized Users", on a license; licensee choice of submitting either a list of activated products or grouping products under atomic numbers 1-83; and guidance for "consortium" members.

Mr. White outlined the summer 2007 timeline for publication of NUREG-1556, Volume 13, Revision 1, and NUREG-1556, Volume 21 in the *Federal Register* for public comment. Mr. White stated that NRC staff would review and address all of the comments received and expected to complete the final guidance documents in fall 2007.

Dr. Howe gave a presentation to inform the Committee about NARM guidance activities that have occurred since the last ACMUI meeting with respect to NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses." Dr. Howe described revisions made to NUREG-1556, Volume 9, which include: the revised definition of byproduct material, conforming changes for non-commercially distributed PET drugs, information on new experienced individuals, amendments for changes to 10 CFR 35.100 and 10 CFR 35.200, and information on strontium/rubidium generators. Dr. Howe also discussed the six new NRC Form 313A's and the guidance for completing the forms in NUREG-1556, Volume 9. Dr. Howe concluded her presentation with information on security measures for NARM and other minor updates to the guidance, which included updated Agreement State numbers and the addition of federally recognized Indian tribes.

UNIT OF AIR KERMA STRENGTH VS. APPARENT ACTIVITY

Ms. Cindy Flannery, NRC, gave a presentation to the Committee to provide examples of medical events caused by errors made when ordering brachytherapy sources in units of Air Kerma Strength (AKS) or apparent activity (mCi). Ms. Flannery provided a summary of these medical events and coded each event into one of the following categories: data entry error, licensee error when placing an order, manufacturer error in filling the order, and conversion error. Ms. Flannery also provided two examples of emails sent to NRC staff recommending the Commission encourage vendors and users to abandon the concept of apparent activity in units of millicuries and only use AKS in the calibration of brachytherapy sources.

Dr. Jeffrey Williamson, ACMUI, gave a presentation to the Committee, which described the concepts of apparent activity and AKS. Dr. Williamson reviewed potential error pathways, practical techniques for mitigating errors, and recommendations for future actions. Dr. Williamson provided detailed calculations and discussed the error pathways for the

vendor/client/physician interface as well as systematic and random errors. Dr. Williamson suggested NRC staff issue an Information Notice (IN) on AKS vs. apparent activity, and the Committee unanimously agreed.

MOTION: NRC staff should issue an (IN), which describes errors previously made and provides examples of best practices with regards units of AKS vs. apparent activity (mCi) for brachytherapy sources. The IN should be done in collaboration with the American Association of Physicists in Medicine (AAPM) and coordinated with Agreement States.

STATUS OF SPECIALITY BOARD RECOGNITION

Ms. Cindy Flannery, NRC, updated the Committee on the recognition status of specialty boards, since this topic was presented at the previous ACMUI meeting.

SPECIALITY BOARD	STATUS	RECOGNITION DATE
Board of Pharmaceutical Specialties	35.55	March 6, 1996
American Board of Nuclear Medicine	35.190, 35.290, 35.390	October 20, 2005*
Certification Board of Nuclear Cardiology	35.290	October 29, 2000
American Board of Health Physics	35.50	Jan. 1, 2005
American Board of Science in Nuclear Medicine Nuclear Medicine Physics and Instrumentation Radiation Protection	 35.50 35.50	 June, 2006 June, 2006
American Board of Radiology (Radiation Oncology) American Board of Radiology (Diagnostic Radiology) American Board of Radiology (Radiologic Physics) Medical Nuclear Physics Diagnostic Radiologic Physics Therapeutic Radiologic Physics	35.390, 35.490, 35.690 35.290, 35.392 35.50 35.50 35.51	June, 2007 June, 2006* June, 2007* June, 2007* June, 2007*
American Osteopathic Board of Radiology (Rad. Onc.) American Osteopathic Board of Radiology (Diag.Rad.)	35.390, 35.490, 35.690 35.290, 35.392	May 1, 2007 July 1, 2000
American Osteopathic Board of Nuclear Medicine	35.290	May 18, 2006
American Board of Medical Physicists	Awaiting input	
Certification Board of Nuclear Endocrinology	Awaiting input	
*Board is verifying the qualifications of diplomates who have obtained their certification prior to the recognition date.		

Following Ms. Flannery's discussion on specialty board recognition, the Committee requested a status report of the Petition for Rulemaking (PRM-35-20) filed by E. Russell Ritenour, Ph.D. on behalf of the American Association of Physicists in Medicine (AAPM). Mr. Edward Lohr, NRC informed the Committee that NRC staff is diligently reviewing the petition and intends to have a resolution by the end of the summer. Mr. Ralph Lieto, ACMUI, requested that the Committee be provided a more detailed briefing on PRM-35-20.

ACTION (1): NRC staff committed to consult legal counsel to determine the feasibility of discussing PRM 35-20 with ACMUI members in a closed executive session.

10 CFR PART 35 TRAINING AND EXPERIENCE IMPLEMENTATION ISSUES

Individuals from the following groups and organizations participated in a four-hour discussion on training and experience implementation issues with regards to 10 CFR Part 35: Advisory Committee on the Medical Uses of Isotopes (ACMUI); Agreement States (AS); American Association of Clinical Endocrinologist (AACE); American Association of Physicists in Medicine (AAPM); American Board of Health Physics (ABHP); American Board of Nuclear Medicine (ABNM); American Board of Radiology (ABR); American College of Medical Physics (ACMP); American College of Radiology (ACR); American Society for Therapeutic Radiology and Oncology (ASTRO); American Society of Nuclear Cardiology (ASNC); Board of Pharmaceutical Specialties (BPS); Bolling Air Force Base; Certification Board of Nuclear Cardiology (CBNC); MDS Nordion; Neo Vista; Nucletron; Oncologix; Organization of Agreement States (OAS); Sirtex; Society of Nuclear Medicine (SNM); and Texas Radiation Advisory Board (TRAB).

The following items were brought to the attention of NRC staff as significant issues with regards to 10 CFR Part 35 training and experience implementation. The Committee made formal recommendations for resolution on several items, and the remaining items will be discussed at a future public meeting to be held via teleconference.

1. Requirement for a signed preceptor statement for board certified individuals and attestation to "competency" for individuals seeking authorization under the alternate pathway.
2. Grandfathering diplomates and the impact of effective date on board certified individuals.
3. Requirement for 200 hours of radiation safety training for 10 CFR 35.390 users under the alternate pathway.
4. NRC interpretation for only allowing one RSO per license.
5. Unintended consequence of prescriptive requirements on certification boards resulting in NRC setting curriculum for training programs.
6. Difficulty for individuals trained in Canada, who did not receive their training under the supervision of an authorized user, to meet NRC criteria.
7. Agreement State request for Compatibility C so that States have the flexibility to impose more stringent regulations vs. the licensed community's request for more "uniform" regulations (i.e. Compatibility B) to ensure that authorized individuals may cross state borders and practice throughout the U.S.
8. Impact of a preceptor who is not able to sign an attestation (e.g. deceased preceptor).
9. Seven year recency of training requirement for individuals seeking authorization.
10. Interpretation of the T&E requirements causing difficulty for individuals seeking authorization to satisfy the requirements.

MOTION (2): NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the minimum training and experience requirements."

MOTION (3): NRC staff should revise the regulations so that previously board certified individuals, who were certified prior to the effective date of recognition, are grandfathered.

MOTION (4): NRC staff should reduce the 200-hour radiation safety training requirement to 120 hours for individuals seeking authorization under the alternate pathway in 10 CFR 35.390.

MISCELLANEOUS ITEMS

Mr. Scott Moore, NRC, discussed several administrative and informational items that resulted in actions for NRC staff.

ACTION (2): NRC staff should arrange a briefing for ACMUI members regarding the Increased Controls Orders to be issued later this year for fingerprinting.

ACTION (3): NRC staff should engage ACMUI in a discussion regarding the review of operational events and data and work towards a goal of minimizing therapeutic medical events, if directed by the Commission to do so.

WEDNESDAY, JUNE 13, 2007

POTENTIAL CHANGES TO 10 CFR PART 35

Dr. Donna-Beth Howe, NRC, gave a presentation to the Committee to open a discussion and seek input from ACMUI on proposed changes to 10 CFR 35.2; 35.12(c)(1); 35.50(c)(2); 35.50(d); 35.57(a); 35.75; 35.491(b)(2); and 35.400, 35.500, and 35.600.

The issues Dr. Howe presented and motions made by ACMUI are outlined below:

10 CFR 35.2 – By definition, individuals that meet the board certification pathway are RSOs; therefore, individuals may sign as a preceptor RSO even though they are not working as an RSO. Dr. Howe requested comments from the Committee on the intent of 10 CFR 35.2.

MOTION (5): NRC staff should not change the current definition for a preceptor RSO.

10 CFR 35.12(c)(1) – Current regulations indicate that the application may be completed using either NRC Form 313A or a letter; however, regulations do not state that the letter must include equivalent information to that which would be submitted in NRC Form 313A. NRC staff proposed that the regulations should clearly state that the letter should contain equivalent information.

MOTION (6): NRC staff should add the words "or equivalent" so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A.

10 CFR 35.50(c)(2) – Currently, an AU, AMP, or ANP is eligible to be an RSO for the same types and uses of materials they are authorized to use, only if listed on the licensee's license.

This requirement is too restrictive and should be expanded to be listed on **any** license for authorized individuals seeking to be an RSO for a similar type of use.

MOTION (7): NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.

10 CFR 35.50(d) – Current regulations require a written attestation, signed by a preceptor RSO, for authorized individuals seeking RSO status. NRC staff proposes this attestation requirement be removed.

MOTION (8): NRC staff should remove the attestation requirement for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or AMP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.

10 CFR 35.57(a) – Experienced RSOs, teletherapy or medical physicists, and nuclear pharmacists listed on a license or permit on or before October 24, 2005 are grandfathered. 35.57(a) states that the individual need not comply with 35.50, 35.51, or 35.55, respectively.

MOTION (9): ACMUI tabled the 35.57(a) issue until the next full ACMUI meeting.

ACTION (4): NRC staff should provide detailed background information for the current and future presentations on the subject of potential changes to 10 CFR Part 35.

10 CFR 35.75 – Patients are permitted to be released if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Although the statements of consideration support the Commission's intent that the 5 mSv dose limit is an annual limit, the regulations, as written, do not clearly distinguish whether the limit is an annual limit or a limit per release.

10 CFR 35.491(b)(2) – The current training and experience requirements for strontium 90 (Sr-90) ophthalmic applicators are not applicable for the new intra-ocular Sr-90 ophthalmic applicators. The training and experience requirements in 10 CFR 35.491 were developed based on the use of the applicator for superficial eye conditions. Since the structure of the new device and the treatment site differ significantly, the training for the use of the old device is not applicable.

10 CFR 35.400, 35.500, and 35.600 – The regulations require licensees to only use sealed sources and devices in these sections as approved in the Sealed Source and Device Registry. If the sealed source or device can only be used as approved in the Registry, other accepted uses under the practice of medicine would be classified as research or not permitted under the regulations. NRC staff proposed that 10 CFR 35.400, 35.500, and 35.600 be revised to exclude the specific medical indications for use, as provided by the manufacturer, while retaining the type of medical use, the physical conditions for use, or other important factors.

MOTION (10): ACMUI accepted the 35.75; 35.491(b)(2); and 35.400, 35.500, and 35.600 items as informational.

ONLY ONE RSO ON LICENSE

Mr. Ralph Lieto, ACMUI, gave a presentation to the Committee and NRC staff to provide historical background and express concerns for NRC only allowing one RSO on a license. Mr. Lieto gave an overview of NRC policy on the issue, reviewed current 10 CFR Part 35 regulations applicable to RSOs, provided a comparison to multiple listings on licenses for AUs, AMPs, and ANPs, and made suggestions to resolve the issue. Committee members and other stakeholders supported Mr. Lieto's views.

MOTION (11): NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC's interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.

MICROSPHERES GUIDANCE

Ms. Ashley Tull, NRC, gave a presentation to the Committee to open a discussion and seek input on the yttrium 90 (Y-90) microspheres guidance. Ms. Tull presented several major revisions to the Y-90 microspheres guidance. Major revisions included: authorizing 10 CFR 35.390 users; requiring individuals to have work experience including at least three cases; requiring training and experience to be supervised by an AU; requiring individuals to obtain written attestation; and suggesting a team approach for Y-90 microspheres brachytherapy treatments. Other minor changes were proposed with regards to specific limited medical use licensees and the addition of a paragraph on contaminants and waste disposal issues.

MOTION (12): NRC staff should include the three-case work experience requirement for individuals seeking authorization for Y-90 microsphere use; however, the three cases do not have to be with the particular type of microsphere for which the individual is seeking authorization. Furthermore, ACMUI recommends the training and experience does not have to be performed under the supervision of an AU, and NRC staff should replace the proposed supervision paragraph with the existing language from 10 CFR 35.690(c).

Note: Motion (12) received five favorable votes, three abstentions, and one opposition.

MOTION (13): NRC staff should delete the attestation requirement for Y-90 microspheres users and incorporate a requirement in the second paragraph of the guidance for individuals seeking authorization to provide and retain documentation of the completion of training.

MOTION (14): NRC staff should incorporate the proposed wording for the team approach section of the Y-90 microspheres guidance with one exception: ACMUI recommends the word "oncology" be replaced by "cancer management."

Ms. Tull sought input from the Committee for using the term 'absorbed dose' or 'activity' in the written directive section of the Y-90 microspheres guidance; however, due to time constraints, the Committee postponed the discussion on this issue.

MOTION (15): ACMUI tabled the absorbed dose vs. activity issue for Y-90 microspheres until the next full ACMUI meeting.

PATIENT RELEASE

Dr. Armin Ansari, CDC, and Luba Katz, Abt Associates, gave a presentation to the Committee and NRC staff pertaining to the release of individuals containing byproduct material in the context of radiation monitoring at security checkpoints. Dr. Ansari provided an overview of literature on this issue and presented data collected from licensees. The data collected included information on and queries about: users' facilities, the individuals interviewed, individual's familiarity with NRC publications, patient understanding of informed consent, decisions to release patients, and types of instructions given to patients upon release. Dr. Katz provided additional insight on the data and methods used to analyze the data.

Dr. Ansari made several observations and recommendations to ACMUI and NRC staff. Dr. Ansari stated that diagnostic patients were less informed than therapy patients and suggested facilities offering outpatient diagnostic procedures could benefit from improved outreach. Dr. Ansari also believed that licensees and support staff may benefit from formal training in patient education. In conclusion, Dr. Ansari stated that more uniform or standardized documentation could be useful, and nuclear medicine and brachytherapy patients should be provided with this standard documentation in the event they activate radiation alarms. Ms. Lynne Fairobent, AAPM, stated that formal documentation given to patients was a useful outreach tool; however, individuals should be aware that terrorist organizations are adept at circumventing procedures of this type and caution should be used in relying on a voice message on a phone line.

Dr. Ansari stated his path forward was to work with the Society of Nuclear Medicine to gain additional attention and support on this issue. Dr. James Welsh, ACMUI, recommended Dr. Ansari also share his findings with ASTRO and the American College of Radiation Oncology. Mr. Mike Peters, SNM, supported Dr. Ansari's presentation and stated that SNM looked forward to collaboration with CDC to educate the community by publishing articles in the Journal of Nuclear Medicine and using additional outreach programs through SNM's press group and the SNM communications team.

RADIOLOGICAL TERRORISM EVENT RESPONSE

Dr. Armin Ansari, CDC, provided a brief presentation to the Committee and NRC staff on the roles and training needs of hospital RSOs and medical physicists in a radiological terrorism event. Dr. Ansari felt the medical community would be heavily involved in response to a radiological terrorism event and provided insight on hospital incident command systems as well as key roles for hospital radiation safety staff.

Dr. Ansari concluded his presentation by stating that clinicians and hospitals should rely on radiation experts in a radiological terrorism event, and those radiation experts should receive additional training and support from upper management. Dr. Leon Malmud, ACMUI Chair, agreed that individuals with specialized radiation safety training should be intimately involved in radiological terrorism event response. Other Committee members and members of the public

gave additional insight on the issue. Dr. Malmud also stated that many hospitals are awaiting federal funds to initiate and support response programs at their facilities. Ms. Sandra Wastler, NRC, brought the Committee's attention to a radiological emergency training course that is provided by Oak Ridge National Lab. Dr. Ansari stated CDC was looking to offer specific radiation safety training courses in a hospital setting for medical personnel, including radiation physicists, medical physicists, and nuclear technologists, since the training is not currently available elsewhere.

NOVEL RADIOTHERAPEUTICS

Dr. Orhan Suleiman, ACMUI, gave an informational presentation to the Committee and NRC staff on new radiotherapeutics, such as: SIR-spheres®, TheraSphere®, Bexxar®, and Zevalin®. Dr Suleiman discussed the issue of new radiotherapeutics becoming a first-line therapy and potential concerns with dosimetry. Dr. Suleiman stated the success or failure of clinical trials and the future of first-line radiotherapeutics may depend on the science and level of accuracy in calculating doses.

SENTINEL LYMPH NODE BIOPSY

Dr. Donna-Beth Howe, NRC, reviewed the applicable NRC regulations and gave a brief overview of the localization and surgical removal of sentinel lymph nodes.

Dr. Douglas Eggli, ACMUI, gave a presentation to the Committee and NRC staff and provided a detailed description of the entire lymphoscintigraphy procedure, as well as information on patient release. Dr. Eggli offered examples of other medical procedures that use byproduct material including heart, thyroid, and tumor scans that are followed by tissue excision. Dr. Eggli also provided estimated doses for personnel who perform lymphoscintigraphy.

Dr. Eggli discussed the consequences that NRC's interpretation will have on facilities performing the surgery, since these facilities will now be required to be licensed. Dr. Eggli stated that mobile nuclear medicine services can no longer operate, the cost to patients has increased due to lack of insurance coverage, and there has been an increase in patient morbidity. Dr. Eggli recommended that lymphoscintigraphy patients be released unconditionally under the current guidance and that NRC should allow released patients to have surgery at facilities that do not possess a radioactive materials license. The Committee unanimously agreed.

MOTION (16): NRC staff should revise the current guidance to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC.

NEW MODALITIES

Dr. Subir Nag, ACMUI, gave an informational presentation to the Committee and NRC staff on new radiation modalities, which included: cesium 131 permanent implants seeds, electronic brachytherapy, and Sr-90 intra-ocular eye applicators. Dr. Nag provided detailed information on each new modality and provided examples of uses, advantages and disadvantages, radiation safety concerns, diagrams for doses and dose rates, and a summary of the clinical future.

The Committee generally agreed that the training requirements under 10 CFR 35.491 are not appropriate for the new Sr-90 eye applicator; therefore, the new eye applicator should be regulated initially under 10 CFR 35.1000. Dr. Nag recommended NRC staff use the Intravascular Brachytherapy (IVB) guidance as a model for the new Sr-90 eye applicator guidance.

ELEKTA PERFEXION, AU APPROVAL FOR BYPRODUCT MATERIAL, AND NMED

Due to time constraints, presentations by NRC staff and ACMUI on the following items were rescheduled for a future ACMUI meeting:

Elekta Perfexion, Dr. Donna-Beth Howe, NRC
AU Approval for Byproduct Material, Dr. James Welsh, ACMUI
Nuclear Material Events Databse (NMED), Michele Burgess, NRC

CLOSING

Ms. Ashley Tull, NRC, suggested dates for the next ACMUI meeting and briefly summarized the motions made by ACMUI. Based on availability of ACMUI members, Ms. Tull scheduled the next ACMUI meeting for October 22-23, 2007 at NRC Headquarters.

ACTION (E): NRC staff should email the ACMUI members a copy of the memo summarizing action items and motions made during the meeting.