briefing book for

the advisory committee on the medical uses of isotopes

Rockville, MD
October 29, 2001

MEMBERS OF THE PUBLIC SIGN IN SHEET
(DO NOT REMOVE THIS FORM)

ACMUI Meeting
October 29, 2001
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3

Please print legibly, as this is a public document.

	NAME		NAME
1	FON S MKLVD, M.D	19	Wayne Powell
2	Laurie Meyers	20	STEPHEN HADDOCK
3	Lynne Fairobent, ACR	21	James A. Baxall
4	Stephanie Coffin, NRC	22	Larry Ayres
5	Al Gorko, VA	23	B. B. Heyliger
6	Rob Forrest	24	DIANE CASE NRC
7	David Gock	25	Patricia Holahan, NRC/NMSS
8	Jeff Bry VA	26	P TRIPURANENI / ASTM
9	Thomas Young	27	
10	Angela Fuccron	28	
11	LARRY CAMPBELL / NRC	29	
12	ALVIN J LOREMAN	30	
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15	Bob Cooper	33	
16	BILL VEFFELMAN	34	
17	Jim Shaffner	35	
18	Richard Hobson	36	

ACMUI SPEAKERS and PARTICIPATING STAFF
October 29, 2001

Robert Ayres, NMSS/IMNS/MSIB

Jeffrey A. Brinker, Society of Cardiac Angiography & Interventions

Frederick Brown, NMSS/IMNS/MSIB

Manuel Cerqueira, ACMUI Chairman

Donald Cool, NMSS/IMNS

Donna-Beth Howe, NMSS/IMNS/MSIB

Geoff Ibbott, University of Texas, M.D. Anderson Cancer Center

Traci Kime, NMSS/IMNS/MSIB

R.K. Leedham, Food and Drug Administration

Jonathan Rivera, NMSS/IMNS/MSIB

Mark Sitek, NMSS/IMNS/MSIB

John Szabo, OGC

Angela Williamson, NMSS/IMNS/MSIB

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 29, 2001
8:00 a.m. - 4:30 p.m.
U.S. Nuclear Regulatory Commission
Two White Flint Building-T2B3
Rockville, Maryland

MEETING AGENDA

8:00 - 8:45	Annual Ethics Briefing (closed session)- John Szabo, NRC Office of the General Counsel
8:45 - 9:00	**BREAK**
9:00 - 9:15	Opening Remarks -Dr. Manuel Cerqueira, Chairman, ACMUI, and John Hickey, NRC Introduction of New Members, Status of Vacancies- Dr. Cerqueira and Mr. Hickey
9:15 - 9:30	Follow-up from April 2001 ACMUI Meeting - John Hickey, NRC
9:30 - 10:00	Part 35 Status/Update - John Hickey, NRC
10:00 -10:15	**BREAK**
10:15 - 11:15	Status of Certification Board Recognitions/Medical Physicist Qualification Criteria -Robert Ayres, NRC
11:15 -12:00	Update on Intravascular Brachytherapy - Donna-Beth Howe, NRC
12:00 - 1:00	**LUNCH**
1:00 - 2:00	Regulation of Mixed Occupational Doses involving both NRC-regulated Material & Fluoroscopy-Frederick Brown, NRC
2:00 - 4:30	Open Discussion as Needed Next Meeting Date and Agenda Topics Meeting Summary Adjourn

ACMUI
January 5, 1995

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

CONTENTS

PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, tand that the resulting reports represent, to the extend possible, the best of which the Committee is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulatins as appropriate.

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the Committee will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with Committee business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the Committee (referred to below as

"the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the committee will review the findings of the Office of the General Counsel regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the committee, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.

2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Commission. The Commission has the final authority for selection. The term of an appointment to the committee is two years, and the Commission has determined that no member may serve more than three consecutive terms.

3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the committee, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations.

5. ADOPTION AND AMENDMENTS

5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.

5.2 Any member of the committee or NRC may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular committee meeting.

5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.

5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.

5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

UNITED STATES NUCLEAR REGULATORY COMMISSION CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(Pursuant to Section 9 of Public Law 92-463)

1. Advisory Committee on the Medical Uses of Isotopes:

   (Committee's Official Designation)

2. Committee's objectives, scope of activities and duties are as follows:

   The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The appointed Chairman of the Committee will conduct all meetings and will prepare minutes summarizing the deliberations of each meeting. The minutes will include the Committee's recommendations for future actions. Subcommittees may be convened to address specific problems when it is not necessary for the full Committee to be present.

3. Time period (duration of this Committee):

   From April 4, 2000, to April 4, 2002

4. Official to whom this Committee reports:

   Donald A. Cool, Director
   Division of Industrial and Medical Nuclear Safety
   Office of Nuclear Materials Safety and Safeguards
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. Agency responsible for providing necessary support to this Committee:

   U.S. Nuclear Regulatory Commission

6. The duties of the Committee are set forth in Item 2 above.

7. Estimated annual direct cost of this Committee

   a. $161,000.000 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 FTE

8. Estimated number of meetins per year:

   Three meetings per year except when active rulemaking is conducted, then five meetings per year.

8. **Estimated number of meetings per year:**

Three meetings per year except when active rulemaking is conducted, then five meetings per year.

9. **The Committee's termination date.**

April 4, 2002

10. **Filing date:**

April 3, 2000

Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the Commission

[Federal Register: September 19, 2001 (Volume 66, Number 182)] [Notices] [Page 48282]
From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr19se01-63]

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes; Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of Meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on **October 29, 2001.** The meeting will take place at the address provided below. All sessions of the meeting will be open to the public with the exception of the first session, which will be closed to provide ethics training for ACMUI members. Topics of discussion in the public session
will include: (1) Status of the new 10 CFR part 35, Medical Use of Byproduct Material; (2) Recognition of Certification Boards; (3) Medical Physicist Qualification Criteria; (4) Intravascular Brachytherapy; and (5) Regulation of Occupational Radiation Doses involving both NRC-regulated Material and Fluoroscopy.

DATES: The public meeting will be held on Monday, October 29, 2001, from 9 a.m. to 4:30 p.m. The closed session will be held from 8 a.m. to 8:45 a.m.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Conference Room T2B3, 11545 Rockville Pike, Rockville, MD 20852-2738.

FOR FURTHER INFORMATION CONTACT: Angela R. Williamson, telephone (301) 415-5030; e-mail arw@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Conduct of the Meeting

Manuel D. Cerqueira, M.D., will chair the meeting. Dr. Cerqueira will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Angela Williamson, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, 11545 Rockville Pike, Rockville, MD 20852-2738. Submittals must be postmarked by October 22, 2001, and must pertain to the topics on the agenda for the meeting.
2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.
3. The transcript and written comments will be available for inspection on NRC's web site (www.nrc.gov) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about December 3, 2001. Minutes of the meeting will be available on or about January 7, 2002.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, part 7.

Dated: September 13, 2001.
Andrew L. Bates,
Advisory Committee Management Officer.
[FR Doc. 01-23332 Filed 9-18-01; 8:45 am]
BILLING CODE 7590-01-P

April 18, 2001 Meeting
Follow-up:

NO HANDOUT PROVIDED

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

October 19, 2001

Angela R. Williamson
U.S. Nuclear Regulatory Commission
Two White Flint North
Mail Stop T8F5
11545 Rockville Pike
Rockville, MD 20852-2738

Re: Advisory Committee on Medical Uses of Isotopes; Announcement of Meeting on October 29, 2001

Dear Ms. Williamson:

The Society of Nuclear Medicine and the American College of Nuclear Physicians (ACNP/ASNM) appreciate the opportunity to provide these comments to the members of the Nuclear Regulatory Commission's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in connection with its meeting scheduled for October 29, 2001. These comments address the agenda item concerning the status of the new 10 C.F.R. Part 35.

As many members of the ACMUI know, ACNP/SNM have long maintained that the NRC's regulations governing the medical use of isotopes are largely an exercise in unnecessary regulation. Our view on this issue is confirmed by the National Academy of Sciences-Institute of Medicine:

> "Compared to the regulatory systems in place for the other 90 percent of medical use of ionizing radiation, the more detailed reporting and enforcement systems required for byproduct materials [subject to NRC regulation] do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public."

National Academy of Sciences-Institute of Medicine, RADIATION IN MEDICINE - A NEED FOR REFORM at p. 171 (1996).

While this is not the time for us to recount in detail the numerous attempts we have made to convince the NRC to adopt a regulatory scheme that bears a meaningful relationship to the very low risks posed by diagnostic nuclear medicine, a brief review is in order. The NAS/IOM Report cited above concluded that:

> [r]egulation of reactor-generated byproducts exceeds in intensity and burden that of all other aspects of ionizing radiation in medicine. The regulation of reactor-generated byproduct material is also more vigorous than that of any other aspect of high-risk health care. It greatly exceeds the regulation of chemotherapy,

surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

The NAS/IOM accordingly recommended that Congress eliminate all aspects of the NRC's medical use program. In an effort to preserve its jurisdiction, the NRC announced that it would begin a major overhaul of its medical use program and adopt a "risk-based" regulatory scheme. Because the risks posed by diagnostic nuclear medicine procedures are minute, we hoped that the NRC would adopt new regulations that would bring meaningful change to the program. Instead, despite a lengthy and expensive rulemaking, the Commission adopted a new Part 35 that is largely a rearrangement of the deck, rather than a new game. Despite the uncontested safety of diagnostic nuclear medicine, it will still be subject to the extreme over-regulation and intrusion into the practice of medicine that the NAS/IOM condemned in 1996. The new Part 35 will do nothing to improve patient or worker safety, yet its implementation will divert dollars from patient care and radiation safety programs.[1]

When the College and the Society complained about the proposed new regulations to the Commission, we were asked to file a citizen petition to propose a more reasonable regulation. In our petition, we noted that:

> The Society and the College, representing 14,000 nuclear medicine physicians, nuclear pharmacists, nuclear medicine technologists, nuclear and medical physicists, radiochemists, radiation biologists and other scientific specialists associated with nuclear medicine, believe that there is no scientific, medical, or public policy basis for most of the Commission's requirements governing diagnostic nuclear medicine. Despite recurring promises to the contrary, the Commission has never adopted a regulatory scheme that matches its requirements to the acknowledged minimal risks posed by diagnostic nuclear medicine. The Commission has spent almost two years revising the regulations governing nuclear medicine in 10 C.F.R. Part 35. Based on the rulemaking documents available to the public, it appears that the revised Part 35, which was supposed to be an enlightened, "risk-informed" regulatory scheme that recognized the minimal risk of diagnostic nuclear medicine, in fact is nothing more than old soup in a new can, somewhat the worse for wear for having been handled too much. Just as the Commission ignored the recommendation of the National Academy of Sciences-Institute of Medicine because it disagreed with them, the Commission staff appears to have completely ignored every significant recommendation made by professional experts board certified in nuclear medicine and nuclear pharmacy. Combined with NRC's increased us of "license conditions" to impose requirements that do not appear in its regulations, the new supposedly "risk-informed" regulations will in fact mark a step backward, not forward. Despite its pledge to adopt a "risk-informed" scheme, the Commission is poised to adopt yet another regulatory scheme that bears no relationship to the risk sought to be protected against, and which will, by its substantial unnecessary costs, adversely

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[1] In addition to ACNP/SNM and the IOM, OMB also has questions about the costs imposed by Part 35. The Director of the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), which could review the paperwork collection requirements of the new Part 35 but not its substance, told Chairman Meserve "that the benefits of regulating medical uses of byproduct materials may not justify the costs of the Part 35 requirements."

impact health care. At a time of ever-increasing demands on limited health care dollars, this approach is unconscionable and must be changed. This is not an insignificant problem. The average American receives 3.8 nuclear medicine diagnostic procedures over his lifetime. The new regulatory product devised by NRC may well adversely affect the entire nation.

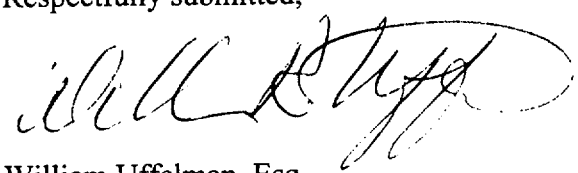
We consider the denial of the petition and the adoption of the new regulations as proof that the NRC is incapable, on its own, of reforming its unrealistic and vastly expensive regulation of diagnostic nuclear medicine. Accordingly, we have asked Congress to intervene, just as the NAS/IOM proposed. Specifically, we have asked Congress to prevent the NRC from implementing the new Part 35 regulations because they are not a meaningful improvement over the current Part 35. As of this writing, the Senate has adopted our proposal; the House bill was passed before we asked for legislative relief so the issue should be resolved by a joint House-Senate conference committee sometime this month. We have taken this action because we strongly believe that the NRC's unnecessarily high level of regulation is ultimately detrimental to patient welfare.

We must disagree with the NRC's public position that the new Part 35 reduces the regulatory burden on medical use licensees. With few exceptions, the requirements that have been removed from Part 35 reappear in the NRC's regulatory guidance and inspection guidance. Although labeled as guidance, these documents impose onerous *de facto* requirements which few licensees have the time or resources to oppose. Indeed, this is part of a continuing trend by the NRC to regulate by the imposition of requirements which have not been adopted through rulemaking.

The action we have taken is the first step in a program whose goal is to assure that the regulation of diagnostic nuclear medicine is appropriate to the very low risk posed by the procedures. We want this done as quickly as possible so that we can all realize the beneficial provisions of the new rule, such as the reduced training and experience requirements. The costs associated with the current level of unnecessary regulation is strangling diagnostic nuclear medicine and will continue to force the closure of nuclear medicine programs, especially in smaller and rural facilities.

We recognize that not all segments of the nuclear medicine community support our position. We have tried to work with our colleagues to assure an outcome that is satisfactory to all concerned. We believe that it is very important for this Advisory Committee to reflect the community it represents and to offer to the Commission advice and comment which reflects the variety of views in that community. We have worked together in the past on behalf of nuclear medicine and we look forward to continuing that relationship.

Respectfully submitted,



William Uffelman, Esq.

Updated Status on NRC Board Recognitions

ACMUI Meeting

October 29, 2001

Board Submissions Previously Discussed with ACMUI

- American Board of Nuclear Medicine
- Board of Pharmaceutical Specialties
- American Board of Medical Physics
- American Board of Health Physics
- American Board of Radiology

Previous Submissions Continued

- American Board of Nuclear Medicine
- American Board of Radiology
- American Board of Science in Nuclear Medicine
- Certification Board of Nuclear Cardiology

Update on Status of Previously Discussed Board Submissions

- American Board of Health Physics
  - Under review
  - Problems with:
    - One year of full-time radiation safety experience with similar types of byproduct materials
    - Written certification of experience signed by a preceptor RSO

American Board of Nuclear Medicine

- Letter to ABNM, dated June 29, 2001, granting NRC recognition for:
  - §35.190
  - §35.290
  - §35.390
  - §35.392
  - §35.394
- Not granting NRC recognition for RSO authorizations under §35.50(a) but pointing out alternative pathway under §35.50(c)

Board of Pharmaceutical Specialties

- Under review
- Written certification of training, signed by a preceptor, remains to be verified

American Board of Medical Physics

- Under review
- Central issue is lack of requirement to complete training for specific modalities:
  - Remote Afterloader
  - Teletherapy
  - Gamma Knife
- AAPM letter

American Board of Radiology

- Requests recognition of board diplomates in each of three specific disciplines:
  - Diagnostic Radiology – 35.190, 35.290, & 35.390 (except (G)(2))
  - Radiation Oncology – 35.392, 35.394, 35.490, 35.491, & 35.690
  - Radiological Physics – 35.50 & 35.51

Status of ABR Issues

- Under review
- Remaining issues:
  - Confirmation of preceptor requirement
  - Medical physicist training on specific modalities
  - RSO qualification under §35.50(a)
- Letter from NRC Chairman

Certification Board of Nuclear Cardiology

- Under review
- Requests recognition of the board diplomats under 35.290
- No outstanding issues – NRC recognition likely

American Board of Science in Nuclear Medicine

- Under review
- Recognition sought for RSO appointments only under §35.50
  - Issues:
    - the 1 year full-time radiation experience
    - RSO preceptor statement
  - Would not qualify under 35.50(c)

Points for Discussion

- Key issues
  - Absence of board requirements to demonstrate specific NRC required training items are met
    - RSO – one year full time medical materials experience
    - Medical Physics – Lack of experience with specific modalities
  - Absence of a requirement for signed preceptor statements in board certification process

Key Issues Continued

- How can such recognitions be accomplished?
  - Can the board(s) alter their certification requirements in the future?
  - What about partial recognitions of board diplomates by NRC?

END

ACMUI MEETING
October 29, 2001

ISSUE: STATUS OF CERTIFICATION BOARD RECOGNITIONS

NRC Contact: Robert L. Ayres, Ph.D.

BACKGROUND: In preparation for the transition to the new 10 CFR Part 35 Rule, "Medical Use of Byproduct Material," the NRC notified, by letter dated June 22, 2000, boards, whose diplomates, under the existing 10 CFR Part 35, automatically fulfill the training and experience requirements, of the new board recognition process. In response, seven of the 12 previously recognized specialty boards (under the present 10 CFR Part 35 regulations) have applied for recognition under the new Part 35 criteria. The status of their applications are summarized as follows:

1. **American Board of Health Physics:** Under review. Issue: The required one year of full-time radiation safety experience,with similar types and uses of byproduct materials, and the written certification of this experience, signed by a preceptor RSO.

2. **American Board of Nuclear Medicine:** NRC response sent by letter, dated June 29, 2001, granting recognition of board diplomates for the following subsections of the new 10 CFR Part 35:

§35.190	Training for uptake, dilution, and excretion studies;
§35.290	Training for imaging and localization studies;
§35.390	Training for use of unsealed byproduct material for which a written directive is required;
§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); and,
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than1.22 gigabecquerels (33 millicuries).

However, the ABNM's request for recognition under §35.50(a) was not granted, based on their lack of a requirement for one year of full-time RSO experience and corresponding lack of an RSO preceptor requirement. It was, however, pointed out that their diplomates had an alternative pathway for appointment as an RSO under §35.50(c).

3. **Board of Pharmaceutical Specialties:** Under review.

4. **American Board of Medical Physics:** Under review. Issue: Lack of requirement to complete training for specific modalities: remote afterloader, teletherapy, gamma knife. See attached AAPM letter.

5. **American Board of Radiology:** The ABR has applied for recognition as follows:

A. Certification in Diagnostic Radiology:

§35.190	Training for uptake, dilution, and excretion studies;
§35.290	Training for imaging and localization studies; and,
§35.390	Training for use of unsealed byproduct material for which a written directive is required.

B. Certification in Radiation Oncology:

§35.390	Training for use of unsealed byproduct material for which a written directive is required;
§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 gigabaecquerels (33 millicuries);
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than1.22 gigabaecquerels (33 millicuries)
§35.490	Training for the use of manual brachytherapy sources;
§35.491	Training for ophthalmic use of strontium-90; and,
§35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

C. Certification in Radiologic Physics:

§35.50	Training for Radiation Safety Officer; and,
§35.51	Training for an authorized medical physicist.

Status: Under review. Issues: (1) confirmation of preceptor requirement and (2) for medical physicists training on specific modalities.

6. **Board of Nuclear Cardiology:** This board has applied for NRC recognition under §35.290 only. The staff's review of this application indicates that this board meets all of the criteria for recognition and that the board's application for NRC recognition should be granted.

7. **American Board of Science in Nuclear Medicine:** This board has applied for RSO certification recognition only. Under review. Issues: Same as for ABHP.

POINTS FOR DISCUSSION:

- Key issues
  - Absence of board requirements to demonstrate specific NRC required training items are met
    - RSO - one year full time medical materials experience
    - Medical Physics - Lack of experience with specific modalities
  - Absence of a requirement for signed preceptor statements in board certification processes

- How can such recognitions be accomplished?
  - Can the board(s) alter their certification requirements in the future?
  - What about partial recognitions?

American Association of Physicists in Medicine

Office of the President
Charles W. Coffey, II, Ph.D.
Vanderbilt Medical Center
Radiation Oncology Dept.
B902 Vanderbilt Clinic
Nashville, TN 37232-5671
Phone: 615-322-2555 Fax: 615-343-0161
E-mail: charles.coffey@mcmail.vanderbilt.edu

September 28, 2001

Dr. Donald A. Cool
Director,
Division of Industrial and
Medical Nuclear Safety
U.S. NRC
Two White Flint North
11545 Rockville Pike,
Mail Stop T8F5
Rockville, MD 20852-2738

Dear Dr. Cool:

Please find enclosed a statement that addresses the American Association of Physicists in Medicine's (AAPM) concerns about the interpretation of the new Part 35, as it pertains to Authorized Medical Physicists. The AAPM strongly believes that board certification is essential to becoming a Qualified Medical Physicist and should not be diminished, as you implement new training and experience guidelines.

Sincerely,

Charles W. Coffey II

Charles W. Coffey, II
President

Authorized Medical Physicists under the New Part 35 – Proposal from the American Association of Physicists in Medicine

Introduction

A strict interpretation of the new Part 35 would diminish the importance of board certification for medical physicists, as board certification alone would not be a sufficient justification for the U.S. Nuclear Regulatory Commission (NRC) to certify an individual as an Authorized Medical Physicist (AMP). This is based upon the assumption that the American Board of Radiology (ABR), which will soon be the only board offering certification in radiation oncology physics, will not require candidates to have explicit experience with Co-60 units and high dose rate remote afterloading units and gamma stereotactic units. In recognizing Board certification as a pathway for certifying an individual as an AMP, the NRC expects that the ABR certification process include all of the training and experience requirements in paragraph (b) of 35.51. The training and experience requirements include a graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in:

35.67 Requirements for possession of sealed sources and brachytherapy sources

35.632 Full calibration measurements on teletherapy units
35.633 Full calibration measurements on remote afterloader units

36.635 Full calibration measurements on gamma stereotactic radiosurgery units
35.642 Periodic spot checks for teletherapy units
35.643 Periodic spot checks for remote afterloader units

35.645 Periodic spot-checks for gamma stereotactic radiosurgery units

35.652 Radiation Surveys

It is expected that physicists, who are currently covered by NRC licenses, would be grandfathered to become AMP's. However, it is not clear how the NRC will handle the situation where a physicist is authorized for HDR, but whose name is not on a teletherapy license or a gamma stereotactic license. It is expected that new physicists would have to meet the above requirements. Under a strict interpretation, board certification would assume secondary importance, as medical physicists would focus on meeting these new regulatory training and experience requirements.

The NRC is focused on implementing this new rule and is not interested in considering changes to it. It is possible to petition for new rule making, but that would take 1.5 to 2 years to accomplish.

There is a consensus definition of a qualified medical physicist (QMP) ,namely a physicist who is board certified and who meets continuing education requirements. This certainly represents an industry standard for a QMP. The American Association of Physicists in Medicine, the American College of Medical Physics, and the American College of Radiology have adopted this concept. (There are minor differences in the exact statement of the various organizations.)

Possible Solutions

The AAPM requests that the NRC define at least three sub-categories of AMP, namely, teletherapy AMP, remote afterloading AMP, and gamma stereotactic AMP.

The AAPM requests that the NRC clarify the situation with respect to physicists who are currently named on licenses for one or two of these categories, but not all three categories.

The AAPM proposes the following criteria for use by NRC staff to evaluate applications from medical physicists to be named Authorized Medical Physicists.

Teletherapy AMP

Board certified physicist

One independent calibration of a Co-60 teletherapy unit and one independent monthly spot check. Calibration and spot check to be signed off on by a teletherapy AMP

OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a Co-60 teletherapy unit

Non-board certified physicist

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a Co-60 teletherapy unit

Remote Afterloading AMP

Board certified physicist

One independent calibration of a remote afterloading unit and one independent monthly spot check. Calibration and spot check to be signed off on by a remote afterloading AMP.

OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a remote afterloading unit

Non-board certified physicist

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a remote afterloading unit

Gamma stereotactic AMP

Board certified physicist

One independent calibration of a gamma stereotactic unit and one independent monthly spot check. Calibration and spot check to be signed off on by a gamma stereotactic AMP.

OR

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a gamma stereotactic unit

Non-board certified physicist

A graduate degree and completion of one year full time training in therapeutic radiological physics and an additional year of full time practical experience under the supervision of a medical physicist at a medical institution uses a gamma stereotactic unit

The justification for only one independent calibration and spot check for a board certified physicist is that board certification is a judgment by peers that a physicist has demonstrated minimum standards in his/her sub-specialty area and that a peer reviewed demonstration that the individual has understood the details associated with calibration or spot checks for that device. The board certified medical physicist could avoid the efforts of a peer reviewed calibration and spot check by meeting the same education and training requirements of the non-board certified physicist. The requirements for the non-board certified physicist are those found in Part 35.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

May 3, 2001

William R. Hendee, Ph.D
Senior Associate Dean and Vice President
Office of Research, Technology and Informatics
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, Wisconsin 53226

Dear Dr. Hendee:

I am responding to your letter of March 26, 2001, requesting answers to questions previously raised about the upcoming revision to 10 CFR Part 35, "Medical Use of Byproduct Material." It is my understanding that in response to a previous letter from you to Dr. Donald Cool, dated September 15, 2000, and a letter from Dr. M. Paul Capp, dated December 26, 2000, acknowledgment letters with interim replies were sent on October 27, 2000, and March 8, 2001. Delays in responding fully to your questions were a result, in part, of the staff's desire to complete the final rulemaking package prior to responding.

The Part 35 rulemaking package was submitted to the Office of Management and Budget (OMB) on March 16, 2001, for review of recordkeeping and reporting requirements. The staff has prepared the enclosed answers to your questions based on the rule text currently under review by OMB.

I appreciate your efforts to bring these questions to our attention. During this rulemaking process, the Commission has placed a high priority on obtaining input from the medical community and other stakeholders, and this process has been helpful and constructive.

If you have any further questions, please contact me.

Sincerely,

Richard A. Meserve

Enclosure: Staff Responses to
Questions on Part 35

cc: Dr. M. Paul Capp, ABR

STAFF RESPONSES TO QUESTIONS FROM THE AMERICAN BOARD OF RADIOLOGY ON THE UPCOMING REVISION OF 10 CFR PART 35, BASED ON THE RULE TEXT PROVIDED TO THE OFFICE OF MANAGEMENT AND BUDGET FOR REVIEW ON MARCH 16, 2001

Question 1: For American Board of Radiology (ABR) certification in Medical Nuclear Physics, would the three years of clinical experience obtained under the supervision of a Radiation Safety Officer (RSO) satisfy the requirement for one year of full-time radiation safety experience specified in § 35.50(b)(1)(ii)?

Response 1: Yes, under certain conditions. The ABR needs to make a determination whether all candidates who meet the three-year clinical experience requirement also meet the one-year radiation safety experience requirement, and whether the associated preceptor statement certifies that the one-year requirement has been met. In this regard, we would accept an ABR finding that the *radiation safety experience* obtained over three years of clinical experience will in all cases be equivalent to one-year of full-time radiation safety experience.

Question 2: For ABR certification in Therapeutic Radiological Physics, does a medical physicist who meets the requirements in 10 CFR 35.51(b) also meet the requirements in § 35.50(b) for an RSO?

Response 2: Yes, in some cases. According to the description provided by ABR, only some physicists who meet § 35.51 also meet § 35.50. Therefore, certification under §35.51 would not necessarily ensure qualification as an RSO under § 35.50. However, note that 10 CFR 35.50(c) allows an authorized medical physicist, who is both identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material, to be appointed as an RSO.

Question 3: For ABR certification in Radiation Oncology under 10 CFR 35.390, 35.392, 35.394, 35.490, 35.491, and 35.690, does a candidate have to obtain the specified hours of work experience separately for each category? For example, to meet the qualifications for both §§ 35.490 and 35.690, does a candidate have to obtain 1000 hours of work experience?

Response 3: No. The hours of work experience do not have to be obtained separately for each modality of medical use in the regulations cited. A candidate could qualify under both §§ 35.490 and 35.690, if: (1) he or she has at least 500 hours of work experience which includes all the topics listed under paragraph (b)(1)(ii) of each section; (2) the work experience is obtained under the supervision of an authorized user who meets the requirements in each section; and (3) the appropriate written preceptor certifications are obtained from preceptors who meet the requirements for an authorized user for each type of use for which the candidate is requesting authorized user status.

5876

Office of Research, Technology and Informatics
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: 414/456-4402
FAX: 414/456-6554
e-mail: whendee@mcw.edu

March 26, 2001

Richard A. Meserve
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Dick:

I hope you will recall our work together on the advisory board for the CASE (Court-Appointed Scientific Experts) project of the American Association for the Advancement of Science. You will be pleased to know that the project has evolved nicely, although we miss your input to the advisory board.

I am writing you to see if you can help the American Board of Radiology obtain answers to questions it has asked about proposed revisions in 10 CFR 35 " Medical Use of Byproduct Material." I am enclosing letters from Dr. Capp (Executive Director of the American Board of Radiology) and myself (Vice President of the American Board of Radiology). These letters, addressed to Mr. Cool of the Commission on September 15, 2000 and December 26, 2000, raise questions about the interpretation of 10 CFR 35. These questions affect how the Board responds to the Commission's inquiry of whether the certification process of the American Board of Radiology satisfies the Commission's education and training requirements.

We have not heard from Mr. Cool in response to either of our letters. Hence, the issues we have raised remain unanswered, and we remain uncertain about certain aspects of our answers to the Commission's inquiry. Would you be able to help us acquire answers to our questions?

Best regards – and please extend my greetings to Greta Dicus on the Commission.

Sincerely,

Bill

William R. Hendee, Ph.D.
Senior Associate Dean and Vice President

Cc: M. Paul Capp, M.D.
Robert R. Hattery, Jr. M.D.
Philip O. Alderson, M.D.
Guy H. Simmons, Ph.D.
Lawrence W. Davis, M.D.
Anthony V. Proto, M.D.

MEDICAL COLLEGE OF WISCONSIN

Office of Research, Technology and Informatics
8701 Watertown Plank Road
Milwaukee, WI 53226
Phone: 414/456-4402
FAX: 414/456-6554
e-mail: whendee@mcw.edu

September 15, 2000

Donald A. Cool
Director, Division of Industrial and Medical Nuclear Safety
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Cool:

I am writing in response to your letter of June 22, 2000 to Dr. Paul Capp of the American Board of Radiology (ABR). Your letter, and the Draft Final Regulatory Text: Training and Experience Criteria, were the subject of intense discussion among trustees of the ABR at our meeting in Santa Fe on September 8-10, 2000. This discussion yielded two questions that must be answered before the ABR can completely address the issues raised in your letter. These two questions are:

35.50: Training for Radiation Safety Officer
Medical physicists frequently serve as Radiation Safety Officers in healthcare institutions. To be eligible for ABR certification in Medical Nuclear Physics, a physicist must have a graduate degree in medical physics or related discipline, and 3 years of clinical experience. The educational requirements for certification include all of the items in (b.1.i), and the three years of clinical experience include all of the items in (b.1.ii.A-G). The three years of clinical experience are obtained under the supervision of a Radiation Safety Officer. However, the experience is usually embedded within a set of clinical responsibilities that extend beyond the specific duties of a Radiation Safety Officer. Strict interpretation of Section 35.50 could imply that such individuals would not satisfy the requirement of one year of full-time radiation safety experience. We wish to know whether the educational and clinical experience of a physicist eligible for certification in Medical Nuclear Physics will be interpreted by the Nuclear Regulatory Commission as satisfying the requirement of one year of full-time radiation safety experience.

35.51: Training for an Authorized Medical Physicist
Medical physicists who are certified in Therapeutic Radiological Physics by the ABR satisfy the requirements described in (b)(1) to be authorized medical physicists for therapeutic medical units as described in (b)(2). Some physicists certified in Therapeutic Radiological Physics also meet the education and clinical experience requirements described in 35.50, with the possible exception of one year of full-time experience in radiation safety, as described in the preceding paragraph. We wish to know whether these physicists satisfy the requirements of the Nuclear Regulatory Commission to serve as an institutional Radiation Safety Officer.

We look forward to your response to these two questions.

Sincerely,

William R. Hendee

William R. Hendee, Ph.D.
Senior Associate Dean and Vice President
Vice President, ABR

cc: Philip O. Alderson, M.D.
M Paul Capp M.D.
Ms. C. Haney
Guy H. Simmons, Ph.D.

December 26, 2000

Donald A. Cool
Director of Industrial and
Medical Nuclear Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Dr. Cool:

This is an official response from the American Board of Radiology to your letter of June 22, 2000 regarding the revision of your medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." The American Board of Radiology grants certification in three specialties: Diagnostic Radiology, Radiation Oncology, and Radiologic Physics. Consequently, the ABR response is by each of the specific disciplines.

Certification in Diagnostic Radiology:

- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.190 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by this board

- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.290 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Diagnostic Radiology has reviewed 10 CFR 35.390 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board. However, at the present time we would restrict 35.390 toward the "low dose" portion of this directive to not include (G) (2) "Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131.

Certification in Radiation Oncology:

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.390 and has determined that our

certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.392 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.394 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.490 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.491 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Radiation Oncology has reviewed 10 CFR 35.690 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

However, we have some serious concerns regarding the interpretation of the document. This regards the specific number of hours that authorized users must have received. We would have no problem in addressing (b)(2) of section 35.490. However, at the present time many radiation oncology residency programs would not be able to meet the specific requirements of (b)(1)(ii) requiring 500 hours of work experience in each of the areas listed above. I have attached a letter from David H. Hussey, MD, who is a trustee of the ABR and Chair of the Radiation Oncology Examination Committee, that was sent to Dr. Sam Jones. We would need further clarification of this problem.

Certification in Radiologic Physics:

- The American Board of Radiology by its certification in Medical Nuclear Physics has reviewed 10 CFR 35.50 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

- The American Board of Radiology by its certification in Therapeutic Radiologic Physics has reviewed 10 CFR 35.51 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board.

However, a strict interpretation of 35.50 could imply that current physicists in training under the supervision of a radiation safety officer may not satisfy the requirement of one year of full-time radiation safety experience.

This could be true for physicists training in both Medical Nuclear Physics as well as Therapeutic Physics. I have included a letter from William R. Hendee, PhD, a physicist trustee of the American Board of Radiology that was sent to you dated September 15, 2000.

The American Board of Radiology has always enjoyed a good relationship with the Nuclear Regulatory Commission in abiding by NRC Guidelines. We hope this relationship continues in the future, and we look forward to hearing from you regarding the above concerns.

Best regards.

Sincerely,

M. Paul Capp. M. D.

MPC/sd

enclosures

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 29, 2001

The American Board of Nuclear Medicine
ATTN: Dr. Ronald L. Van Heertum, Chairman
900 Veteran Avenue
Los Angeles, CA 90024-1786

Dear Dr. Van Heertum:

I am replying to your letters dated July 10, 2000, and November 29, 2000, to Donald Cool, requesting formal recognition, under the new 10 CFR Part 35, "Medical Use of Byproduct Material", for American Board of Nuclear Medicine (ABNM) diplomates.

In your letter of July 10, 2000, you stated that the ABNM certification process meets all of the requirements of the following subsections of new 10 CFR Part 35:

§35.190	Training for uptake, dilution, and excretion studies;
§35.290	Training for imaging and localization studies;
§35.390	Training for use of unsealed byproduct material for which a written directive is required;
§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 gigabaecquerels (33 millicuries); and,
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than1.22 gigabaecquerels (33 millicuries).

We have reviewed your request, and concluded that the ABNM certification process, as described in your letter and your board's application requirements, does meet the new requirements for each of the requested subsections listed above for which you are requesting recognition. In particular, your required "Evaluation of Clinical Competence" certification requirement would appear to meet the individual subsection requirements for written certification, signed by a preceptor authorized user, that the diplomate has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses defined in the five subsections for which you have applied for recognition. After Part 35 is issued in final form, we plan to list on our web site the boards which have been recognized. We will include ABNM on that list.

In your letter of November 29, 2000, you also requested Commission recognition of ABNM diplomates under 10 CFR 35.50(a) for Radiation Safety Officer (RSO), which requires the board certification process to include all of the requirements in §35.50(b). Our review of this request, along with your board's certification process, does not show that your process includes either: (1) the requirement for one year of full-time radiation safety experience under the supervision of

an RSO; or, (2) written certification, signed by a preceptor RSO that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee. Thus, at this time, your board certification process does not meet the requirements of 10 CFR 35.50(a) for an RSO.

However, since your board diplomates are recognized by the Commission to be authorized users, they can be appointed RSO's under §35.50(c) if they are identified on a medical use license and have radiation safety experience with similar types of use of byproduct materials for which the individual has radiation safety responsibilities. Also, an ABNM certified individual can still be authorized as an RSO at a medical use licensee facility, if: (1) the licensee submits a license amendment request which demonstrates that the person meets the criteria specified in the new §35.50(b); or (2) the person is currently listed as an RSO at a medical use licensee facility as specified in the new §35.57(a).

If you have any questions, please contact Dr. Robert Ayres at 301-415-5746 or e-mail at rxa1@nrc.gov .

Sincerely,

John W. Hickey, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety

Presentation to the Advisory Committee on Medical Use of Isotopes

Geoffrey S. Ibbott, Ph.D.
on behalf of
The American Association of Physicists in Medicine (AAPM)
and the American College of Radiology (ACR)

Qualified Medical Physicist

- Consensus definition of qualified medical physicist = board certification plus meeting continuing education requirements
- Definition, in concept, adopted by the AAPM, ACR and the American College of Medical Physics

Board Certification

- Under the board certification pathway, NRC expects board certification to include all training and experience requirements as specified in 10 CFR §35.51(b).
- Strict interpretation of 10 CFR §35.51(b) may diminish the importance of board certification.

Board Certification

- Board certification is the only widely accepted credentialing system for clinical physicists.
- Current boards do not require explicit experience with Co-60 teletherapy, high dose rate afterloading units and gamma stereotactic units.

Board Certification

- Any regulatory move that diminishes the incentive to become board certified jeopardizes public health.
- AAPM and ACR urge NRC to accept board certification as a default pathway for complying with many individual requirements in 10 CFR §35.51(b).

Grandfathering Current Medical Physicists

- In accordance with 10 CFR §35.57 previously and currently licensed medical physicists = AMP under new regulation without limitation on their scope of practice.

Single AMP Category

- Due to limited number of facilities utilizing Co-60 teletherapy and radiosurgery, it may not be practical for all AMPs to have training and experience in all modalities.
- Sub-category AMPs should be defined emphasizing importance of board certification.

Possible Solutions

- NRC should define three sub-categories of AMP
  - –Teletherapy AMP
  - –Remote afterloading AMP
  - –Gamma stereotactic AMP

Teletherapy AMP

- **Board certified** plus independently perform one full calibration of a Co-60 teletherapy unit and one monthly spot check under the supervision of a teletherapy AMP, or

Teletherapy AMP

- **Non-certified medical physicist** must have a graduate degree and one year full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a facility using Co-60 teletherapy unit.

Remote Afterloading AMP

- **Board certified** plus independently perform one full calibration of a remote afterloading unit and one spot check under the supervision of a remote afterloading AMP, or

Remote Afterloading AMP

- **Non-certified medical physicist** must have graduate degree and one year full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a facility using remote afterloading unit.

Gamma Stereotactic AMP

- **Board certified** plus independently perform one full calibration of a gamma stereotactic unit and one spot check under the supervision of a gamma stereotactic AMP, or

Gamma Stereotactic AMP

- Non-certified medical physicist must have a graduate degree and one year full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a facility using gamma stereotactic unit.

Conclusion

- AAPM and ACR believe that the importance of board certification should not be diminished by implementation of the new 10 CFR part 35.
- AAPM and ACR are willing to work with ACMUI and the NRC staff to develop guidance for implementing the requirements of 10 CFR § 35.51.

ACMUI MEETING

October 29, 2001

Issue: Intravascular Brachytherapy Licensing Guidance and Possible Misadministrations.

NRC Contact: Donna-Beth Howe, Ph.D.

BACKGROUND: NRC provided generic guidance to its regions January 26 and February 5, 2001. This guidance was revised June 12, 2001 following discussions during the last ACMUI meeting and with the FDA.

The major differences between the earlier and revised guidance are:

- The authorized use is not restricted to the procedures in the labeling reviewed and approved during the FDA premarket approval (PMA) process.
    - The use is not restricted to in-stent restenosis of the native coronary arteries
    - Source stepping would be permitted if the licensee established appropriate procedures in accordance with 10 CFR 35.32(2) to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user.
- The physical presence requirement was revised to ensure at least one individual with the appropriate radiation safety experience (i.e., the authorized user or the medical physicist) is physically present during radiation administration.
- The cover letter to the licensee reminds the licensee that source separations during treatment should be evaluated as possible misadministrations.

Possible Misadministrations:

-Aug 17, 200	During Sr-90 procedure the authorized user could not visualize end of the source train and the sources were successfully retracted. The manufacturer determined particulate material in the fluid lumen of the device caused blockage and prevented part of the source train from exiting the device.
-Jan 26, 2001	During the Sr-90 dwell time, the fluid syringe needed to be exchanged, but the inability to reinsert second syringe into port resulted in the decision to abort the procedure.
-Aug 27, 2001	Not all Sr-90 sources returned to the IVB applicator. Second attempt to remove sources to applicator failed and catheter was removed.
-Sept 26, 2001	Sr-90 sources stuck at kink in catheter and sources did not go to treatment site. The authorized user and cardiologist were not certain they could see proximal and distal markers but confirmed sources were in chest. Catheter was removed and new catheter used.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 12, 2001

Generic Use
Publicly Available

MEMORANDUM TO: George C. Pangburn, Director
Division of Nuclear Materials Safety, RI

Douglas M. Collins, Director
Division of Nuclear Materials Safety, RII

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety, RIII

Dwight D. Chamberlain, Director
Division of Nuclear Materials Safety, RIV

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: REVISED GUIDANCE FOR LICENSING INTRAVASCULAR BRACHYTHERAPY PROCEDURES

This memorandum provides revised guidance for licensing intravascular brachytherapy (IVB) procedures. It supersedes my memorandums dated January 26 and February 5, 2001.

The attached guidance should be used in reviewing medical use applications requesting authorizations for IVB procedures. The key changes from the previous guidance include: (1) licensees are not limited to procedures involving coronary arteries, (2) physical presence requirements have been modified, and (3) the source strength authorization for the Novoste device has been increased.

Attachment: Revised IVB Licensing Guidance

CONTACTS: John Hickey or Robert Ayres, NMSS/MSIB
(301) 415-5746

Attachment

(Revised 6/12/01)
Guidance to NRC Regions for Licensing
Cordis and Novoste Intravascular Brachytherapy Systems

NRC Contacts: John Hickey and Robert Ayres, 301-415-5746

General approach: License as a brachytherapy procedure pursuant to an exemption from 35.400, "Use of sources for brachytherapy". Intravascular brachytherapy (IVB) is not listed in 35.400 as an authorized use. Therefore, an exemption from this provision of Part 35, "Medical Use of Byproduct Material", is being issued by license condition, pursuant to 10 CFR 35.19. This exemption is based on a finding that it is authorized by law, and will not endanger life or property or the common defense and security, subject to the additional license conditions discussed below.

The exemption does not relieve the licensee from compliance with the other requirements of 10 CFR Part 35. In particular, 10 CFR 35.32, "Quality management program", requires licensees to establish and maintain a written quality managment program to provide high confidence that radiation from byproduct material will be administered as directed by the authorized user. [Note: "Source stepping" is permitted, if the licensee establishes appropriate procedures in accordance with 10 CFR 35.32(a). Source stepping procedures are not covered by the manufacturers' instructions, so the licensee could not merely follow the manufacturer's instructions if the licensee chooses to conduct source stepping.]

Note that, because IVB is a new technology, and the devices deliver high dose rates (greater than 1200 rads per hour), certain training and physical presence guidance is included.

The authorized use is not restricted to procedures reviewed and approved by FDA as part of the FDA pre-market approval (PMA). Note that 35.7 states that nothing in Part 35 relieves a licensee from complying with applicable FDA, other Federal, and State requirements.

A. IVB Guidance for Limited Specific Use Medical Licensees

1. Conditions for both Cordis and Novoste Systems

–Commit that authorized users will meet the training and experience requirements in 10CFR 35.940, "Training for use of brachytherapy sources".

–Commit that the authorized user, interventional cardiologist/physician, and medical physicist will receive the vendor training for use of the device.

–Commitment or license condition as follows: Procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and medical physicist prior to initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the medical physicist.

–Commit that prior to treatment, the written directive will specify treatment site, the radionuclide, and dose.

–Commit to independent measurement of source output by the medical physicist, prior to the first patient treatment.

–Commit to developing, implementing, and maintaining written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

2. Conditions for the Cordis System

–Commit that source trains will not be used after the "use by" date.

–Applicant should submit calculations and/or measurements demonstrating compliance with Part 20 requirements, and guidance on the use of portable shields, as appropriate.

–License condition 8 should read (for each ribbon set requested): No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10, or 14 seeds per ribbon, 1.1 curies total (per set)

–License condition 9 should read: Notwithstanding the requirements of 10 CFR 35.400, for use in the Cordis Checkmate Catheter System for intravascular brachytherapy.

--Cover letter should state that the licensee's Quality Management Program should be revised as appropriate.

3. Conditions for the Novoste System

–In order to protect the radiation safety of patients and to reduce the risk of misadministrations, commit to use of an introducer sheath, unless such use is contraindicated for an individual patient.

–In order to protect the radiation safety of patients and to reduce the risk of misadministrations, commit to use of a dual syringe system, unless such use is contraindicated for an individual patient.

–Commit to locked storage of the storage container in a secure location.

–Commitment or license condition that the device shall be inspected and serviced at intervals recommended by the manufacturer, and that maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

–License condition 8 should state: 12 sources per train, not to exceed 4.2 millicuries mean activity per source, 51 millicuries total. (for each source train requested by applicant)

Note: As of May 15, 2001, the FDA Pre-Market Approval (PMA) allows Novoste to distribute Model A1732 devices with source trains up to 48 millicuries, with a maximum mean source activity of 4.0 millicuries per source. The license authorization of 4.2 millicuries mean source activity and 51 millicuries total allows for measurement variations between Novoste and the licensee users.

–License condition 9 should read: Notwithstanding the requirements of 10 CFR 35.400, for use in Novoste Beta-Cath System Model A1732 devices for intravascular brachytherapy.

–Cover letter should state that: (1) the licensee's Quality Management Program should be revised as appropriate, and (2) source separations during treatment should be evaluated as possible misadministrations.

–Note: Shielding calculations are not necessary for areas outside the treatment room and device storage areas, because Sr-90 is a beta emitter.

B. IVB Guidance for Medical Broad Licensees

–If the medical broad license already covers possession of the radioactive material, then no amendment is required to authorize intravascular brachytherapy. Note that condition 9 of broad medical licenses does not limit brachytherapy uses to those listed in 35.400.

–If the medical broad license possession limits do not cover the radioactive material, then the possession limits can be amended accordingly by the licensing staff.

NMED 010537 Event Details

ABSTRACT: The licensee reported a medical event involving a patient undergoing intravascular brachytherapy with the Novoste Beta-Cath System. The patient was scheduled to receive 2,300 cGy (rad) from a 261 second treatment using a seed train containing 16 Sr-90 seeds. Introduction of the seed train was being followed under fluoroscopic control. The gold tip became visible; however, the end tip did not. The seed train was immediately retracted without incident. The licensee estimated that five of the 16 seeds exposed the area for three seconds. The radiation dose to this area was calculated to be 8.26 cGy (rad). This represents an underdose of 99.6%. This dose was considered to be insignificant by the authorized radiation oncologist. The patient was successfully treated by another licensee and given the rest of the dose. The Novoste System was returned to the manufacturer for analysis. The manufacturer determined that there was particulate material in the fluid lumen of the transfer device. The particulate material resulted in the blockage, which prevented a portion of the radiation source train from exiting the device. Novoste supplies each transfer device with a protective quartz cap, and places it within a latched source container to minimize contamination. Each transfer device is functionally evaluated to ensure there is no blockage in the hydraulic system prior to device release and shipment to customers. It appears that the particulate material most likely occurred at the licensee's facility and this event does not constitute a failure of the device. The Massachusetts Radiation Control Program determined that a misadministration did not occur in the event due to the underdosage to intended tissue and the fact that the treatment was successfully completed at another licensee authorized site. The reportability status for the medical event has not yet been determined by the NRC.

Event Date	Discovery Date	Report Date
08/17/2000	08/17/2000	08/18/2000

Licensee / Reporting Party Information:
Agreement State Regulated: YS
Reciprocity: NONE
License Number: MA-44-0044
Licensee: BRIGHAM & WOMEN'S HOSPITAL
Docket: NA
City: BOSTON
Program Code: NA
State: MA
NRC Region Office: 1

NMED 010547 Event Details

ABSTRACT: The licensee reported a medical event involving a patient that received a 40% under treatment during a brachytherapy procedure. A brachytherapy procedure was requested to prevent in-stent restenosis of the patient's coronary artery. The prescribed dose for the patient was 1,840 cGy (rad) using a Novoste beta-cath device. The activity of the Sr-90 source was 2.05 GBq (55.4 mCi). The patient's referring physician placed the guiding catheter in the lesion and then the oncologist placed the active source in the beta-cath device. During the source dwell time, the fluid syringe needed to be exchanged. This was not accomplished in a timely fashion. The inability to reinsert the second syringe into the port led to the decision to abort the procedure and that time. The emergency source recovery procedure was followed. The patient received 1,110 cGy (rad). No adverse impact on the patient is expected. The physicians were notified of the event. This was
the first time the referring physician had used this beta-cath device. Additional training was given by the manufacturer and it has been used since then without any problems.

Event Date	Discovery Date	Report Date
01/26/2001	01/26/2001	02/15/2001

Licensee / Reporting Party Information:
Agreement State Regulated: YES
Reciprocity: NONE
License Number: TN-R-19001-B98
Licensee: SAINT THOMAS HOSPITAL
Docket: NA
City: NASHVILLE
Program Code: NA
State: TN
NRC Region Office: 2

Event # 38384 PARK VIEW HOSPITAL REPORTED A MEDICAL MISADMINISTRATION

During an intravascular bracytherapy treatment with strontium-90 to a heart artery, a possible medical misadministration occurred at the completion of the treatment. At the conclusion of this treatment, not all the sources returned to the Novoste applicator. The sources were seen to have left the vessel and heart within the appropriate time(5 sec), but they did not all return to the device. Another attempt to remove the sources was made, but was unsuccessful, so the entire treatment catheter was removed(within 18 secs) from the patient as per their emergency procedures. The physician and manufacturer of the device did not consider this as a medical misadministration, however an NRC inspector felt that it was for that additional 18 secs to remove the treatment catheter. This incident occurred 8/27/01. It was decided not to notify the patient because of the patient's condition.

September 28, 2001

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-01-042

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region IV staff on this date.

Facility
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813
Docket: 03014522
License: 531653302

Licensee Emergency Classification
___ Notification of Unusual Event
___ Alert
___ Site Area Emergency
___ General Emergency
_X_ Not Applicable

SUBJECT: MEDICAL MISADMINISTRATION

DESCRIPTION: At 10:07 p.m. (EDT) on September 26, 2001, the licensee's Radiation Safety Officer notified the NRC Operations Center that a medical misadministration occurred at The Queen's Medical Center in Honolulu, Hawaii earlier that day when a patient undergoing a intravascular brachytherapy (IVB) procedure for restenosis of a cardiac vessel received a dose of 23 gray (2300 rads) to an unintended treatment site.

The patient was treated using the Novoste BetaCath system. The intent was to deliver 23 gray to the patient's right coronary artery. Following the established procedure, the treatment segment of the BetaCath was positioned in the angiography catheter using fluoroscopy. The source train was then deployed into the patient. Because the radiation oncologist and cardiologist were not certain they could see the proximal and distal markers of the source train on the fluoroscopy monitor, the physicist performed a radiation survey and confirmed that the source train was in fact in the patient's chest. The treatment then proceeded with fluoroscopy checks being conducted every 30 seconds. At the end of the treatment, the source was retracted. Following retraction of the source, the radiation oncologist and cardiologist decided to re-check the delivery pathway to ensure the source indeed reached the proper position. The source was deployed and the cardiologist opened the fluoroscopy field of view to pan the patient's chest. It was then that the cardiologist observed that the source train was stuck at a bend in the patient's aortic arch. Consequently, this caused the treatment to be given to the wrong site. The cardiologist then removed both the BetaCath and the catheter and observed that the catheter was kinked at a distance corresponding to the aortic arch. A new catheter was inserted and the intended treatment was delivered successfully.

It appears that the direct cause of the misadministration was the failure of the source train to reach the treatment site because of a kink in the catheter. This was not apparent because the radiation oncologist and cardiologist thought they could see the source train markers on the fluoroscopy image. A survey of the patient indicated the source train was in the chest, which gave credence to their belief.

The licensee believes that no adverse effect to the wall of the aorta from this dose is anticipated.

Region IV will perform a reactive inspection beginning on October 1, 2001. Region IV has informed NMSS, OPA, OEDO and the State of Hawaii.

This information has been discussed with the licensee and is current as of 1:30 p.m. (CDT) on September 28, 2001.

CONTACTS: Mark R. Shaffer
817-860-8287

Richard Leonardi
817-860-8187

August 3, 2001

MEMORANDUM TO: Manuel D. Cerqueira, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Donald A. Cool, Director /RA/ Susan M. Frant, for
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE APRIL 18, 2001 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations of the April 18, 2001 meeting, along with the U.S. Nuclear Regulatory Commission (NRC) staff's response.

STAFFING VACANCIES THAT OCCUR ON THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

ACMUI recommendation: The ACMUI recommended that the procedure for recruiting and appointing ACMUI members begin as soon as the vacancy becomes known and not at the time of the actual vacancy.

Staff response: Staff has put in place procedures for filling vacancies more expeditiously. All three current vacancies are expected to be filled before the next ACMUI meeting.

RISK-INFORMED REPORTING LIMIT

ACMUI recommendation: Whereas the committee believes that licensees have no control over the actions of patients once patients are released from their care, the ACMUI reaffirmed it's November 8, 2000 recommendation that a risk-informed reporting limit of 5 rem be limited to reporting of errors made in the release of patients, and/or reporting of errors made in the delivery of instructions to patients. The ACMUI recommended that the reporting be limited to the aforementioned conditions because the more prescriptive rule would be impossible to implement, unworkable, unenforceable, resource-intensive, and intrusive to the patient.

Staff response: The staff has included the ACMUI recommendation in a paper transmitting the proposed rule to the Commission.

FORMULATION OF SUPPLEMENTARY TRAINING REQUIREMENTS FOR AUTHORIZED MEDICAL PHYSICISTS

ACMUI recommendation: The ACMUI recommended that staff involve qualified members of ACMUI, specialists, or consultants, in the detailed discussions leading to the formulation of

supplementary training requirements that will allow board-certified radiation oncologists and medical physicists to become authorized medical physicists and authorized users in modalities in which they lack the specific training and experience thereof.

Staff response: The staff agrees with this recommendation, and will involve outside parties as recommended when guidance is developed.

BROAD AUTHORIZATION FOR BRACHYTHERAPY LICENSING

ACMUI recommendation: The ACMUI recommended that NRC immediately reaffirm the concept of broad authorizations for brachytherapy licensing, rather than restricting the licensing authorization to strictly follow the Food and Drug Administration-approved indications for use.

Staff response: Revised guidance was issued on June 12, 2001, which reflects the ACMUI recommendation.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)
SELF-EVALUATION

Spring 2001

1. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the committee?

Yes. Staff and ACMUI members continue to communicate in a manner that is both open and effective. Before meetings, staff solicits committee input into the agenda items. During the meeting, these items are discussed, usually in a presentation format. The public participates by asking questions and receiving answers by staff and/or committee members.

Additionally, staff has implemented a measure that continues to promote effective communication between ACMUI and NRC staff. This measure was discussed during the April 18, 2001, meeting. In this measure, recommendations raised during meetings are answered by the director, Industrial Medical and Nuclear Safety, and forwarded directly to the committee members.

2. Do the committee members clearly define issues for the staff and provide timely, useful, objective information to the staff when requested?

Yes. Before meetings, the committee provides staff with issues it thinks should be addressed during regular meetings. At the meetings, these issues are discussed with staff, and when appropriate, with the public. Committee members contemplate solutions before meetings, and are usually able to provide on-the-spot suggestions and formal recommendations, which are reflected in the transcript.

3. Does the committee provide critical review and oversight of issues?

Yes. Because the committee is comprised of experienced professionals, it is able to give staff practical solutions/suggestions. Because it is also diverse, opinions are varied and balanced. Furthermore, as discussed in Question 2, committee members review issues before meetings, and come prepared to suggest solutions.

4. Does the committee provide expertise/advice that is not available from within the Agency?

Yes. The committee has professionals ranging from nuclear cardiologist to patient's rights advocate. Thus, the committee is not only able to give advice from a professional stand-point, but also from a "real-world" point-of-view. The Agency does not have this broad perspective, nor does it have the kind of current professional expertise represented on the committee.

5. Does the committee meet frequently enough to address issues in a timely manner?

Yes. ACMUI continues to meet twice every year. However, when issues of pressing importance arise and they cannot be addressed during regular meetings, the committee will convene extra committee meetings, or ad hoc subcommittee meetings. This option is exercised

when it is necessary to discuss evolving issues such as new technologies in diagnosis and therapy.

6. Do committee members bring issues from all elements of the medical community to the attention of NRC staff?

Yes. As discussed in Questions 2 through 4, ACMUI's diversity ensures that many viewpoints are contemplated and represented during meetings. Committee members frequently raise issues that are current within their specialties.

7. Does the committee facilitate/foster communication between the public/medical community and NRC?

Yes. The public is invited to all open meetings via Federal Register, and; when appropriate, is expressly encouraged to participate in discussions. Public participants often include members from professional societies, who sometimes participate by giving presentations to ACMUI.

Furthermore, because committee members are active in their current professions, they are able to immediately express NRC viewpoints to the medical community, while keeping NRC abreast of the medical community's current activities.

8. Does the committee consider NRC's resource constraints when recommending new or enhanced regulatory programs?

Yes. Although the committee did not recommend any new or enhanced regulatory programs during its last meeting, it does have a history of considering NRC resource constraints when doing so.

9. Does the committee make effective use of subcommittees to assist the staff on specific tasks or projects?

Yes. When necessary, the committee uses subcommittees.

10. Does the size and scope of the committee meet NRC's current needs?

Yes. The size and scope of the committee continue to provide NRC with valuable, useful advice that it cannot receive otherwise. The size and scope continue to assure that a broad perspective on contemporary issues is maintained. ACMUI's current positions are:

- Nuclear medicine physician
- Nuclear cardiologist
- Nuclear pharmacist
- Radiation oncologist (two positions that represent diverse high-risk modalities)
- Medical physicist (nuclear medicine)
- Medical physicist (therapy physics)
- Radiation safety officer
- Healthcare administrator

- Radiation safety officer
- Healthcare administrator
- Patient's rights and care advocate
- State or local government representative
- Food and Drug Administration representative

However, although the ACMUI's current size and scope are generally adequate, we believe it is prudent to recommend that the Commission continue to contemplate a point that we believe is worth further consideration. Several cardiology professional medical societies have requested that the ACMUI include an interventional cardiologist as a voting member of the committee. The expertise that such a member represents in this evolving technology is one that ACMUI lacks, and with the intra-coronary applications of brachytherapy to prevent restenosis, there are an increasing number of issues related to safety and training in the environment of the cardiac catheterization laboratory. This profession's participation was valuable at the committee's last meeting. Furthermore, the American College of Cardiology and the Society for Cardiac Angiography and Interventions have had to provide us with temporary, nonvoting members to attend committee meetings to give us the expert advice we needed. Therefore, we would suggest that the Commission continue to take the addition of this specialty to ACMUI under advisement.

ACMUI MEMBERS
Fall 2001

NAME	SPECIALTY
Manuel D. Cerqueira, M.D. Georgetown University Medical Center Division of Cardiology (5-PHC) 3800 Reservoir Rd. NW Washington, DC 20007-2197	**Nuclear Cardiology** Email: cerqm@concentric.net Phone: 202-687-7190 FAX: 202-687-4593
[VACANT]	**Nuclear Medicine Physician**
David A. Diamond, M.D. Florida Oncology Network Walt Disney Memorial Cancer Institute 2501 N. Orange Ave., Suite 181 Orlando, FL 32804	**Radiation Oncologist** Email: dagdmail@yahoo.com Florida Hospital - Orlando Phone: 407-303-2030 FAX: 407-303-2042
Nekita Hobson National Association of Cancer Patients 2070 Ridgeline Avenue Vista, CA 92083	**Patient Advocate** Email: nohobson@aol.com Phone: 760-598-8289 FAX:
A. Eric Jones U.S. Food and Drug Administration 5600 Fishers Lane HFD - 160, Parklawn Building Rockville, MD 20857	**FDA Representative** The choice of FDA appointees is made by FDA. Dr. Jones chooses the FDA representative for each meeting. Email: jonesa@cder.fda.gov Phone: 301-827-6315 FAX: 301-480-6036
Ruth McBurney Division of Licensing, Registration and Standards Bureau of Radiation Control Texas Department of Health 1100 West 49th Street Austin, TX 78756-3189	**State Representative** Email: ruth.mcburney@tdh.state.tx.us Phone: 512-834-6688 FAX: 512-834-6716

NAME	SPECIALTY
Subir Nag, M.D. Division of Radiation Oncology Department of Radiology Arthur G. James Cancer Hospital and Research Institute Ohio State University 300 W. Tenth Avenue Columbus, OH 43210	**Radiation Oncologist** Email: nag.1@osu.edu Phone: 614-293-8415 FAX: 614-293-4044
Sally Wagner Schwarz Division of Nuclear Medicine Mallinckrodt Institue of Radiology Washington University School of Medicine 510 south Kingshighway Blvd. St. Louis, MO 63310	**Nuclear Pharmacist** Email: schwarzs@mir.wustl.edu Phone: 314-362-2799 FAX:
Richard J. Vetter, Ph.D. Mayo Clinic Medical Sciences B-28 Rochester, MN 55905	**Radiation Safety Officer** Email: vetter.richard@mayo.edu Phone: 507-284-3332 FAX:507-284-0150
Jeffrey F. Williamson, Ph.D. Mallinckrodt Institute of Radiology Washington University Medical Center Radiation Oncology/Physics 510 South Kingshighway Blvd. Box 8224 St. Louis, MO 63110	**Therapy Physicist** Email: williamson_jf@castor.wustl.edu Phone: 314-362-2267 FAX: 314-362-2682
Ralph P. Lieto St. John Hospital and Medical Center Dept. of Nuclear Medicine 22101 Moross Road Detroit, MI 48236	**Medical Physicist, Nuclear Medicine** Email:ralph.lieto@stjohn.org Phone: 313-343-7719 FAX: 313-343-7323
Leon S. Malmud, M.D. Dean, Temple University School of Medicine Temple University Health System 3401 N. Broad St Philadelphia, PA 19140	**Health Care Administrator** Email: martinp@tuhs.temple.edu or Malmudls@tuhs.temple.edu Phone : 215-707-8000 (Pat Martin) Phone: 215-885-0756