# POLICY ISSUE
(Information)

September 24, 2002 SECY-02-0173

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES — UPDATE ON COMMITTEE ACTIVITIES

PURPOSE:

To provide the Commission with an update on the actions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) as they relate to the amendment of the training and experience (T&E) requirements in the revised Title 10, Code of Federal Regulations, Part 35, the "Medical Use of Byproduct Material" (10 CFR 35).

BACKGROUND:

In a briefing to the Commission on February 19, 2002, the ACMUI suggested that the revised 10 CFR 35 will better serve the public interest if its training and experience requirements were amended to more efficiently produce authorized users (AU), radiation safety officers (RSO), authorized nuclear pharmacists (ANP), and authorized medical physicists (AMP). ACMUI suggested that this improvement could be attained by amending the T&E requirements so that board certification would become the preferred pathway for certifying these medical professionals. In response to that suggestion, the Commission issued an SRM that directed the staff to develop an "Options Paper." The Options Paper's purpose is to present to the Commission various options for addressing the T&E issue before the revised final rule becomes effective.

Regarding the actions ACMUI took to address the T&E issue, the Committee met on February 20, 2002, and agreed to form a Subcommittee whose charge was to develop a draft rule to amend the T&E requirements of AUs, RSOs, ANPs, and AMPs in the revised 10 CFR 35.

CONTACT: Angela R. Williamson, NMSS/IMNS
301-415-5030

The Commissioners

The intent of the draft rule was to propose practicable improvements to 10 CFR 35 regarding the T&E requirements of AMPs, ANPs, AUs, and RSOs.

On June 21, 2002, the ACMUI Subcommittee held a public meeting at NRC Headquarters in Rockville, Maryland. During this meeting, the Subcommittee formulated some recommendations to revise the T&E requirements, and agreed to meet with the full ACMUI on July 8, 2002, so that its recommendations could be refined and dispositioned.

On July 8, 2002, the full ACMUI met in a public, teleconferenced meeting at NRC Headquarters and discussed and refined the Subcommittee's recommendations on modifying the T&E requirements. ACMUI agreed to finalize the discussed refinements and later forwarded them to NRC staff on August 1, 2002. The staff will include the ACMUI's finalized T&E recommendations with the Options Paper.

DISCUSSION:

During the July 8, 2002, ACMUI meeting at NRC Headquarters, the ACMUI devoted most of its time to refining the recommended changes to the T&E requirements. However, to further improve the Subcommittee's recommended changes to the T&E requirements, ACMUI discussed and adopted several measures they believed would enhance the revisions.

Following is the list of the measures that the ACMUI agreed should be applied to all sections within the T&E that the Subcommittee had amended:

- recognized boards should be listed in the rule;
- the criteria for board acceptance should be listed in the rule;
- the preceptor's role should be revised so that the preceptor attests to the completion of training rather than to the competency of the trained individual;
- an alternative pathway to the board certification pathway (for the purpose of gaining recognition as an ANP, AU, RSO, or AMP) should be retained in the rule;
- a modality-specific training requirement should be added to ensure that individuals gain practical experience in the application of the modality to be practiced; and
- the rule should be configured so that changes to all sections are similarly formatted.

The Commissioners

Each of the above measures is explained in greater detail in the attached summary minutes under the heading “Committee Consensus.” The July 8, 2002, ACMUI full discussion of the above measures is accessible in ADAMS under accession number ML022190466.

***/RA/***

William D. Travers
Executive Director
for Operations

Attachment: Summary minutes of the 07/08/02,
ACMUI meeting

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
July 8, 2002

One member of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) was present at NRC Headquarters during the July 8, 2002, meeting: Manuel Cerqueira, MD, Nuclear Cardiologist, ACMUI Chairman.

All other ACMUI members participated in the meeting via telephone discussion. These members include:

| | |
|---|---|
| David A. Diamond, MD | Radiation oncologist |
| Jeffrey A. Brinker, MD | Interventional cardiologist |
| Douglas F. Eggli, MD | Nuclear medicine physician (designee) |
| Nekita Hobson | Patients' rights advocate |
| Ralph P. Lieto | Medical physicist |
| Leon S. 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 |

The following NRC staff members were present at NRC Headquarters during the meeting:

| | |
|---|---|
| John Hickey | Office of Nuclear Material Safety and Safeguards/Division of Industrial and Medical Nuclear Safety (NMSS/IMNS) |
| Angela Williamson | NMSS/IMNS/Material Safety and Inspection Branch (MSIB) |
| Linda Psyk | NMSS/IMNS/MSIB |
| Lloyd Bolling | Office of State and Tribal Programs |

The meeting came to order at 1:04 p.m.

**OPENING REMARKS**

Dr. Manuel Cerqueira made a few opening remarks, and, on behalf of ACMUI, thanked John Hickey for his service to the ACMUI as the Designated Federal Official. This meeting was Mr. Hickey's final meeting in his service to ACMUI as the Designated Federal Official, because he was moving on to other responsibilities at NRC. After thanking Dr. Cerqueira for his remarks, Mr. Hickey welcomed the newest ACMUI member, Dr. Douglas F. Eggli, as the committee's nuclear physician representative; and Dr. Jeffrey A. Brinker, as the Committee's first appointed interventional cardiologist. Mr. Hickey then turned the meeting over to Dr. Cerqueira.

After a few more remarks, Dr. Cerqueira began discussing the recommendations by systematically reviewing - with ACMUI input - each paragraph within 10 CFR Part 35, (the Medical Use of Byproduct Material) for which the Subcommittee had recommended changes.

The ACMUI discussion of the recommended changes is detailed in the next section, SYNOPSIS OF RECOMMENDED CHANGES.

**SYNOPSIS OF RECOMMENDED CHANGES**

Remarks: This section gives a brief overview of the changes that each ACMUI Subcommittee member made to the paragraph(s) that (s)he was responsible for revising. Some of these changes are unique to the paragraph(s) within 10 CFR Part 35 that each Subcommittee member amended. However, during the course of the discussion, ACMUI came to unanimous[1] agreement on several changes they believed should be applied universally to the revisions the Subcommittee members made. These universal suggested changes are explained in the section entitled COMMITTEE CONSENSUS.

Paragraph 35.50, Training for Radiation Safety Officer

Dr. Richard J. Vetter was the Subcommittee member who was responsible for the recommended changes to Paragraph 35.50.

Dr. Vetter added Subparagraph (e) to Paragraph 35.50. Subparagraph (e) was added to satisfy the second charge of the Subcommittee, which was to make any modality-specific training requirement a responsibility of licensees and not professional boards. Dr. Vetter explained that 35.50(e) would require licensees to demonstrate to the boards that any prospective radiation safety officer has the necessary training in radiation safety, regulatory issues, emergency procedures, proposed clinical procedures, etc., for any modality for which the licensee is licensed or seeks authorization. Thus, although the boards in themselves would not be directly responsible for this training, their certification processes would need to be able to demonstrate that the licensee is meeting this requirement. Other than what was discussed in COMMITTEE CONSENSUS, ACMUI had no other substantive recommended refinements to Dr. Vetter's changes to this section.

This discussion of training for radiation safety officers begins on Page 8 of the meeting transcript.

Paragraph 35.51, Training for Authorized Medical Physicist

Dr. Jeffrey F. Williamson was the Subcommittee member who was responsible for the recommended changes to Paragraph 35.51.

ACMUI's only substantive suggested refinement to Dr. Williamson's changes was to Paragraph 35.51(c). In that paragraph, ACMUI recommended the inclusion of a list of tasks for which prospective authorized medical physicists (AMPs) must be versed, rather than listing paragraphs that refer to the tasks. ACMUI recommended this change to avoid the possibility that licensees may interpret the listing of the paragraphs as a requirement that prospective AMPs have experience in everything listed in the paragraph, rather than in the specific tasks appropriate to the authorization they are seeking.

[1] Subsequent to the July 8, 2002 meeting, Ralph Lieto, an ACMUI member, registered a vote of dissention on two issues. The first was his objection to several revised paragraphs he believed needed further minor adjustment. Those paragraphs have since been adjusted, with Mr. Lieto's approval. His second objection was to the board criteria in Section 35.50(a) that the ACMUI voted to approve. Mr. Lieto believed that the criteria in 35.50(a), Training for Radiation Safety Officers, may not allow recognition to the American Board of Radiology in certain physics specialties.

This discussion of training for authorized medical physicists begins on Page 57 of the meeting transcript.

Paragraph 35.55, Training for an Authorized Nuclear Pharmacist

Ms. Sally W. Schwarz was the Subcommittee member who was responsible for the recommended changes to Paragraph 35.55.

ACMUI made a couple of substantive suggested refinements to Ms. Schwarz's changes to Paragraph 35.55. One of the suggestions was with regard to the length of training in Paragraph 35.55(b)(3)(a-d). ACMUI indicated that the amount of training was quite lengthy, and thus should probably be represented as "hours" instead of "credit hours." There was also a suggestion that Subparagraph (d) under Paragraph 35.55(b)(3) be deleted because it lists a precise number of credit hours one must obtain in a certificate program. The number of credit hours to obtain a nuclear pharmacy certificate varies slightly from university to university, and several committee members were concerned that requiring what proved to be a rather arbitrary number of credit hours was too prescriptive.

This discussion of training for authorized nuclear pharmacists begins on Page 62 of the meeting transcript.

Paragraph 35.190, Training for Uptake, Dilution, and Excretion Studies; and Paragraph 35.290, Training for Imaging and Localization Studies

Ms. Ruth E. McBurney was the Subcommittee member who was responsible for the recommended changes to Paragraphs 35.190 and 35.290.

With respect to ACMUI's substantive suggested refinements to Ms. McBurney's changes, it was noted that Paragraph (2) in 35.190(b) requires the completion of written and oral exams. Since the professional boards are now moving to administering computer-based exams, ACMUI explained that the prescriptive reference to examinations being administered either written or orally should be removed so as not to exclude exams given in this manner.

As for Paragraph 35.290, ACMUI only recommended small editorial changes similar to those made for 35.190. This discussion of training for authorized users begins on Page 78 of the meeting transcript.

Paragraph 35.390, Training for the Use of Unsealed Byproduct Material for Which a Written Directive Is Required; Paragraph 35.392, Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities less than or Equal to 1.22 Gigabecquerels (33 Millicuries); Paragraph 35.394, Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than or Equal to 1.22 Gigabecquerels (33 Millicuries); Paragraph 35.490, Training for Use of Manual Brachytherapy Sources; Paragraph 35.491, Training for Opthalmic Use of Strontium-90; and Paragraph 35.690, Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Dr. David A. Diamond was the Subcommittee member who was responsible for the recommended changes to these paragraphs.

For Paragraph 35.490, Dr. Diamond indicated that he made a major change by adding a list of residency programs that the licensee must ensure the prospective authorized user completes. The only substantive suggested refinement made by ACMUI was to physically re-arrange the subparagraphs in 35.490 to make the training requirements more clear.

This discussion of training for authorized users begins on Page 34 of the meeting transcript.

**COMMITTEE CONSENSUS**

Remarks: The "remarks" section of SYNOPSIS OF RECOMMENDED CHANGES alluded to several recommended amendments that ACMUI believed should be applied universally to the paragraphs that the various Subcommittee members revised. Since the ACMUI unanimously agreed to these recommended amendments, where appropriate, they apply to all the paragraphs discussed in SYNOPSIS OF RECOMMENDED CHANGES.

Following is an explanation of these suggested amendments:

- The Listing of Boards. In the newly published 10 CFR Part 35, professional medical boards whose certifying processes are acceptable to NRC are not listed; however, ACMUI believed that all boards whose certifying processes are acceptable to NRC should be listed in the rule. Therefore, ACMUI recommended that the Subcommittee further amend their recommendations by listing these boards.

- Board Criteria. The newly published 10 CFR Part 35 lists the criteria that every certifying board should meet. The ACMUI agreed that listing these criteria is important, and suggested the Subcommittee retain this attribute in their amendments to their respective sections within 10 CFR Part 35.

- The Alternate Pathway Option. Detailing an alternate pathway to certifying an individual as an authorized medical physicist, authorized nuclear pharmacist, radiation safety officer, and authorized users was present in the newly published Part 35. The ACMUI agreed that a defined alternate pathway should remain in the rule, and urged the Subcommittee to retain this attribute in their amendments to their respective sections within 10 CFR Part 35.

- The "Competency" Preceptor Statement. The recently published 10 CFR Part 35 mandated that, as part of the training requirement, a preceptor sign a written statement that affirms the competency of the trained individual. However, the ACMUI believed that board certification affirms competency; therefore, no preceptor should be responsible for avowing to this credential. Instead, ACMUI believed it more appropriate that preceptors affirm that the trained individual completed his/her modality-specific training. Therefore, each Subcommittee member agreed to remove any wording that states a preceptor must vouch for the competency of the trained individual, and instead, replace it with a statement that affirms the individual completed the training.

- The Modality-Specific Training Requirement. ACMUI agreed that a person could obtain board certification in a modality, yet have no real practical experience in that modality. To prevent the occurrence of a person with only "book knowledge" freely practicing a modality, the ACMUI believed it necessary to add a modality-specific training requirement. Therefore, each

Subcommittee member agreed to add a statement that requires the prospective radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or authorized user (AU) to obtain modality-specific training.

- Parallel Formatting of Part 35. ACMUI agreed that all paragraphs in their respective sections should be formatted similarly. The suggested formatting is as follows:

  - ✓ Paragraph (a) should list all the boards that gained NRC recognition as certifying entities.
  - ✓ Paragraph (b) should list the criteria that boards must meet to become certifying entities.
  - ✓ Paragraph (c) should display the alternate pathway to becoming an AMP, ANP, AU, or RSO, as appropriate.

The meeting concluded at 3:36 p.m.