MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 22-23, 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.

MONDAY, OCTOBER 22, 2007

OLD BUSINESS

Ms. Ashley Tull, NRC, reviewed and discussed recommendations and action items from the previous ACMUI meetings held on: June 12-13, 2007; August 15, 2007; August 16, 2007; and September 20, 2007. ACMUI members asked questions and offered comments, and Ms. Tull provided updates on the status of the recommendations.

RECENT SECURITY ACTIVITIES

Ms. Janet Schlueter, NRC, gave a presentation on radioactive material security and licensing with regards to the Government Accountability Office (GAO) report published on July 12, 2007. Ms. Schlueter outlined the following: actions NRC has taken to improve security; recommendations from GAO, Senate, and Office of the Inspector General (OIG); and NRC's action plan to further improve security. Ms. Schlueter emphasized the coordination that has taken place with Agreement States and other Federal partners and provided detailed information on the various working groups that have been formed in response to the GAO report. Ms. Schlueter's presentation also covered topics such as pre-licensing guidance, the National Source Tracking System (NSTS), Web Based Licensing (WBL), and general licenses.

Dr. Vetter raised a concern about the new licensing system preventing legitimate licensees from ordering material. NRC acknowledged this concern. Mr. Lieto asked how increased controls were incorporated, and Ms. Schlueter clarified that increased controls were somewhat related but only applied to Category 1 and 2 sources. Dr. Van Decker communicated the importance of delivering the new action plans in a timely manner and in coordination with stakeholders. Ms. Schlueter assured ACMUI that NRC would carefully consider advanced outreach to stakeholders and would solicit input, if necessary, before action plans were fully implemented.

AU APPROVAL OF BYPRODUCT MATERIAL

Dr. James Welsh, ACMUI, gave a presentation on the need for an Authorized User's (AU) signature on all byproduct material orders. Dr. Welsh provided background information and explained the scenario that initiated this concern that radioactive material could be shipped without the expressed knowledge of the AU. Dr. Welsh suggested that all orders for byproduct material have the signature of the AU.

Dr. Eggli asked if the AU's signature would be necessary for orders of material regulated under 10 CFR 35.200. Dr. Welsh clarified that only those orders for the use of byproduct material requiring a written directive should be signed. Drs. Eggli, Fisher, Malmud, Nag, Suleiman, Thomadsen, Vetter, Mr. Lieto, and Ms. Schwarz stated various concerns mainly about the unavailability of the AU at larger facilities and the possibility of micromanagement, if Dr. Welsh's proposal was to be implemented at all licensed facilities. Several ACMUI members agreed that this issue should be handled through internal procedures at each institution.

MOTION (1): The AU should be required to place a signature on orders for radioactive material before the supplier can legally ship the material to an institution.

Eight members opposed the motion, and two members abstained. The motion did not pass.

NARM

Mr. Duane White, NRC, provided an update on NRC's efforts to implement the requirements of the Energy Policy Act of 2005 for certain naturally occurring and accelerator-produced radioactive material (NARM). The final NARM regulations were published on October 1, 2007, and are effective November 30, 2007. Mr. White also provided a status update of the guidance associated with the NARM regulations. The following major guidance documents are being finalized: NUREG-1556 Volume 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator"; NUREG-1556 Volume 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses"; and NUREG-1556 Volume 9, "Program-Specific Guidance About Medical Use Licenses." Mr. White also discussed the NARM transition plan and outreach to Agreement States, Non-Agreement States, Federal Agencies, and Federally Recognized Indian Tribes.

ELEKTA PERFEXION

Dr. Donna-Beth Howe, NRC, gave a presentation on the new Elekta Perfexion® gamma knife guidance. Dr. Howe indicated that the Elekta Perfexion® had been substantially redesigned and re-engineered in comparison to the original gamma knife, which is regulated under 10 CFR 35.600; therefore, Dr. Howe suggested the Elekta Perfexion® gamma knife should be regulated under 10 CFR 35.1000. Dr. Howe discussed the major features of the new Elekta Perfexion® and how the written directive, spot checks, calibration, and training and experience would vary from the original gamma knife.

Dr. Nag raised several concerns on behalf of the radiation oncology community with regards to the Elekta Perfexion® being regulated under 10 CFR 35.1000 instead of 10 CFR 35.600. Drs. Fisher, Suleiman, Thomadsen, Vetter, Welsh, Mr. Lieto, and Ms. Gilley asked questions and provided their insights on the topic as well. Ms. Lynne Fairobent from the American Association of Physicist in Medicine (AAPM) also offered historical background and suggestions for the regulation of the Elekta Perfexion®.

MOTION (2): The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated in 10 CFR 35.600.

Six members supported the motion. Two members opposed, and two members abstained. The motion passed.

ACTION (1): ACMUI should form a subcommittee to address issues with 10 CFR 35.600 as they relate to the Elekta Perfexion®. The subcommittee includes: Dr. Nag (chair), Dr. Thomadsen, Dr. Welsh, and Mr. Lieto. The subcommittee should consult with: Ms. Gilley on behalf of the Agreement States; the vendor; the American Society for Therapeutic Radiology and Oncology (ASTRO); and the AAPM.

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 35.57(a); 35.75; 35.491; and 35.400, 35.500, and 35.600.

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

10 CFR 35.57(a) – An experienced Radiation Safety Officer (RSO), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) that is listed on a license or permit before certain dates is grandfathered under 35.57(a), and the regulations specifically state the individual "need not comply with the training requirement of 10 CFR 35.50, 35.51, or 35.55, respectively."

Dr. Howe proposed revising 35.57(a) so that experienced RSOs, AMPs, and ANPs would be required to receive additional training to be authorized for new uses. Mr. Lieto raised concerns about changing regulations with regards to grandfathering; however, Dr. Vetter moved for approval of NRC's proposed revision, and Dr. Eggli seconded.

MOTION (3): NRC staff should require experienced RSOs, AMPs, and ANPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.

Nine members supported the motion, and one member abstained. The motion passed.

Dr. How proposed revising 35.57(a) so that experienced RSOs, who receive additional training to be authorized for new uses, are not required to obtain a written attestation from a preceptor RSO stating the individual has satisfactorily completed the training and experience requirements for the new use and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

Dr. Nag suggested that words similar to "not required to meet the attestation requirement" be used instead of stating 10 CFR 35.50(d) does not apply to experienced RSOs.

MOTION (4): NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.

The motion passed unanimously.

10 CFR 35.75 – Currently 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). At the time the patient release rule was promulgated, NRC did not expect a patient to receive more than one treatment in a year from the licensee; therefore, NRC's intent was for the release criteria to be 5 mSv/year (0.5 rem/year).

Drs. Eggli, Fisher, Nag, Suleiman, Thomadsen, Vetter, Ms. Schwarz, Mr. Lieto, and Doug Pfeiffer of the AAPM engaged NRC staff in a lengthy discussion on the implications of making NRC's proposed change.

MOTION (5): NRC staff should revise 10 CFR 35.75 to read "5 mSv/year (0.5 rem/year)."

Six members, including the Chairman, supported the motion. Five members opposed the motion.

Dr. Van Decker suggested the ACMUI form a subcommittee to further investigate the implications of the proposed change.

ACTION (2): ACMUI should form a subcommittee to further discuss the proposed change to 10 CFR 35.75 to release patients, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv/year. The subcommittee includes: Dr. Vetter (chair), Dr. Eggli, and Dr. Fisher.

On the following day the subcommittee reported to the ACMUI. After further discussion a second vote was taken. Two members favored the motion, and 9 members opposed. Motion (5) did not pass. Action (2) was closed.

10 CFR 35.491 – A new strontium-90 ophthalmic device has been developed for intraocular use. The structure and treatment site for the new device differs significantly from those of the superficial ophthalmic device.

Dr. Howe provided two options: (1) Regulate the intraocular device under 10 CFR 35.1000 and develop web-based guidance that can be easily revised as experience is gained; (2) Revise 10 CFR 35.491 to address the training require for the two different types of ophthalmic devices.

Dr. Howe initially suggested option (2) and gave examples of the revised 10 CFR 35.491(b)(2) and (b)(3).

Dr. Nag asked for clarification on several of the issues, and Mr. Lieto suggested the intraocular device be regulated under 10 CFR 35.490. Dr. Nag agreed.

MOTION (6): NRC staff should modify 10 CFR 35.491(b)(2) to specify "superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.

The motion passed unanimously.

MOTION (7): NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.

The motion passed unanimously.

10 CFR 35.400, 500, 600 – Currently licensees are required to only use the sealed sources and devices regulated in these sections for the "principle use" approved in the Sealed Source and Device Registry (SSDR). This implies that devices cannot be used for anything other than that which is listed in the SSDR unless it is used for research. NRC staff believes limiting the use of the device interferes with the practice of medicine.

Dr. Howe proposed revising 10 CFR 35.400, 500, and 600 to exclude the specific medical indications for use provided by the manufacturer while retaining the type of medical use, as applicable in 10 CFR 35.400, 500, or 600; the physical conditions for use; or other important factors. Dr. Howe clarified that the SSDR could not be changed by NRC; therefore, resolution of the issue required rulemaking.

MOTION (8): NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.

The motion passed unanimously.

10 CFR 35.290 – Currently not all facilities have a generator available or prepare kits, which prevent physicians seeking authorization from easily obtaining work experience for generator elution. These facilities usually make arrangements with a nuclear pharmacy for the physician seeking authorization to obtain hands-on training from an ANP; however, the ANP provides the training under the AU's supervision.

Dr. Howe suggested simplifying the process by allowing an ANP to provide the training as the supervising individual.

Mr. Lieto believed the proposal was too prescriptive; however, Dr. Eggli, as an authorized user preceptor, supported the amendment. Drs. Vetter, Nag, and Ms. Schwarz also voiced support for the change.

MOTION (9): NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.

Nine members favored the motion, and one member opposed. The motion passed.

TUESDAY, OCTOBER 23, 2007

NMED

Ms. Michele Burgess, NRC, gave a presentation on the Nuclear Materials Events Database (NMED) and provided examples of how NMED can be a useful technical tool to gather data to evaluate generic issues or to look for trends. Ms. Burgess performed an online demonstration

to show how NMED is easy to use, flexible enough to meet ACMUI needs, and powerful enough for more complex searches.

Dr. Nag asked about the possibility of using NMED data in public forums or specifically for the radiation oncology community. NRC staff explained that NMED data was only to be used for official NRC business; however, NMED data can be exported and analyzed for specific use outside of NRC on a case-by-case basis. Dr. Vetter inquired if there was an attempt to establish a denominator for events reported, so that rates of occurrence could be calculated. After an in-depth discussion, it was concluded that a calculated denominator is not feasible at this time.

ACTION (3): NRC staff should set-up NMED accounts for new members and reset passwords for other members, as needed, following the October meeting.

MEDICAL EVENTS

Dr. Donna-Beth Howe, NRC, provided an update on the status of reported medical events. Dr. Howe summarized medical events into the following categories: diagnostic, therapy (35.300), brachytherapy (35.400), high dose-rate (HDR), gamma knife, Y-90 microspheres (35.1000), and other. Several members asked for specific or additional information on various events, and Dr. Howe provided explanations. NRC staff clarified that typically one event equals one patient; however, there are several instances when one event may involve several patients, and NRC's statistics are based on the number of events, not the number of patients. Dr. Nag gave additional insight with regards to the HDR medical events. Dr. Thomadsen also added that the University of Wisconsin did a study on contract with the NRC and the International Atomic Energy Agency, which analyzed events and root causes.

ACTION (4): NRC staff should add an item to the spring 2008 agenda for Dr. Thomadsen to provide a presentation to ACMUI members and NRC staff on the causes of medical events. Dr. Thomadsen's presentation will also provide suggestions for questions NRC should ask to receive more accurate information on the causes of events.

Mr. Ralph Lieto, ACMUI, provided an update on the status of other reported events that relate to the medical use of radioactive materials. Mr. Lieto summarized other reported events into the following categories: lost sources, leaking sealed sources, landfill alarms, miscellaneous. Mr. Lieto noted that search queries yielded different and incomplete results for the same endpoint, and multiple search queries were needed to capture all reported events involving the medical use of radioactive material. Mr. Lieto suggested several improvements for NMED, which included: searching by specific licensee type; searching with multiple keywords; and allowing Boolean searches to account for varied reporting criteria between NRC and Agreement States.

ACTION (5): ACMUI should form a subcommittee to annually review byproduct material events, perform analysis, and report to the full Committee. NMED data should continue to be presented to ACMUI at the fall meetings, and the subcommittee should analyze the data presented at the fall meeting in order to provide a full report at the spring meeting. The subcommittee includes: Mr. Lieto (chair), Dr. Nag, Dr. Thomadsen, and Dr. Suleiman. The subcommittee will consult with an Agreement State representative, Ms. Gilley, and designated NRC staff, as appropriate.

ACTION (6): ACMUI byproduct material events subcommittee should publish reports, as necessary, to ensure end-users receive the message.

MICROSPHERE GUIDANCE

Ms. Ashley Tull, NRC, gave a presentation proposing several modifications to the current microsphere use guidance. To open the topic, Ms. Tull introduced Dr. Andrew Kennedy on behalf of microsphere manufacturer, Sirtex. Dr. Kennedy, a radiation oncologist, gave a detailed presentation comparing glass and resin microspheres and highlighted differences in calculating doses for the glass and resin microspheres. At the conclusion of Dr. Kennedy's presentation Dr. Nag provided additional insights on the topic, and Dr. Fisher added detailed information on dose calculations and modeling with the Medical Internal Radiation Dose (MIRD) system.

MOTION (10): NRC staff should revise the microsphere guidance to allow the written directive to include either "dose to target tissue (Gy or rad)" or "activity administered (mCi or GBq)."

Nine members supported the motion. One member abstained.

Ms. Tull also proposed several additional revisions to the microsphere guidance. ACMUI members, NRC staff, Dr. Kennedy, and Dr. Riad Salem of Northwestern University discussed the revisions. ACMUI made the following recommendations:

MOTION (11): NRC staff should revise the microsphere guidance to include a paragraph referencing medical event reporting for microsphere use. (10 CFR 35.3045 Medical Event Reporting)

Nine members supported the motion. One member abstained.

NRC staff inadvertently removed a paragraph from the original guidance on quantifying dose during the September revision process. NRC staff proposed reinserting this paragraph.

> "Procedures for administrations requiring a written directive should, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive."

MOTION (12): NRC staff should revise the microsphere guidance to reinsert the proposed paragraph with modification. The paragraph should state, "Procedures for administrations requiring a written directive should, for yttrium-90 microsphere administration, be performed in accordance with the written directive."

Nine members supported the motion. One member abstained.

MOTION (13): NRC staff should revise the microsphere guidance to allow an experienced AU for a certain type of microsphere to become an AU for the same type of microsphere use on a license. (10 CFR 35.14 Notification)

Nine members supported the motion. One member abstained.

Dr. Howe stated that this was the first example of 10 CFR 35.14 applying to a 10 CFR 35.1000 use. Dr. Howe added that NRC staff intended to add notification provisions to the guidance for other 35.1000 uses as well.

MOTION (14): NRC staff should revise the microsphere guidance to add a paragraph which states, "Training in manufacturer's procedures, commensurate with the individual's duties to be performed, must be provided to individual preparing, measuring, performing dosimetry calculations, or implanting microspheres."

Seven members supported the motion. Three members abstained.

MOTION (15): NRC staff should revise the microsphere guidance to read, "The written directive should include after implantation but before release of the patient from licensee control: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose or administered activity.

Nine members supported the motion. One member abstained.

Dr. Salem stated that the interventional radiologists were a very interested and important constituency in the use of microspheres. Ms. Tull clarified that currently the guidance was not written to specifically include interventional radiologists for microsphere use and that the interventional radiologist must meet all of the appropriate requirements for the alternate pathway in 10 CFR 35.390. Dr. Eggli emphasized that the threshold for training was clear and that the issue would probably be better addressed with the American Board of Radiology in their decision on how to train their diplomats.

SPECIALITY BOARDS

Ms. Cindy Flannery, NRC, provided an update on the status of recognition for specialty boards. Ms. Flannery highlighted one update to the table since the June ACMUI meeting. The Canadian College of Physicists in Medicine applied for recognition under 10 CFR 35.51. Ms. Flannery also explained that the Certification Board of Nuclear Endocrinology, once recognized, will be granted a partial recognition under 10 CFR 35.190 rather thanall uses under 10 CFR 35.190, since the endocrinologists are only interested in uptakes and not dilution and excretion.

Specialty Board:	**Status:**	**Recog. 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	35.50	June, 2006
Radiation Protection	35.50	June, 2006
American Board of Radiology (Radiation Oncology)	35.390, 35.490, 35.690	June, 2007
American Board of Radiology (Diagnostic Radiology)	35.290, 35.392	June, 2006*
American Board of Radiology (Radiologic Physics)		
Medical Nuclear Physics	35.50	June, 2007*
Diagnostic Radiologic Physics	35.50	June, 2007*
Therapeutic Radiologic Physics	35.51	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	
Canadian College of Physicists in Medicine	Under review by NRC	
*Board is verifying the qualifications of diplomates who have obtained their certification prior to the recognition date.		

TRAINING AND EXPERIENCE

Ms. Ashley Tull, NRC, summarized the ten training and experience (T&E) implementation issues ACMUI had identified at previous ACMUI meetings and opened the floor for further discussion on the final issue, "Increased Complexity, No Additional Benefit." ACMUI discussed the various T&E issues briefly, and Dr. Malmud summarized ACMUI's major areas of concern.

MOTION (16): ACMUI recommended for each training program, including radiology, radiation oncology, radiation physics, and nuclear pharmacy, that the curricular requirements be established by those boards, which recognize the importance of the NRC standards for radiation safety and radiation physics. ACMUI also recommended the deletion of the word "competence" and suggested replacing it with a statement regarding the successful completion of a residency training program. Additionally, ACMUI recommended that the word 'minimum' be removed from Motion (2) from the June 12-13, 2007 ACMUI meeting. Motion (2) should read, "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 training and experience requirements."

The motion passed unanimously.

PETITION FOR RULEMAKING (PRM 35-20)

Mr. Dennis Rathbun, NRC, provided an overview of the NRC petition process and gave an update on the Petition for Rulemaking (PRM) 35-20, E. Russell Ritenour Petition. Mr. Rathbun outlined how the Division of Intergovernmental Liaison and Rulemaking (DILR) handles petitions within the Working Group and the Petition Review Board (PRB). Mr. Rathbun stated that the PRB decision is considered to be the resolution of the petition. If the petition is granted in whole or in part, the proposed rule goes into the rulemaking process. If the petition is denied, the denial package is prepared for signature by the NRC Executive Director of Operations or NRC Chairman. The denial is published in the *Federal Register*.

Mr. Rathbun gave a timeline for PRM 35-20 starting when the petition was docketed at the NRC on September 13, 2006, through April 11, 2007, when the Working Group began analysis. Mr. Rathbun stated that PRM 35-20 was currently under review by the Working Group and that the Working Group expected to make a recommendation to the PRB by the end of 2007.

Mr. Rathbun recognized ACMUI's request and NRC's commitment from the June 12-13, 2007, ACMUI meeting to discuss PRM 35-20. The original action item is stated below:

JUNE 12-13, 2007 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.

Mr. Rathbun opened the floor for discussion. Dr. Nag inquired whether ACMUI's recommendations had more or less weight in comparison to the petition and petition process. NRC staff explained how handling of recommendations from ACMUI differed from the petition process. Mr. Lieto raised several issues and described the impact the current regulations are having on the AMP and RSO communities. Mr. Rathbun suggested ACMUI send supporting data to NRC for the Working Group to consider.

CLOSING

Ms. Ashley Tull, NRC, suggested dates for the next ACMUI meeting and briefly summarized the motions and actions proposed by ACMUI. Based on availability of ACMUI members, Ms. Tull tentatively scheduled the next ACMUI meeting for April 7-8, 2008, at NRC Headquarters.

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