SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
October 28, 2002

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on October 28, 2002.

ACMUI members present at the meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Jeffrey A. Brinker, MD	Interventional cardiologist (designee)
David A. Diamond, MD	Radiation oncologist
Douglas F. Eggli, MD	Nuclear medicine physician (designee)
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist
Leon Malmud, MD	Healthcare administrator
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

Staff from various NRC Offices, Divisions, and Branches participated in the meeting. Office representation included the Office of State and Tribal Programs (OSTP), and the Office of Nuclear Material Safety and Safeguards (NMSS). Division representation included Industrial and Medical Nuclear Safety (IMNS), and Branch representation included the Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB). Specific participating staff members are listed below:

Lloyd Bolling	OSTP
Frederick Brown	NMSS/IMNS/MSIB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Official
Paul Lohaus	OSTP
Angela Williamson	NMSS/IMNS/MSIB
Thomas Young	NMSS/IMNS/RGB

Invited guest present at the meeting: Ryan T. Coles, Government Accounting Office

The meeting came to order at 10:03 a.m.

OPENING REMARKS

Dr. Manuel Cerqueira welcomed everyone to the meeting, and Thomas Essig, Designated Federal Official, made opening remarks.

REVIEW OF DOMESTIC REGULATION OF NUCLEAR MATERIAL

Mr. Ryan T. Coles of the U.S. Government Accounting Office (GAO), made a presentation on this topic. This topic was not an agenda item, but was included at the last minute at the request of the GAO.

Mr. Coles explained that the GAO is conducting an investigation into the accountability of radiation sources worldwide, and is doing so at the request of Senator Daniel Akaka, Chairman of the Subcommittee on International Security, Proliferation, and Federal Services; Senate Committee on Governmental Affairs. Mr. Coles stated that GAO believed it was worthwhile to brief ACMUI on this subject because they represent major stakeholders that use radioactive material.

Mr. Coles explained that GAO divided this investigation into three broad sections. These sections are: 1) a review of radioactive material used domestically; 2) a review of radioactive material used internationally; and, 3) an "aeroscope" review of the U.S. Department of Energy's Offsite Source Recovery Program. Mr. Coles then discussed GAO's planned review of radioactive material used domestically, and spoke specifically of their focus on byproduct material use.

Regarding the review of radioactive material used domestically, Mr. Coles relayed three questions GAO is attempting to answer. The first question is "What is the extent of (radioactive) material usage (specifically, types of material, number of licensees, maximum activities used, and uses of this material)?" The second question is "How effective is the current Federal and State regulatory framework?" The third question is "What actions have the NRC and/or the States taken since September 11, 2001, to improve/modify the regulation of nuclear materials in the United States?"

Mr. Coles went on to explain the approach GAO will use in their attempt to answer these questions. The approach involves the use of three investigative devices. These are: 1) the use of surveys that GAO will send to NRC regions and the Agreement States; 2) GAO interviews of Agreement States licensees; and 3) GAO observation of NRC during their Integrated Materials Performance Evaluation Program reviews of the Agreement States and NRC regions.

Mr. Coles ended his presentation by recounting the outcomes GAO will attempt to achieve. They are:

- As a neutral third party, educate Congress on the regulation of nuclear materials.
- Provide the Bush Administration with a list of Federal/State best practices that can be applied to other industries (e.g., chemical facilities).
- Identify the successes and challenges of the current regulatory system, and provide recommendations, if warranted.
- Examine the need for legislative changes, e.g., amending the Atomic Energy Act to allow NRC regulation of accelerator-produced material.

This presentation begins on page 85 of the meeting transcript.

UPDATE: ACMUI TRAINING AND EXPERIENCE RECOMMENDATIONS TO THE REVISED 10 CFR PART 35

Thomas Essig, NRC/NMSS, provided the update on this topic. Mr. Essig informed ACMUI that the recommendations they drafted to modify the training and experience (T&E) requirements contained within the revised 10 CFR Part 35 were forwarded to the Commission in a paper drafted by the staff called an "options paper." He explained that the options paper consisted of three options for Commission consideration, and that their T&E recommendations were one of the options. ACMUI expressed concern that they had not been kept informed about the options paper. Subsequent to the meeting, a pre-decisional copy was distributed to the advisory committee members.

This presentation begins on Page 98 of the meeting transcript.

AGREEMENT STATE COMPLIANCE WITH 10 CFR PART 35

Lloyd Bolling, NRC/OSTP, briefed ACMUI on this agenda topic. He began his presentation by providing a brief overview of Section 274 of the Atomic Energy Act, which allows states to become Agreement States. Next, Mr. Bolling outlined the status of Agreement State activities to adopt a rule compatible with the revised 10 CFR Part 35.

With respect to training and experience, Mr. Bolling explained that the training and experience sections of the revised 10 CFR Part 35 were at the Category B level, so that State rules had to be essentially identical. Mr. Bolling also explained that Agreement States have 3 years to adopt rules compatible with NRC's rules, but if any State has difficulty in meeting the 3-year time limit because of its rule promulgation process, it may use "Legally Binding Requirements" (such as orders and/or license conditions as interim measures) until the promulgation process is completed and compatible medical rules become effective.

Mr. Bolling finished his presentation by providing ACMUI with the time table Agreement States would need to adopt rules compatible with the revised 10 CFR Part 35. He also shared the results of a survey of the Agreement States that showed all Agreement States indicating they would have a compatible rule by the due date.

This presentation begins on Page 111 of the meeting transcript.

DISCUSSION OF THE NATIONAL MATERIALS PROGRAM

Paul Lohaus, NRC/OSTP, made a presentation on this topic. Mr. Lohaus began his presentation by informing ACMUI that a National Materials Program (NMP) is in place, and that it is a program that has evolved and will continue to evolve. Then he briefly outlined the background documents that helped shape the evolution of the NMP:

✓ SECY 01-0112, in which NRC staff provided a copy of the NMP Working Group report presenting options for an NMP;

✓ SECY 02-0074, in which the staff provided the Commission with five pilot projects that can be used to provide a further base of information on how the states and NRC can work together to implement the Alliance Option, the option the NMP Working Group recommended;

✓ SECY 02-0107, an addendum to SECY 02-0074, in which staff and the Organization of Agreement States and the Conference of Radiation Control Program Directors provided the Commission with a recommendation to use a blending of the "Current Program" with the Alliance Option for carrying out the pilot projects.

Mr. Lohaus went on to inform ACMUI that the Commission approved the use of blending of the Current Program with the Alliance Option for the pilot projects.

Regarding the status of the NMP today, Mr. Lohaus informed ACMUI that the Agency is working toward moving more of the shared responsibility for development of rules and guidance to the Agreement States, given the larger proportion of Agreement State licensees versus NRC licensees. However, Mr. Lohaus clearly stated that in terms of evaluating Agreement State program performance, NRC will always have lead responsibility, as that responsibility is a legislative mandate that cannot be delegated. Regarding ACMUI input, Mr. Lohaus requested comments from the ACMUI on the pilot projects outlined in SECY 02-0074 and feedback on other NMP issues.

This discussion begins on Page 130 of the meeting transcript.

Follow-up: in response to Mr. Lohaus's request that ACMUI review SECY 02-0074 and provide feedback, as well as general feedback on any issue or area, ACMUI reviewed the National Materials Program Working Group report that staff forwarded to the Commission in May of 2001. In their two-page response entitled, "Summary Statement on the National Materials Program," ACMUI highlighted several concerns. These concerns include:

- NRC's possible regulation of naturally occurring and accelerator-produced radioactive material (NARM). ACMUI is concerned that NRC regulation of NARM will result in increased regulatory burden and cost to the Agreement States without significant improvement in safety.

- Lowering of standards. ACMUI believes that Agreement States with existing strong programs may be forced to lower their standards, so as to be in harmony with Agreement States that have weaker programs.

- Funding issues. ACMUI is concerned that any change in NRC regulatory authority will necessitate a change in the current funding mechanism, an issue they stated that the NMP Working Group report did not address.

- Maintaining expertise in the Agreement States. ACMUI believes that the assumption that the Alliance Option will work, with its requirement that the Agreement States maintain a level of technical and regulatory expertise equal to or better than that of the NRC, may not be a realistic expectation.

To review the ACMUI's "Summary Statement on the National Materials Program, " refer to the enclosure to these minutes.

HEALTH AND HUMAN SERVICES DATABASE

Frederick Brown, NRC/NMSS, made a presentation on this topic. In his presentation, which was presented to the ACMUI primarily for information purposes, he discussed the Health

Integrity and Protection (HIPDB) database. He explained that a goal of the database was to maintain a multi-jurisdictional record of health care providers found guilty of major infractions.

During the heart of his discussion, Mr. Brown informed ACMUI that certain sections of Title 45, Part 61, of the Health and Human Services regulations, require all Federal agencies, as well as the Agreement States, to provide reports to the HIPDB. He explained that NRC limits reports to the database to actions that are final, publicly available, relate to medical practice, and are subject to an adjudicatory process.

Members of the ACMUI expressed concern that being reported to HIPDB would be "punitive." With regard to fair treatment, they also believed there would be disparities between NRC licensees, subject to escalated enforcement action, versus Agreement States licensees, not subject to enforcement action.

Although Mr. Brown indicated that he presented this information to the ACMUI mainly for information purposes, he also indicated that he was willing to accept ACMUI feedback on the management directive the Agency will use to implement the action of reporting to the database. He committed to provide the Committee members with additional background information on the applicable requirements.

This discussion begins on Page 173 of the meeting transcript.

STATUS OF IMPLEMENTATION OF REVISED RULE

Update on Revised Inspection Guidance

Thomas Young, NRC/NMSS, gave a presentation on this agenda topic. In this presentation, Mr. Young informed the ACMUI on the status of the medical inspection procedures that are being updated to support the new requirements in the revised 10 CFR Part 35.

Mr. Young began by explaining that NRC's inspection program is documented in Manual Chapter 2800, which is publicly available at NRC's website. He explained that the new medical inspection procedures are being implemented under a pilot program, and they are designed to streamline the inspection administrative procedures outlined in Manual Chapter 2800. Further, these inspection procedures have been adjusted to direct the inspectors' focus toward more risk-informed activities.

Mr. Young summarized his presentation by pointing out that the procedures have been reduced in size and reformatted, with an emphasis placed on risk-informed activities.

In response, one ACMUI member, Dr. Vetter, relayed his own recent experience with an inspection done under the revised inspection procedures at his organization. He informed the staff that the inspection was risk informed, with very little time spent reviewing records. He characterized the inspection as very professional and very well conducted.

This presentation begins on Page 196 of the meeting transcript.

Update on NUREG-1556, Volume 9

Frederick Brown led the discussion on this agenda topic. He began by giving a brief overview of actions staff previously took to finalize NUREG-1556, Volume 9. These were: the March 2002 draft Volume 9 the staff issued for public comment; staff work to address the comments; staff review and revision of the incorporated comments; and staff approval of the revised Volume 9.

Mr. Brown explained that during the review process, staff kept in mind certain concerns that must be observed while developing a guidance document. Foremost was that the document be written in such a way as not to become de facto regulation. The other concerns that staff carefully observed were that Volume 9 be worded to impose no unnecessary burden on licensees, and would also be a document that had clarity and simplicity, while not compromising safety. Next, Mr. Brown informed the ACMUI that NUREG-1556, Volume 9 is finalized and available.

In response, Committee members expressed a desire that staff regard NUREG-1556, Vol. 9 as a work in progress. They believed staff should continue to engage ACMUI in discussions of Vol. 9 (for instance, areas where the committee members disagree with the staff, such as patient release calculations.)

This discussion begins on Page 205 of the meeting transcript.

Implementation Issues and Release of a Regulatory Issue Summary

Mr. Brown informed ACMUI of two issues that arose out of the stakeholder workshops that NRC held on the new rule.

The first issue revolves around a 10 CFR 35.2432 recordkeeping requirement that brachytherapy seed calibrations be signed by an AMP. Although the rule does not require that an AMP perform the calibration, the requirement that licensees have an AMP on staff may be implicit in the requirement that an AMP sign the calibration. This situation will likely lead to difficulties in licensees' ability to secure an AMP. As Mr. Brown explained, this was not the intent of the procedural part of the rule (10 CFR 35.432), and staff was taking action to address the problem.

The second issue relates to the Strontium-90 (Sr-90) eye applicator calculation of treatment times. Mr. Brown explained that 10 CFR 35.433 does not clearly outline the type of qualifications an AMP who does those calculations must meet. The question was: Is it feasible to introduce a "limited" AMP (one that has not met all the T&E for an AMP) who nonetheless possesses demonstrated credentials that prove (s)he can perform decay corrections for Sr-90 opthalmic treatments?

ACMUI indicated they were uncomfortable with the creation of a "sub" AMP, created just for the purpose of performing Sr-90 decay corrections. Furthermore, Committee members believed AMP involvement in the licensed activity was important. The Committee indicated they were more comfortable reviewing, on a case-by-case basis, the credentials of those individuals who are not AMPs, but who desired to perform this function.

Finally, Mr. Brown presented ACMUI with a Regulatory Issue Summary (RIS), dated October 21, 2002. He informed them that staff released this RIS to notify licensees that three specific new modalities will be regulated under 10 CFR 35.1000.

After reviewing the RIS, ACMUI indicated that 10 CFR 35.1000 covers emerging technologies that could straddle the boundary between radiation oncology and nuclear medicine.

They suggested that the best strategy for addressing these modalities would be to form a standing subcommittee to review 10 CFR 35.1000 licensing guidance and provide NRC staff with recommendations. Toward that end, ACMUI made the following recommendation:

ACMUI recommends that the Chairman, ACMUI, form a standing subcommittee to review 35.1000 licensing guidance as it is developed by NRC staff.

This discussion begins on page 236 of the meeting transcript.

SEALED SOURCE MODEL NUMBERS AS LICENSE CONDITIONS ON NRC LICENSES

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown quickly summarized the issue: 10 CFR Part 35 has no requirement for licensees to list individual sources on licenses. However, 10 CFR Part 30 does. Title 10 CFR Part 30 governs over 10 CFR Part 35, unless 10 CFR Part 35 has a more restrictive requirement.

Regarding listing sources on licenses, 10 CFR Part 30 governs. This creates a situation where licensees are required to list, by manufacturer and model number, all of their individual sources, or in the case of multiple sources in a single device, they must list the device. This new requirement is more burdensome than what was previously required.

With respect to listing multiple sources, Mr. Brown offered an example of how existing licensees have tackled this issue. The strategy used was to register multiple sources for use in one device that is then listed in the license. This way, the licensee does not need to update the license every time a new source comes out; the licensee would simply update the Sealed Source and Device Registry to reflect the use of the new source. ACMUI then discussed practical problems they encounter when trying to list a device (rapid change in manufacturers, for instance). ACMUI believed that the basis of this issue is the 10 CFR Part 30 overriding requirement that devices must be listed by manufacturer and model number. They believed that a change in 10 CFR Part 35 would resolve this issue.

The following recommendation was made:

ACMUI recommends that a rule making process be initiated to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1) to allow more generic listing of interstitial seeds and sources.

This discussion begins on Page 255 of the meeting transcript.

PRACTICAL ISSUES ASSOCIATED WITH MANUAL BRACHYTHERAPY SEED IMPLANT

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown explained that during a stakeholder meeting, staff identified some licensee concerns in the ability to determine “medical events” associated with manual brachytherapy. For example, during prostate

implantation, which requires the use of a needle that must travel through the patient's body, at what point is the source in the prostate versus the area of the prostate? Mr. Brown asked whether further guidance was necessary. ACMUI discussed the issues identified at the stakeholder meeting, then concluded that there was not a need for additional guidance at this time.

This discussion begins on Page 267 of the meeting transcript.

IMPLICATIONS OF INTERMEDIATE PACKAGING AND STERILIZATION OF BRACHYTHERAPY SEEDS

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown began by explaining that NRC requires vendors and distributors to have registration for a seed that is new or modified. He explained that NRC also requires device reviews if the packaging of the seed could affect the spacing of the seed (as it is placed into the patient), or if packaging could cause temperature or manual pressure stresses that would adversely affect the integrity of the seed. He also pointed out that the new 10 CFR 35.432 calibration requirements could not be performed after seeds were packaged in strands or devices by intermediate distributors.

Mr. Brown asked ACMUI to provide feedback on whether individual seeds received in bulk and then handled individually represent more or less of a safety problem than do pre-loaded, pre-sterilized seeds packaged by an intermediate distributor. Also, he requested that ACMUI provide an opinion as to whether spacing, temperature, and/or mechanical pressure on seeds was a significant issue.

After discussion, the ACMUI indicated that the loading of seeds by intermediate distributors was not of major concern. However, they recommended that licensees who use prepackaged seeds establish traceability programs in which they can demonstrate that the seeds are properly calibrated.

This discussion begins on Page 285 of the meeting transcript.

UPDATE: RECOMMENDATIONS FROM SPRING 2002 MEETING

Angela Williamson, NRC/NMSS, led the discussion on this topic under which she reviewed the disposition of the two recommendations, both related to T&E, that ACMUI made to staff at the Spring 2002 meeting.

Ms. Williamson reiterated that the T&E recommendations the ACMUI subcommittee developed had been forwarded to the Commission (earlier in this meeting, Thomas Essig informed them of this under the agenda topic "Update: ACMUI Training and Experience Recommendations to the Revised 10 CFR Part 35"). ACMUI then asked Ms. Williamson to provide a specific date when the Commission will render a decision. NRC staff informed the ACMUI that a definite date could not be given. ACMUI then expressed a desire to be immediately informed of the Commission's decision once it is made, and toward that end, made a recommendation.

The ACMUI's recommendation is as follows:

The ACMUI recommends that the ACMUI Chairman contact the Chairman, NRC to inquire about the status of the training and experience recommendations ACMUI composed to amend the T&E in the revised 10 CFR Part 35.

UPDATE: ACMUI VACANCIES

Angela Williamson, NRC/NMSS, led the discussion on this topic. Ms. Williamson informed the ACMUI that three members were due to rotate off the Committee in 2004. They are Dr. Manuel Cerqueira, nuclear cardiologist and ACMUI Chairman; Ms. Ruth McBurney, State Representative; and Ms. Nekita Hobson, Patient Advocate.

ACMUI made the following recommendation:

Regarding replacement of ACMUI members due to rotate off the Committee, ACMUI recommended that NRC staff initiate the replacement process.

This discussion begins on Page 310 of the meeting transcript.

The meeting concluded at 5:09 p.m.

Summary Statement on National Materials Program (NMP)
ACMUI Meeting
October 28, 2002
Presented by Ralph P. Lieto

I was asked to obtain comments from ACMUI members on the National Materials Program (NMP) Working Group report. We recognize the report originated from a 1999 directive from the Commissioners, and the report was submitted in mid-2001. However, the ACMUI did not become aware of it until earlier this year. The report was lengthy and not all members responded.

Based on review of the information sent before the October 28 meeting of the ACMUI, ACMUI members expressed the following observations and concerns which are summarized in the following:

A major concern is that the regulation of NARM by the NRC would increase the regulatory burden and increase the cost to existing Agreement States without any significant improvement in safety. Adverse effects would be in the use of positron emission tomography (PET), which is used exclusively in diagnostic nuclear medicine. A single agency setting standards for the use of all radioactive materials would be consistent with all industrialized nations.

Another concern is Agreement States with existing strong programs would be tied to or forced to lower their practices. In other words, the "lowest common denominator" would become the standard. The focus should be in bringing outdated State programs up to minimum standards and not impede progressive programs.

The funding of this program from the NRC perspective is not addressed in the Working Group report. The funding of NRC activities, especially in the nonreactor arena, cannot continue to be funded by fees from the non-Agreement licensees. Any change in NRC regulatory authority also must address a change in NRC's current funding mechanism. It is unclear how cost savings would be demonstrated with program expansion under fee-supported program.

An assumption for success of the Alliance option is that "States develop and maintain a level of technical and regulatory expertise at least equal to or better than the NRC." This may not be realized because approximately one-third of the States do not or cannot achieve this expertise. What incentive is there for States to change? If this assumption cannot be realized, how does this affect this Alliance or other NMP options?

The stated mission, goals, and objectives have merit and benefit to medical users. The Four Components proposed in the Working Group report are supported:

- Use centers of expertise
- Seek authority to regulate NARM
- Maintain an information infrastructure
- Create a standing compatibility committee

However, a major concern from the medical user perspective involves seeking authority to regulate NARM. This has to do with potential increased regulatory burden in an area not previously regulated by the NRC and intrusion into the use of PET, the area of greatest potential and growth in Nuclear Medicine.
