MEMORANDUM FOR: Document Control Desk

FROM: Torre Taylor
Medical and Academic Section
Medical, Academic and Commercial
Use Safety Branch

DATE: June 10, 1994

SUBJECT: PLACEMENT OF TRANSCRIPT OF MAY 19 AND 20, 1994 MEETING OF THE ADVISORY COMMITTEE FOR THE MEDICAL USES OF ISOTOPES MEETING INTO THE PUBLIC DOCUMENT ROOM

I am submitting an advanced copy of the transcript for the May 19 and 20, 1994 meeting of the Advisory Committee for the Medical Uses of Isotopes into the public document room. If you have any questions, please call me at 504-1062.

DISCLAIMER

This is an unofficial transcript of a meeting of the Advisory Committe of the Medical Use of Isotopes, of the United States Nuclear Regulatory Commission, held on May 19 and 20, 1994 at the Holiday Inn, Bethesda, Bethesda, Maryland. The meeting was open to the public, with the exception of one session which was closed to discuss the training and experience of a physician (noticed in 58 FR 23901). This transcript has not been reviewed, corrected or edited (except as indicated below), and it may contain inaccuracies.

The transcript is intended solely for general informational purposes. As provided by 10 CFR 9.103, it is not part of the formal or informal record of decision of the matters discussed. Expressions of opinion in this transcript do not necessarily reflect final determination or beliefs. No pleading or other paper may be filed with the Commission in any proceeding as the result of, or addressed to, any statement or argument contained herein, except as the Commission may authorize.

The following errors were noticed in the transcript:

- page 26 - line 25: "not" should be inserted before "NRC"
- page 58 - line 5: Mr. Camper's statement should read, "We don't want to condemn the use of consultants."
- page 59, - line 14: RCM should read RSNA

AGENDA

May 19 and 20, 1994

May 19, 1994

8:00 to 10:00 — NUREG: "Management of Radioactive Material Programs at Medical Facilities"

Presenters: Larry W. Camper/Janet R. Schlueter

10:00 to 11:00 — National Academy of Science Presentation

Presenter: National Academy of Science - Dr. Kate-Louise Gottfriev, with Introduction by Patricia Rathbun, Ph.D.

11:00 to 12:00 — Brachytherapy

Presenter: John E. Glenn, PhD

- Rulemaking - Fractionated HDR treatment
- What could we do to prevent or minimize sources from moving after implantation?
- Should there be QA requirements for brachytherapy in Part 35 (as there are for teletherapy)?

12:00 to 1:00 — Lunch

1:00 to 2:30 — Inadvertent administration to the wrong patient and Patient notification issues

Presenters:

Larry W. Camper - Wrong Patient
Patricia K. Holahan, Ph.D. - Patient Notification

2:30 to 3:00 — American Osteopathic Board of Radiology Certification

Presenter: Larry W. Camper

3:00 to 4:30 — Status Reports

- Proposed amendments to 10 CFR 35.75, Release of Patients Containing Radiopharmaceuticals or Permanent Implants

Presenter: Kitty Dragonette, Office of Research

AGENDA

May 19 and 20, 1994

- Proposed amendments on Preparation, Transfer, and Use of Byproduct Material for Medical Use

  Presenter: Sher Bahadur, Ph.D., Office of Research

- Administration of Byproduct Material or Radiation from Byproduct Material to Patients who may be Pregnant or Nursing

  Presenter: Sher Bahadur, Ph.D., Office of Research

- Abnormal Occurrence Criteria

  Presenter: Larry Camper (if SRM is available, AEOD will make a presentation)

4:30 to 5:00 Closed session - review of training and experience of physician

Presenter: John E. Glenn, PhD

May 20, 1994

8:30 to 10:00 ACMUI Bylaws

Presenter: John E. Glenn, PhD
Susan Fonner from OGC will provide overview of FACA as a law.

10:00 to 12:00 ACMUI preparation for Commission Briefing - June 22, 1994

Presenter: Larry W. Camper

Advisory Committee on Medical Uses of Isotopes: Meeting Notice

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The Nuclear Regulatory Commission will convene its next regular meeting of the Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 19 and 20, 1994. Topics of discussion will include: A discussion of the possible need for the inclusion of Quality Assurance requirements in 10 CFR 35.400, use of sources for brachytherapy; a presentation by the National Academy of Science; a discussion of the NRC NUREG: "Management of Radioactive Material Programs at Medical Facilities;" a discussion of inadvertent administration to the wrong patient; and the discussion of American Osteopathic Board of Radiology Certification as acceptable training for radiopharmaceutical therapy. The committee will draft ACMUI Bylaws and will prepare for the Commission Briefing scheduled for June 22, 1994.

In addition, the NRC staff will provide status reports on proposed rulemaking, including: "Proposed Amendments to 10 CFR 35.75, Release of patients containing radiopharmaceuticals or permanent implants"; "Proposed Amendments on Preparation, Transfer, and Use of Byproduct Material for Medical Use"; and "Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May Be Pregnant or Nursing." The NRC staff will also provide a status report on issues regarding the Abnormal Occurrence (AO) report to Congress.

DATES: The meeting will begin at 8 a.m., on May 19 and 20, 1994.

ADDRESSES: The Holiday Inn, Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Larry W. Camper, Office of Nuclear Material Safety and Safeguards, MS 6–H–3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301–504–3417.

SUPPLEMENTARY INFORMATION: The following information is provided concerning the topics to be discussed at the meeting:

Efficacy of Quality Assurance Requirements for Brachytherapy: The NRC staff will provide a discussion of the possible need for QA requirements to be included in 10 CFR 35.400, use of sources for brachytherapy, similar to those included in 10 CFR 35.600 for teletherapy.

National Academy of Science Presentation: The National Academy of Science will brief the ACMUI on the progress of the contract to perform an independent review of the NRC's medical use regulatory program.

NUREG: "Management of Radioactive Material Programs at Medical Facilities.": The NRC staff will discuss the progress on the Draft NUREG since the last ACMUI meeting. Included will be the comments received during the recent peer review, and plans for publication.

Inadvertent administration to the wrong patient: The staff will seek comments regarding reporting of the inadvertent administration of byproduct material to the wrong patient or individual when the dose does not meet the criteria for a misadministration.

American Osteopathic Board of Radiology Certification (AOBR): The staff will provide the AOBR certification requirements for ACMUI review to determine ACMUI's recommendation as to whether AOBR certified individuals meet the criteria specified in 10 CFR 35.930.

Status reports on proposed rulemaking:

Proposed Amendments to 10 CFR 35.75, Release of patients containing radiopharmaceuticals or permanent implants: The staff will provide a status report regarding proposed rulemaking in response to three petitions for rulemaking, one from Carol Marcus, M.D. (February 6, 1991); and two from the American College of Nuclear Medicine (January 14, 1992, and April 21, 1992), regarding criteria for the release of patients administered byproduct material.

Proposed Amendments on Preparation, Transfer, and Use of Byproduct Material for Medical Use: In June 1989, the American College of Nuclear Physicians and Society of Nuclear Medicine (ACNP/SNM) filed a petition with NRC addressing five issues relating to the preparation and use of radiopharmaceuticals. A proposed rule was published for public comment (58 FR 33396; June 17, 1993). The staff has considered comments on the proposed rule and expects to submit the final rule to the Commission for approval by June 1994.

Administration of Byproduct Material or Radiation from Byproduct Material to Patients Who May Be Pregnant or Nursing; Pregnancy and Breast-feeding: The staff will provide a status report on issues and recommendations concerning unintended radiation doses or dosages to an embryo, fetus, or nursing infant, resulting from administration of radiopharmaceuticals or radiation to pregnant or breast-feeding patients.

Abnormal Occurrence Criteria: The staff will provide a status report regarding the proposed revision of criteria for reporting medical misadministrations as abnormal occurrences.

Conduct of the Meeting

Barry Siegel, M.D., will chair the meeting. Dr. Siegel 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 Larry W. Camper (address listed above). Comments must be received by May 13, 1994, to ensure consideration at the meeting. The transcript of the meeting will be kept open until May 27, 1994, for inclusion of written comments.

2. Persons who wish to make oral statements should inform Mr. Camper, in writing, by May 9, 1994. Statements must pertain to the topics on the agenda for the meeting. The Chairman will rule on requests to make oral statements. Members of the public will be permitted to make oral statements if time permits. Permission to make oral statements will be based on the order in which requests are received. In general, oral statements will be limited to approximately 5 minutes. Oral statements must be supplemented by detailed written statements, for the record. Rulings on who may speak, the order of presentation, and time allotments may be obtained by calling Mr. Camper, 301–504–3417, between 9 a.m. and 5 p.m. EDT, on May 16, 1994.

3. At the meeting, questions from attendees other than committee members, NRC consultants, and NRC staff will be permitted at the discretion of the Chairman.

4. The transcript, minutes of the meeting, and written comments will be available for inspection, and copying, for a fee at the NRC Public Document Room, 2120 L Street NW, Lower Level, Washington, DC 20555, on or about May 30, 1994.

5. Seating for the public will be on a first-come, first-served basis.

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

Dated: April 20, 1994.

John C. Hoyle,

Advisory Committee Management Officer

[FR Doc. 94–9997 Filed 4–25–94; 8:45 am]

BILLING CODE 7590–01–M

The remaining portions of this meeting from 9 a.m. to 5:30 p.m. on June 14, 1994 and from 8 a.m. to 2:30 p.m. on June 15, 1994 are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of February 8, 1994, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue NW., Washington, DC 20506, 202/682–5532, TTY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne Sabine, Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5439.

Dated: April 28, 1994.

Yvonne M. Sabine,

Director, Office of Panel Operations, National Endowment for the Arts.

[FR Doc. 94–11020 Filed 5–6–94; 8:45 am]

BILLING CODE 7537–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on 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 its next regular meeting of the Advisory Committee on Medical Uses of Isotopes (ACMUI) on May 19 and 20, 1994. The Meeting was noticed in the Federal Register on April 26, 1994. In accordance with Subsection 1(d) of the Federal Advisory Committee Act, Public Law 92–463AA, a portion of this meeting may be closed to protect the privacy of a physician whose training and experience will be reviewed by the ACMUI in connection with the physician's application to be an authorized user under a license authorizing medical use of byproduct material.

The description of the discussion of inadvertent administration to the wrong patient in the Federal Register Notice of April 26, 1994, is clarified to provide notice that this discussion will include patient notification following misadministration.

During the discussion of Efficacy of Quality Assurance Requirements for Brachytherapy, the staff will invite comments on the significance of fractionation of high-dose-rate brachytherapy.

DATES: The closed portion of the meeting will begin at 4:30 p.m., May 19, 1994.

ADDRESSES: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Larry W. Camper, Office of Nuclear Material Safety and Safeguards, MS 6–H–3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301–504–3417.

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

Dated: May 3, 1994.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 94–11022 Filed 5–6–94; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Nuclear Waste; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold its 60th meeting on Tuesday and Wednesday, May 17 and 18, 1994, in room P–110, 7920 Norfolk Avenue, Bethesda, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy pursuant to 5 U.S.C. 552b(c)(6).

The agenda for the subject meeting shall be as follows:

Tuesday, May 17, 1994—8:30 a.m. until 6 p.m.

Wednesday, May 18, 1994—8:30 a.m. until 6 p.m.

During this meeting the Committee plans to consider the following:

A. *Tectonics of the Proposed Yucca Mountain Site*—Discuss research and technical assistance being performed by the NRC staff and the Center for Nuclear Waste Regulatory Analyses related to the tectonics of the Yucca Mountain site.

B. *National Academy of Science's Panel on the Technical Bases for Yucca Mountain Standard*—Hear a report from a member of ACNW who attended an April 28–29, 1994 meeting of the Academy's Panel to update the Committee on current progress.

C. *Preparation of ACNW Reports*—Prepare ACNW reports on issues considered during this and previous meetings.

D. *Future Activities*—Discuss topics proposed for consideration by the full Committee or working groups.

E. *New Members*—Discuss matters related to the appointment of new members, and organizational and personnel matters related to the ACNW members and ACNW staff. Portions of this session may be closed to public attendance to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy pursuant to 5 U.S.C. 552b(c)(6).

F. *Miscellaneous*—Discuss miscellaneous matters related to the conduct of Committee activities and organizational activities and complete discussion of matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACNW meetings were published in the Federal Register on June 8, 1993 (58 FR 32095). In accordance with these procedures, oral or written statements may be presented by members of the public, electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Committee, its consultants, and staff. The ACRS Office is providing staff support for the ACNW. Persons desiring to make oral statements should notify the Executive Director of the ACRS Office as far in advance as practical so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the ACNW Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Executive Director of the office of the ACRS, Dr. John T. Larkins (telephone 301/492–8516), prior to the meeting. In view of the possibility that the schedule for ACNW meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the ACNW Executive

A sign-in sheet for members of the public was available at the meeting; however, we were unable to located the sign-in sheet at the close of the meeting.

NUREG

Presenters:
Larry Camper
Janet Schlueter

ACMUI Meeting - May 19, 1994

PURPOSE OF NUREG

- Provide guidance on mgt. issues associated with program mgt.; and Provide guidance on effective tools for programs of various size, rather than specifics of day-to-day operations

- Clarify the roles of each component of the mgt. triangle and describe their interrelationships

- No new requirements proposed or inferred

PROGRESS SINCE NOV. 1993

- Presentations at annual meetings of the ACNP, ACRO, and RSNA

- Scheduled for presentations at annual meetings of the SNM and ABMP

- Continued drafting/editing

PROGRESS cont.

- Peer review by 9 organizations:

ACR	AAPM
BNL	NCRP
ACMP	OAS
ACNP	SNM
ACRO	ACMUI

- Peer review by NRC staff and management in headquarters and the regions

SUMMARY OF PEER COMMENTS

General Comments:

o Majority were Favorable - "well written, comprehensive, interesting, insightful, useful, much needed guidance, very supportive of NRC's effort. . . "

o Criticism - "too long, repetitive, presentation of ideas is not developed," specific editorial comments were offered by reviewers

General Comments (cont.):

ACNP/SNM: "Serious concerns re: vol. of extraneous infor." that goes beyond current requirements..(specific examples were provided). "Document does little to clarify existing regulations."

ACNP/SNM requests that (in the Bkgnd sec.) NRC note that ACNP/SNM has serious concerns about the development of this NUREG

General Comments (cont.):
OAS: 13 States commented

- "Overall, States were impressed"

- "Hope that the document will be available to Agreement States on diskette"

- "Many states want to use this document as a training tool"

- Document may be too large to be useful to licensees

General Comments (cont.):
OAS:

- A "scope of purpose" may help define the intended purpose

- Some words make reading the text difficult

- A list of acronyms used be useful

- The summaries should not introduce new material

Specific Comments on Chapter 1:
"Role of Executive Management"

Clarify "executive management;" and that an "outside" inspection of the program may be helpful to assess the RSO and RSC's performance, but is not required

Specific Comments on Chapter 2:
"Role of RSC"

Exec. Mgt. should not be a RSC member; RSO should not be RSC Chair; discuss possible problems with "large-user" as RSC Chair who may be in conflict with RSO; Mgt. rep. should be RSC Chair

OAS COMMENTS ON CHAPTER 1 and 2:

- Varying reactions on the idea of an exchange program with other licensees to evaluate effectiveness of the program because of the resource implications

- Clarify whether all components of the mgt. triangle have equal importance and roles

- Clarify broad scope licensees' authority to approve authorized users

Specific Comments on Chapter 3:
"Selecting the RSO"

RSO should be independent of clinical use of RAM; Deputy RSOs should be allowed; Tech as RSO is not ideal; recommend that NRC reference all regulations including guidance on T&E criteria for RSOs at broad scope programs; Role of RSO and IRB/RDRC needs to be clarified

OAS COMMENTS ON CHAPTER 3:

- Emphasize good communication as a powerful tool

- Emphasize the advantages of the Health/Medical Physicist - RSO

- Additional guidance on adequate time commitment by consultant-RSO

Specific Comments on Chapter 4:
"Role of the RSO"

More emphasis is needed for facilities on iodination and preparation of large dosages of I-131; Historically, no clear delineation of authority for contracted MD-RSO to supervise or be responsible for facility employees

OAS COMMENTS ON CHAPTER 4:

- Expand discussion on delegation of responsibilities during absence of RSO

- Some States strongly disagree with NRC's failure to recognize alternate- or assistant-RSOs

Specific Comments on Chapter 5:
"Role of AU and Supervised Indiv."

Need greater delineation of responsibilities of medical physicists and dosimetrists;
Training of AU should be discussed;
AU must be responsive to the concerns of the RSC and RSO

OAS COMMENTS ON CHAPTER 5:

- Additional discussion on State and NRC regulatory concerns re: an AU's ability to safely handle RAM

Specific Comments on Chapter 6:
"Resources for the RS program"

Commenting on salaries seems outside NRC's role - reduce or eliminate this sec.; Much stronger emphasis on proper resource allocations is needed; salary comparisons between medical and univ. facilities is difficult

OAS COMMENTS ON CHAPTER 6:

- Need hard numbers for adequate resources

- Mention resource needs for training materials for inservices

- Mention that decommissioning and decontamination may be needed for remodeled or relocated Nuclear Medicine departments

Specific Comments on Chapter 7:
"Use of Consultants or Service Contractors"

Consultants provide indep. verification that the RS program is properly implemented; Chptr should be removed because NRC regs do not mention consultants; therefore it is inappropriate

OAS COMMENTS ON CHAPTER 7:

- Strongly agree that ultimate responsibility for compliance rests with the licensee and not a consultant

- Some States do not authorize a consultant as RSO

Specific Comments on Chapter 8:
"Conduct of Audits"

"NRC regulations do not specifically address a mgt. audit; therefore, the discussion should be removed"

Mgt. audits are an effective tool to meet requirements described in 10 CFR 35.22, 20.1101, and are required if a licensee commits to RG 10.8, Appendix G

OAS COMMENTS ON CHAPTER 8:

- Discuss how audits are to be documented and presented

- Information regarding follow up to findings

Specific Comments on Chapter 9: "Incident Response"

Reference the FDA's mandatory reporting requirements applicable to medical devices- MEDWATCH

OAS COMMENTS ON CHAPTER 9:

- RSO should be afforded the opportunity to confer with a patient subject to a misadministration, when indicated

- Ambulance services and EMTs should be addressed in the discussion on handling of accident victims

Specific Comments on Chapter 10: "Interactions with Regulatory Agencies"

Regulatory inspec. should be done on short-notice, rather than unannounced; discussion should be more critical of the regulatory agencies and less neutral

OAS COMMENTS ON CHAPTER 10:

- Differing opinions re: whether to include this chptr because existing guides may be sufficient

- Strengthen discussion of radiation surveys by inspector

- Add discussion on interviewing allegers

COMMENTS ON APPENDICES

Useful, full of practical information;

Add equipment needed by the radiation safety office to Appendix J - "Sample list of equipment"

No comments were offered by peers on other sections of the DRAFT

OAS COMMENTS ON APPENDICES

- Delete list of Ag. St. due to evolution
- Add "use of survey eqpmt" to training subject list
- Delete the sample licenses not helpful, do not reflect Agreement State licenses
- Delete description of NRC's Enforcement Policy, it should be described in another document

KEY THEMES IN NUREG

- Management Triangle

- Implementation of the radiation safety program - active RSC, audits, supervision and training

- RSO responsibilities

- Resource implications - staffing, space, equipment, use of contractors

- Management tools/guidance

QUESTIONS

- Is the guidance applicable to most medical programs using byproduct material?

- Are there additional topics that should be addressed, or topics that should be eliminated or reduced in volume?

QUESTIONS cont.

- Is each element of the management triangle (executive management, RSO and RSC) adequately discussed in relation to each other?

- Are the appendices helpful and comprehensive?

DEPARTMENT
OF HEALTH

Bureau of Radiological Health
111 LIVINGSTON STREET - ROOM 2006
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To JANET SCHLUETER	From R. KULIKOWSKI
Co. U.S NRC	Co. OAS
Dept. MED/ACAD - NMSS	Phone # 718-643-7967
Fax # 301-504-2620 301 415-5369	Fax # 718-643-4616

May 17, 1994

Janet Schlueter, NUREG Project Manager
Medical and Academic Section
MS TWFN 8 F 5
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Ms. Schlueter:

Enclosed is a letter from the Organization of Agreement States on the draft NUREG on Management of Radiation Safety Programs at Medical Facilities. This is a substantially complete draft of the letter, but it has not received concurrence by the other two members of the Executive Committee of the Organization. It is being provided today so that the information will be available for the ACMUI meeting on May 19 and 20. We anticipate transmitting our formal letter early in June following the CRCPD annual meeting.

If you have any questions, please feel free to contact me or Kathy Allen at (217) 785-9931, who compiled the comments for the Organization.

Sincerely,

Robert R. Kulikowski, Ph.D.
Chairman
Organization of Agreement States

cc: G. Wayne Kerr
Richard Ratliff
John Glenn, Ph.D.

94K0123

ORGANIZATION OF AGREEMENT STATES

DEPARTMENT
OF HEALTH

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- DRAFT -

[DATE]

Janet Schlueter, NUREG Project Manager
Medical and Academic Section
MS TWFN 8 F 5
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Ms. Schlueter:

Thank you for the opportunity to comment on the Draft NUREG on Management of Radiation Safety Programs at Medical Facilities. Overall, states were impressed with the document and the effort it took to compile so much information. It was clear from the Disclaimer and the text that NRC and Agreement State representatives cooperated on the document, and we hope this is a trend that will continue.

We hope that the document will be available to Agreement States on diskette, and available to Agreement State licensees. Although quite lengthy, many states want to use this document as a training tool for their license reviewers and inspectors, and some felt it would be useful guidance for facilities having trouble keeping control of their radiation safety program.

Thirteen Agreement States provided comments on the document, and their comments are summarized below. Minor editing remarks are not included in this letter. However, I have included copies of all comments received, including the detailed comments from New Hampshire, which I hope you will find useful.

General Comments

There is some concern that the document is too large to be useful to licensees. The volume of material may be overwhelming or intimidating, and the document may not be used. Because of this, some suggestions for deleting information is incorporated in these comments.

The purpose of the document does not seem to match the title. The title appears to be targeted at management, but the text reads like a broad medical licensing guide. A "Scope of Purpose" may help define the intended purpose and intended audience.

There are differing opinions on the usefulness of the references to broad scope programs. Some request additional information to make the document complete for all medical broad scopes, and others suggest deleting broad scope references because this document is not intended to be a broad scope guide.

Some of the words chosen make reading the text difficult. Words such as "collegial" and "palaverous" should be replaced. All references to "byproduct" material should be changed to "radioactive" to make the document more universal in its approach. A list of acronyms used would be useful.

NRC regulations and documents should always include an indication that it is an "NRC document" or "10 CFR" to lessen confusion when an Agreement State licensee reads the NUREG.

The summary paragraphs at the end of the sections need to be fixed to be more like an abstract. Many of these summaries actually introduce new material.

Page Disclaimer

iii Private physician office should be "institutions." Delete it from disclaimer section because we don't include private physician offices as facilities that have an RSC. The other sections of the document do a better job of explaining the private physician situation.

Chapter 1 - Role of Executive Management

3 The second sentence needs to be fixed because it appears it was intended to compare facilities that do and do not have an RSC, when in fact, it compares situations that do not and do not have an RSC.

3 Point out that the license is issued to the company (or facility) as an entity as a whole, and specific duties and responsibilities are assigned to individuals within that organization.

4 The first full sentence says that the single most important person is the RSO, but on page 33, the RSO, RSC and management are referred to as equal components.

6 Why discuss content of RSC meetings when the purpose of the section is attendance at meetings? The fourth sentence needs to be re-worded.

6 If management attendance at RSC meetings is required by NRC, then say it is required.

Page Chapter 1 - Role of Executive Management (continued)

7 The idea of an exchange program with other licensees was met with varying reactions ranging from a comment that it was a good idea worth mentioning, to a comment indicating that licensees complain they are too busy with their own program to evaluate other facilities.

8 The first paragraph in this section needs to be re-worked. Why imply that "firm enforcement" must be done either unprofessionally or with disrespect? RSO's must face users with varying attitudes toward voluntary compliance, usually gaining compliance based on bad consequences promised by management if regulatory requirements are not met.

8 We suggest inserting the following sentence after the 6th sentence, "The existence of a mutual respect between the users and the RSO is needed to make the program work well." The following sentence should be edited and broken into two sentences.

8 The rules do not require the RSO to brief the RSC on the radiation safety program status. Technically, the RSO is only required to review events and dosimetry. Consultants frequently attend quarterly meetings and provide audit findings and other program information.

9 Delete second sentence in the second paragraph. This statement may inspire consultants to withhold availability of audit reports to clients.

9 Delete "Conduct of Required Audits" since this is already mentioned on page 8, second to the last paragraph under Assessing RSO/RSC Performance.

Chapter 2 - Role of the Radiation Safety Committee

15 The third sentence indicates that broad scope licensee's authority to approve or disapprove of authorized users without prior review of regulatory agencies "could be awkward." This needs to be explained.

15 The review conducted by the RSC, and approvals granted by broad scope RSCs must be within the scope of the license authorization.

17 We could find no definition of RAZE program.

17 The title "Quarterly Dosimetry Audits" should be modified to delete "dosimetry" because this section applies to things other than just dosimetry.

20 This Chapter is very good, but it seems out of place. It may be easier to select the RSO after you have an idea of the RSO's duties and responsibilities.

Page Chapter 3 - Selecting a Radiation Safety Officer (continued)

20 Add more emphasis to the concept of good communication being a powerful tool.

26 In general, try to rearrange paragraphs so the first paragraph under each section lists the advantages, and the second paragraph lists the disadvantages.

26 It is unfortunate that there are so few positive endorsements for the HP/MP as RSO. This type of person may be able to successfully delegate the nuclear medicine duties and provide technical leadership at the facility. If this person is dedicated to the facility with no conflicting outside interests, this type of individual may be the best person for the job.

26 The last section under "Health/Medical Physicist" discusses time commitments. These drawbacks are true of any individual selected.

26 The problems regarding physicians as RSO are accurately stated. There is a difference in opinion as to whether a physician would be the best choice for RSO. Some suggest that the problems associated with physician-RSOs need to be addressed more forcefully. For example, physician-RSOs often delegate duties to an individual who is not qualified, does not understand, or does not have the time to accomplish the assigned tasks. Others think a physician would have a better understanding of what needs to be done, but would lack the time necessary to do everything the NUREG suggests.

28 The state of Kentucky has indicated that in the past, NRC has indicated that a technologist could not be named as RSO because they would not meet the training requirement of having spent one full year in full-time radiation safety.

28 Another drawback to add to the technologist category would be to indicate that this type of person may concentrate on nuclear medicine, and may have problems handling operations in radiation therapy or oncology.

28 It would be beneficial to have some guidance on how much time would be considered adequate for a consultant to spend at a facility in order to be named as RSO. Even some broad guidance would be useful.

Chapter 4 - Role of the RSO

40 The third sentence under "Radioactive Waste Management" is confusing because it indicates that licensees with long-lived radioactive material should have an area for short-term storage.

Page Chapter 4 - Role of the RSO (continued)

41 The reference to "status of indicators" in the second sentence under "Medical devices" needs to be fixed.

42 Make the last paragraph of "Delegation of Tasks" the lead-in paragraph for this section, and expand section to discuss instances when an RSO is absent.

42 Some states strongly disagree with the position taken that an assistant or alternate RSO would not be recognized. Many states will accept and name an alternate RSO along with statements from the licensee indicating lines of authority and responsibility. The language should be modified in this section to indicate the differences between some states and NRC.

Chapter 5 - Role of Authorized Users and Supervised Individuals

The term "supervised individual" also refers to patients in this Chapter. While requirements are put on the licensee regarding patients, patients should probably not be included in the working definition of "supervised individual."

47 Immediately after the first sentence of the second paragraph, we suggest adding, "The distinguishing feature of an authorized user physician and the reason they are named on a license is that only they have the authority to administer or to order the application of radioactive material to humans." There should be more discussion concerning the "practice of medicine" and the state and NRC regulatory concerns with someone's ability to safely handle radioactive materials.

47 In general, the duties/responsibilities of users should be: ALARA; control of radioactive sources; nature of radiation hazards; safe work procedures; emergency procedures; location of records. Stress that the individual user is ULTIMATELY responsible for the safe use of material.

Chapter 6 - Radiation Safety Program Resources

56 This chapter needs a better theme. There are not enough hard numbers (hours of time, number of staff, etc.)

62 The second sentence in the last paragraph should include new regulations, new uses of radioactive material and <u>any</u> significant change.

63 Add the following idea at the top of the page: also, resources must be allocated for written instruction (such as handouts and booklets) to be prepared and distributed, and videos to be made or purchased.

- D R A F T -

Page Chapter 6 - Radiation Safety Program Resources (continued)

65 Add a reminder that radiation surveys are required before material can be released as no longer radioactive.

67 Maybe mention that on a smaller scale, remodeling or relocation of a nuclear medicine department has to undergo similar decontamination and decommissioning.

Chapter 7 - Use of Consultants and Service Companies

70 Agreement States strongly agree that the ultimate responsibility for compliance with the rules remains with the licensee, not with a consultant.

71 Many Agreement States do not allow consultants to be named as an RSO. Some states recommend not even including this option, saying that consultants can be used to augment a program, not run a program.

Chapter 8 - Conduct of Audits

Add information regarding how audits are to be documented and presented to management.

Information regarding what to do after a problem is discovered should be enhanced to bring the document full circle.

Chapter 9 - Incident Response

93 The second and seventh sentences in the first paragraph should probably be deleted, or at least reduced to only one statement.

93 The last paragraph uses the phrase, "patient, if absolutely necessary ..." This phrase may result in the RSO being prohibited or discouraged from speaking to the patient. Regulatory authorities may speak to patients, and the RSO should be afforded the same opportunity.

94 Dose rate surveys should be required under the "Equipment/Device Failure" section.

95 Ambulance services should be included as facilities that need preparation for handling the accident patient, and EMTs and ambulances should be included as facilities that need to be decontaminated.

96 The phone number for REAC/TS was confirmed on 4/11/94 to be (615) 481-1000.

- D R A F T -

Page Chapter 10 - Interactions with Regulatory Agencies

There are differing opinions concerning the need for this Chapter. Some made comments because it was included in the document, and some believe that existing licensing guides already describe these interactions.

104 The statement that implies that an inspector may or may not have a survey meter and may or may not perform contamination surveys should be changed. Many programs do not allow inspectors to go into a facility without a survey meter, and independent wipes are almost always taken. The language in this section should be strengthened accordingly.

106 It is not clear why the words "surprises" and "field notes" are in quotes.

107 Add a paragraph on Part 19 interviews with allegers.

Appendices

A Delete. It is not appropriate to put this information in an Appendix because it goes out of date so quickly, and does not list the people that licensees should contact. Maybe just indicating that someone can contact NRC or CRCPD to get a name and/or phone number would be better.

H Add "use of survey equipment" under the specific information for individuals handling radioactive materials.

I Add reporting of recordable events to the checklist?

J The actual radioactive material (flood sources) should be added to this list because this could be a significant expenditure. A thyroid phantom and gamma camera should also be added.

K Add item 18(b) to deal specifically with afterloaders?

M Delete. This information is not really helpful to licensees. The sample licenses do not cover the whole range of types of licenses, and definitely do not reflect Agreement State license document formats.

N Delete. See above.

O Delete. NRC should describe its enforcement policy in a separate document.

-DRAFT-

Thank you again for the opportunity to comment. This is the first document of its kind that tries to address the radiation safety program requirements for a class of licensees. We appreciate the tremendous effort it took to accomplish this task. I hope our comments have been useful.

Sincerely,

Robert R. Kulikowski, Ph.D.
Chairman
Organization of Agreement States

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May 9, 1994

UCLA SCHOOL OF MEDICINE
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DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

John E. Glenn, Ph.D., Chief
Medical, Academic & Commercial Use
Safety Branch
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Dr. Glenn:

This is in response to your request for my evaluation, as your advisor, of the Draft NUREG entitled, "Management of Radioactive Material Safety Programs at Medical Facilities".

In your letter of 17 Mar 94 you indicated that NRC was soliciting comments from OAS, ACNP, SNM, ACR, AAPM, BNL, AND NCRP. However, at least two of those organizations were given a 4 May 94 deadline which is certainly insufficient time. I wonder why ACRO (American College of Radiation Oncology), ASTRO, and HPS were not included? When the President of ACRO called NRC for a copy, his request was denied. One cannot help but wonder whether NRC's request for comment is genuine. You will recall that initially ACNP and SNM were not even included in the announcement; they only heard about this document incidentally from AAMC (American Association of Medical Colleges). ACNP and SNM's request for scientific input was rejected; all ACNP received was a vague presentation with zero science from Janet Schlueter. SNM did not pursue the issue after the ACNP experience. The Agreement States have been denied significant input in the development of this NUREG, and so was the ACMUI. I bring all this up so that there should be no mistake. <u>This is definitely not in any way the collective work of knowledgeable nuclear professionals involved in medical programs.</u> It is exclusively the work of NRC staff who are in dire need of the scientific and medical expertise that should have come over the past two years from such outside professionals.

This NUREG is approximately 170 pages long, and I do not intend to correct it line by line. It is exceedingly "palaverous" (NRC's word, not mine) and repetitive; its gross errors are repetitive also. The premises upon which this document is developed are erroneous, and there is so much disinformation, false inference, and "spin doctoring" therein that it has no serious value. The authors obviously lack certain essential qualitative and virtually all quantitative knowledge of radiation

physics, radiation biology, and health physics. They also have no useful understanding of the practices of medicine and pharmacy or the management of medical institutions.

Bizarre assumptions of inflated radiation hazard abound; they may well describe a nuclear weapons factory or perhaps even a nuclear power plant, but to imply that they have anything to do with a medical institution, and funnier yet, a nuclear medicine department, is ridiculous. What is frightening is that NRC materials management watched this activity go on for two years, and never realized it was sheer nuclear nonsense. They may not even realize it now. It seems that there is a "breakdown in the management of the radiation safety program", all right, but the breakdown is at NMSS.

It is not surprising that much of the practice of medicine information is naive, far-fetched, and wrong, because there are no staff or management at NRC who understand anything about medicine at all. No one, that is, except Dr. Pollycove. Did he have an opportunity to thoroughly review this document before publication and concur in its entirety?

Aside from the severe scientific and medical shortcomings of this document, we have the unveiling of a vicious plan for license abuse, the secret imposition of arbitrary requirements not subject to public scrutiny through the rulemaking process. I believe that there is going to be a problem with the Administrative Procedures Act. And while we are mentioning law, let me remind you that FDA has jurisdiction over radiologic devices, not NRC, and that NRC's escalation of sealed source device evaluation authority into dual-regulation and super-regulation of FDA is highly inappropriate.

Even in something as elementary as the Glossary, the authors have numerous clumsy definitions. They do not understand an IRB, have strange definitions for medical institutions and non-institutions, have an incomplete definition of "Nuclear Medicine", and have an erroneous definition of an "x-ray".

This manuscript should be a profound embarrassment to NRC management and the Commission, and I recommend that it be discarded. I also recommend an investigation into how and why it was written, and why management did not exert any competent control over this activity. I also recommend that the cost of

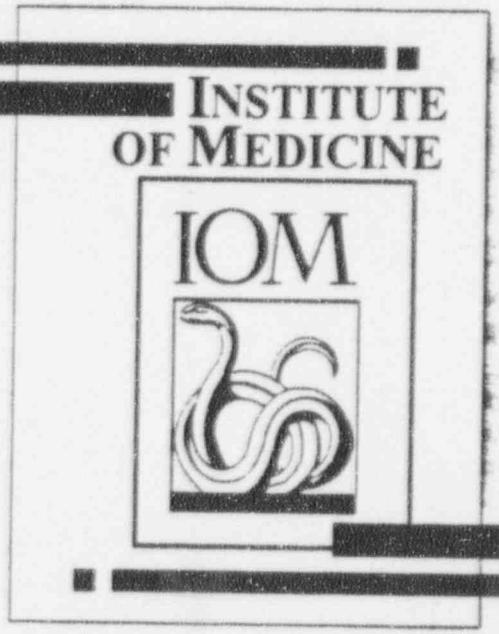
this NUREG effort not be borne by medical licensees, but be taken out of SES bonuses, in just compensation for NRC management failure.

I request that this letter, in its entirety, be made a part of the official transcript of the ACMUI meeting of May, 1994, where this draft NUREG will be discussed.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

CSM:sfd



COMMITTEE FOR REVIEW AND EVALUATION OF THE MEDICAL USE PROGRAM OF THE NUCLEAR REGULATORY COMMISSION

NATIONAL ACADEMY OF SCIENCES

COMMITTEE FOR REVIEW AND EVALUATION OF THE MEDICAL USE PROGRAM OF THE NUCLEAR REGULATORY COMMISSION

The U.S. Nuclear Regulatory Commission (USNRC) is responsible for regulating the medical (diagnostic and therapeutic) use of byproduct materials, especially for protecting the public from undue risk attendant upon their use in health care applications. (Byproduct materials, or radionuclides, include such substances as Cobalt-60, Iodine-131, and Radium-223 used for diagnosis and treatment of cancer and Iodine-125 used for the diagnosis of osteoporosis.) This "medical use" responsibility derives from its more general public health and safety responsibilities for regulating all aspects of nuclear reactor safety.

The Nuclear Regulatory Commission has requested from the Institute of Medicine (IOM) a detailed independent review and evaluation of the adequacy of that program as well as recommendations for needed changes. The IOM has established a 16-member committee of experts to conduct a 24-month study. The project has three major goals:

• *First, the USNRC is interested in an examination of the overall risk associated with the use of ionizing radiation in medicine.* In this context, it is seeking two types of comparative analyses: (1) the frequency of errors and consequences associated with the use of licensed byproduct materials in relation to other medical procedures (such as chemotherapy, surgery, general anesthesia, or administration of pharmaceuticals); and (2) given the total use of licensed byproduct materials, the error rate, mortality, and morbidity of misadministrations compared to administrations of licensed byproduct material that are properly carried out.

• *The second is an examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes.* These issues involve: (1) the adequacy of the 1979 Medical Use Policy Statement and the consistency of USNRC regulations and guidance with it; (2) the extent of USNRC's responsibility to the patient involved in a misadministration, including notification and follow-up; (3) the appropriate role for the USNRC medical consultant in the medical use program; and (4) whether the USNRC's regulatory policy could more effectively promote better patient care or safer medical uses of radioisotopes.

• *Third, the USNRC also requests a critical assessment of the current framework for the regulation of the medical uses of byproduct material.* The issues here include, among others, the appropriateness of the statutory framework, both federal and state, for regulation of (a) the medical uses of byproduct material, (b) other sources of ionizing radiation, and (c) devices used in these arenas; both issues of risk and the broad policy questions just noted provide a context for assessing the current regulatory framework and potential modifications to it. Similarly, the USNRC is also concerned with the appropriateness of the regulatory relationships that exist among the USNRC, so-called agreement states, the Food and Drug Administration, and various state boards.

Combining all these topics, the USNRC asks that the IOM provide recommendations on two major issues: (1) a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate commerce for application of radiation to human beings should be allocated among federal government agencies and between the federal and state governments; and (2) appropriate criteria for measuring the effectiveness of the regulatory program(s) to protect public health and safety.

To date, the study committee has held its first meeting (March 22-24, 1994). It plans to hold five more committee meetings, a public hearing, convene expert panel workshops, conduct site visits, commission papers and prepare a report that will be subject to the usual National Research Council review process. If you would like additional information please write to: NAS/IOM, 2101 Constitution Avenue, N.W., Washington, D.C., 20418; or call (202) 334-3805.

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RULEMAKING ON HIGH DOSE RATE (HDR) FRACTIONATED TREATMENT

ISSUE: WHAT CONSTITUTES A SIGNIFICANT ERROR FOR FRACTIONATED DOSES, AND WHAT LEVEL OF DETAIL SHOULD BE INCLUDED IN THE WRITTEN DIRECTIVE

QUESTION:

IN VIEW OF THE TYPES OF FRACTIONATED ERRORS REPORTED IN THE PRELIMINARY NOTIFICATIONS, WHAT HARM OR RISK, IF ANY, DOES THE COMMITTEE BELIEVE IS ASSOCIATED WITH THE LEVELS OF ERRORS SEEN?

QUESTION:

GIVEN THAT EXISTING MISADMINISTRATION THRESHOLDS ARE ESTABLISHED AT OR BELOW THE LEVEL FOR DETERMINISTIC EFFECTS, WHAT IS THE APPROPRIATE THRESHOLD FOR MISADMINISTRATIONS OR RECORDABLE EVENTS FOR HDR FRACTIONATED DOSES?

BRACHYTHERAPY

GENERAL DISCUSSION ON BRACHYTHERAPY MANUAL AND REMOTE

ISSUE: MISADMINISTRATIONS THAT OCCUR BECAUSE OF SOURCE MOVEMENT OR IMPROPER PLACEMENT

QUESTION:

WHAT IS THE STANDARD OF CARE WITH RESPECT TO PROPER PLACEMENT AND OPERATION OF OTHER IMPLANTED DEVICES IN THE MEDICAL PROFESSION

- HOW OFTEN ARE DEVICES CHECKED TO ENSURE THINGS ARE AS THEY SHOULD BE?

QUESTION:

DO ANY PROFESSIONAL MEDICAL ORGANIZATIONS HAVE A STANDARD FOR ACCURACY OF PLACEMENT OF BRACHYTHERAPY SOURCES?

QUESTION:

DOES THE COMMITTEE FEEL THAT EXISTING STANDARDS AND PROCEDURES ARE ADEQUATE?

QUESTION:

WHAT COULD WE REQUIRE LICENSEES TO DO TO PREVENT OR MINIMIZE THE LIKELIHOOD OF BRACHYTHERAPY SOURCES FROM MOVING AFTER IMPLANTATION?

ISSUE: SHOULD THERE BE QUALITY ASSURANCE CHECKS AND MEASUREMENTS FOR BRACHYTHERAPY IN PART 35 AS THERE ARE FOR TELETHERAPY?

10 CFR PART 35
EXISTING QUALITY ASSURANCE REQUIREMENTS FOR TELETHERAPY

- 36.630 DOSIMETRY EQUIPMENT
- 35.632 FULL CALIBRATION MEASUREMENTS
- 35.634 PERIODIC SPOT CHECKS
- 35.636 SAFETY CHECKS
- 35.641 RADIATION SURVEYS

QUESTION:

DO ANY PROFESSIONAL MEDICAL ORGANIZATIONS HAVE EXISTING STANDARDS ON CALIBRATION OF BRACHYTHERAPY SOURCES?

QUESTION:

WHO WITHIN THE MEDICAL INSTITUTION DETERMINES THE APPROPRIATE SCHEDULE FOR PREVENTATIVE MAINTENANCE FOR DEVICES?

WHO NORMALLY PERFORMS THE PREVENTIVE MAINTENANCE? IF SOMEONE OTHER THAN THE MANUFACTURER, WHAT TYPE OF TRAINING IS PROVIDED?

QUESTION:

WHAT TYPES OF TESTS/CHECKS ARE PERFORMED AT SOURCE EXCHANGE?

Part 35—Medical Use of Byproduct Material

Section 35.2 Definitions

To consolidate the definitions, all definitions were moved to § 35.2. Based on the public comments, lessons learned from the pilot program, and recommendations from ACMUI, the following proposed definitions have been deleted from the final rule: Basic Quality Assurance, Diagnostic Event, and Diagnostic Referral. The other definitions were adopted with some modifications and are discussed in alphabetical order.

Diagnostic Clinical Procedures Manual. This definition has been modified as follows:

(1) The word "diagnostic" was added to clarify that this term only applies to diagnostic procedures.

(2) The proposed phrase "in a single binder" was deleted to permit the use of multiple binders.

Misadministration. The term "misadministration" as used in proposed § 35.2 and described in proposed §§ 35.33(b) and 35.34(b) has been retained. Table 2 provides a summary of the mistakes captured by the terms "misadministration" and "recordable event," although the requirements themselves should be consulted for the precise definitions of these terms.

TABLE 2.—MISTAKES CAPTURED BY THE TERMS "RECORDABLE EVENT" AND "MISADMINISTRATION"

Procedure	Recordable event	Misadministration
All Diagnostic Radiopharmaceuticals (including <30 μCi NaI, I-125 or I-131).		• Wrong patient, radiopharm, route, or dosage *and* • Dose >5 rem Effective Dose Equivalent or 50 rem to organ.
Sodium Iodide Radiopharmaceuticals (where >30 μCi NaI I-125 or I-131).	• Admin dosage differs by >10% prescr dosage *and* >15 μCi. • W/o written directive • W/o daily dosage record	• Wrong patient • Wrong radiopharm • Admin dosage differs by >20% prescr dosage *and* >30 μCi.
Therapeutic Radiopharmaceuticals	• Admin dosage differs by >10% prescr dosage • W/o written directive • W/o daily dosage record	• Wrong patient • Wrong radiopharm • Wrong route of admin • Admin dosage differs by >20% prescr dosage.
Teletherapy	• Calculated weekly dose 15% >prescr dose • W/o written directive • W/o daily dose record	• Wrong patient • Wrong mode of treatment • Wrong treatment site • Calculated weekly dose 30% >prescr dose • Calculated total dose differs by >20% total prescr dose • If <3 fractions, calc total dose differs by >10% total prescr dose.
Brachytherapy	• Calc dose differs by >10% prescr dose • W/o written directive • W/o daily dose record	• Wrong patient • Wrong radioisotope • Wrong treatment site • Leaking sources • Failure to remove sources for a temporary implant • Calculated admin dose differs by >20% prescr dose.
Gamma Stereotactic Radiosurgery	• W/o written directive • W/o daily dose record	• Wrong patient • Wrong treatment site • Calculated total admin dose differs by >10% total prescr dose.

Six categories of misadministrations are defined in the final amendment. Paragraphs (2), (3), (4), (5) and a part of paragraph (1) replace therapy misadministration as proposed in § 35.34(b). Paragraph (6) and a part of paragraph (1) replace diagnostic misadministration as proposed in § 35.33(b).

Each category of misadministration under this definition is discussed here in the same sequence as it appears in the definition of misadministration in § 35.2 of the final rule.

(1) This paragraph applies to any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. Paragraph (1)(i) is essentially the same as the corresponding items in proposed § 35.34(b)(1). However, the phrases "wrong target organ" and "wrong route of administration" were deleted because the thyroid is the only target organ for sodium iodide and it concentrates in the thyroid regardless of the route of administration. Paragraph (1)(ii) is the same as proposed § 35.34(b)(2) with two modifications. First, the threshold is now 20 percent, instead of 10 percent. Recall that if the administered dosage differs from the prescribed dosage by more than 10 percent, a recordable event has occurred that the licensee is required to respond to internally within the institution. Since the licensee is detecting these smaller deviations and taking the appropriate actions, these events do not need to be reported to NRC. However, larger deviations that exceed 20 percent are required to be reported because they could possibly indicate a deficiency in the QM program, not because they necessarily indicate a significant risk to the patient. For these reasons, the threshold was increased to 20 percent.

Secondly, an additional threshold of 30 microcuries is added. If the difference between the administered dosage and the prescribed dosage is 30 microcuries or less, it is not reported even if the difference exceeds 20 percent. This additional threshold was added to avoid the unnecessary work associated with the generation of reports on events with small differences and that pose relatively minor risks to the patients.

(2) This paragraph applies to any therapeutic radiopharmaceutical administration except those involving sodium iodide I–125 or I–131. Paragraph (2)(i) is the same as the corresponding items in proposed § 35.34(b)(1). The phrase "wrong target organ" was deleted because the

2.7 V.A. Medical Center (Hines, IL) - Misadministration (Glenn)

On April 8, 1994, the licensee informed Region III that an error had occurred during the radiation treatment of a patient using a Gamma Med II HDR unit and an iridium-192 sealed source. The patient was scheduled to receive a series of two treatments of 600 rads (6 gray) for a total dose of 1,200 rads (12 gray). Because of an error in the treatment parameters, the patient received 1,000 rads (10 gray) in the first treatment on April 7, 1994.

On April 6, 1994, during treatment planning, the licensee entered the wrong date in to the HDR unit. The date, "4-6-94," was incorrectly entered as "6-4-94." The treatment time is based on the computed strength of the iridium-192 source. Since the iridium-192 source with a 74-day halflife would have a lower strength on 6-4-94, the HDR unit increased the calculated treatment time resulting in the greater than intended dose.

The licensee intends to modify the written directive for the treatment to compensate for the error. For the second treatment, the dose will be 200 rads (2 gray).

ABNORMAL OCCURRENCE?

ACTION:

DUE DATE:

2.8 Fox Chase Cancer Center (Philadelphia, PA) - Misadministration (Glenn)

On April 14, 1994, an NRC inspector determined that the following event was a misadministration. The licensee stated that they were unaware that the reporting requirement applied to each administered fraction.

On August 18, 1993, a therapeutic misadministration occurred at the licensee's facility when a patient who was scheduled to receive a 700 centigray (cGy) dose of radiation to his esophagus actually received a 1000 cGy dose. The licensee stated that a treatment plan was developed to deliver the 700 cGy and that this plan was reviewed by the physicists and physician and found to be correct. However, prior to administering the dose, the physicist reassessed the HDR treatment planning system to modify some non-critical factor. The physicist reported having a problem maneuvering between the various menus in the treatment planning system. According to the physicist and chief physicist, the modified plan was input into the HDR control computer without an additional indepth review and the treatment was delivered. The licensee identified the error during a routine physics check conducted that same day. The chief physicist stated that they originally believed that the HDR manufacturer's treatment planning system software may have been at fault and they notified the manufacturer of a possible program problem. The chief physicist and physicist stated that they spent several hours trying to reproduce the error but were unable to do so. The chief physicist stated that after consultation with the manufacturer, she concluded that the problem resulted from an error made by the physicist

ABNORMAL OCCURRENCE?

ACTION:

DUE DATE:

2.5 Orlando Cancer Center (Orlando, FL) - Brachytherapy Misadministration (OSP)

On April 4, 1994, the State of Florida notified Region II of a medical misadministration to one patient while using a Nucletron, Microselectron model, High Dose Rate (HDR) device containing 9.6 curies of iridium-192. Initial information indicates that the licensee performed a source exchange on March 30, 1994. The old source containing 4.35 curies was replaced with a 9.6 curie source. The Physicist intended to recalibrate the device over the weekend, since no treatments had been scheduled for the rest of the week. On Friday, April 1, a treatment was given using the "old" activity of 4.35 curies, resulting in an overexposure.

The treatment reportedly called for 1200 cGy (rads) to be delivered in two fractionated doses. Instead, approximately 1200 rads were given in one dose. Florida has confirmed that no additional patients will be treated until the State is assured that adequate protective actions have been taken by the licensee.

ABNORMAL OCCURRENCE?

ACTION:

DUE DATE:

2.6 Harrisburg Cancer Center (Harrisburg, IL) - Teletherapy Misadministration (OSP)

On April 1, 1994, Region III was notified by the Illinois Department of Nuclear Safety (IDNS) that on March 28, 1994, the licensee identified that a patient receiving a cobalt-60 teletherapy treatment was administrated a dose of 4,200 rad (4,200 centiGray) to the brain instead of the prescribed 3,000 rad (3,000 cGy). The patient's prescription called for a series of 15 radiation treatments of the lungs and a series of 10 treatments of the brain. After 14 treatments had been delivered to both the lungs and brain, the error was detected and the brain treatments were terminated. The last treatment was administrated to the lungs as planned.

ABNORMAL OCCURRENCE?

ACTION:

DUE DATE:

INADVERTENT ADMINISTRATIONS OF DIAGNOSTIC RADIOPHARMACEUTICALS

APPLICABILITY OF THE PROVISIONS OF 10 CFR 20.1301 TO ADMINISTRATION OF A RADIOPHARMACEUTICAL TO THE *WRONG* PATIENT

CASE SUMMARY

- hospital patient underwent an unintended diagnostic nuclear medicine procedure (Tc-99m)
- due to misorder from medical student under the supervision of the patient's referring physician
- resulting dose of ~800 mrem (8 mSv) was higher than what is allowed members of the public (10 CFR 20.1301) but below the whole body threshold criteria of 5 rem (50 mSv) in 10 CFR Part 35
- 1989-1990: staff is aware of about 200 reports involving administration of a diagnostic radiopharmaceutical where none was intended

PROPOSED STAFF OPTIONS

- Part 20 is controlling because patient is considered a member of the general public who was not intended for any nuclear medicine procedure

- Part 35 is controlling because the exposure occurred as a result of an error in administering a radiopharmaceutical, which is addressed in the misadministration regulation in Part 35

- Issue requires clarification through rulemaking and staff should exercise enforcement discretion during the interim

STAFF REQUIREMENTS MEMORANDUM

- SRM dated May 10, 1994
- Commission approved the following action:
  - no violation of 10 CFR Part 20 in the cited case
  - staff should proceed with rulemaking to clarify that the medical administration of radioactivity or radioactive materials to a patient (which includes a "wrong patient") is the exclusive province of Part 35

STAFF REQUIREMENTS MEMORANDUM
(Continued)

- **Staff to seek public comment on notification following errors in administration where no administration was intended and the threshold for misadministration was not exceeded:**

  Are there practical ways to apply 10 CFR Part 20 to such inadvertent administrations without defeating the policies behind the definition of misadministration? OM rule- diag. minor risk. devote resources to more serious error.

  Would notification in these cases impose recordkeeping and procedural requirements upon licensees beyond those explicitly set forth in 10 CFR Part 35?

QUESTIONS

What are the ACMUI recommendations on the issues identified in the SRM?

What are the ACMUI recommendations for definition of "patient" and/or "wrong patient", particularly as they apply to those individuals that are not scheduled to receive byproduct material?

10 CFR 35.2 - DEFINITIONS

- Wrong patient
- Wrong radiopharmaceutical
- Wrong route of administration
- Wrong mode of treatment
- Wrong treatment site
- Wrong radioisotope

What is captured by the term "wrong patient"?

FOR ACMUI MEETING

RADIOPHARMACEUTICAL FINAL RULEMAKING

A proposed rule was published for public comment on June 17, 1993. The NRC has received 284 comment letters: 280 letters supported the rule, 1 letter opposed, and 3 letters provided comments without specifically indicating support or opposition. The final rule text remains essentially the same as the proposed rule except for minor modifications to clarify the intent of the rule.

For example, proposed § 35.6, "Provisions for research involving human subjects," would have required that licensees obtain informed consent from the human research subject and obtain prior approval by an Institutional Review Board (IRB). In the final rule, the requirements remain the same but a phrase has been added to clarify that the informed consent and IRB approval must be done in compliance with the provisions of the Federal Policy for the Protection of Human Subjects. Furthermore, a section entitled, "Training for experienced nuclear pharmacists" (§ 35.981), has been added to the final rule to clarify that qualified individuals working in hospital-based nuclear pharmacies may be grandfathered as authorized nuclear pharmacists in a manner similar to § 32.72 in the proposed rule for grandfathering qualified individuals working in commercial nuclear pharmacies.

The final rulemaking package will be submitted to the EDO with the guidance documents which are expected to be completed in the Fall of 1994. The staff is making efforts to ensure that the final rule becomes effective by January 1, 1995 when the interim final rule expires.

PATIENT NOTIFICATION

NRC INFORMATION NOTICE 93-36

- Issued May 7, 1993
- survey of data on therapeutic misadministrations for CY90-92
- notification of referring physician - 97%
- verbal notification of patient - 72%
  - medical decision of harm - 32%
- written notification of patient - 56%

REQUESTS FOR OGC GUIDANCE

- issuance of letter to licensees not in compliance with 10 CFR 35.33 in May 1993
- since IN 93-36 and letter were issued, additional issues raised by licensees and NRC staff
- staff conferred with OGC on interpretation of the current misadministration rule
- based on guidance, staff prepared draft IN to provide further clarification of requirements

ISSUE 1

Notification of patient's responsible relative in those cases where the patient is a competent, consenting adult and the referring physician has informed the licensee that, based on medical judgment, telling the patient would be harmful

- **responsible relative or guardian must be notified even if patient is a competent adult when:**

  - **medical decision of harm to patient**
  - **patient is a minor**
  - **patient is unconscious or incapable of comprehending**
  - **patient has died**

- **supported by regulatory history**

ISSUE 1 (Cont'd)

- duty of confidentiality aspect of "physician-patient" relationship consistent with AMA's 'Principles of Medical Ethics'

- AMA states principles are not laws, but standards of conduct

  Principle IV: "A physician shall ... safeguard patient confidences within the constraints of the law"

  Principle III: "A physician shall respect the law and the rights of patients"

- any duty of confidentiality must be reconciled with a patient's right to know of a misadministration

ISSUE 2

Documentation of a referring physician's decision not to notify the patient

- **o if reliance is placed on referring physician to notify the patient, the licensee should:**

  - **- confirm notification of the patient; or**

  - **- document (and evaluate) reason for not informing the patient**

- **o referring physician may decide not to tell the responsible relative if he/she has knowledge that telling the individual would be harmful**

ISSUE 3

Licensee's provision of a written report to the patient when the patient has been notified

- **licensee must provide a written report to patient, regardless whether the patient was notified by the licensee or the referring physician**

ISSUE 4

Retention of misadministration records

- **10 CFR 35.21(b)(2)(xi) - establish and implement written procedures for keeping a copy of records and reports required by Commission regulations**

- **licensee reports to patients are required (10 CFR 35.33(a)(4)) and therefore must be retained**

ISSUE 5

Notification of NRC Operations Center of incidents determined by NRC to be misadministrations

- **in those cases that licensee may not believe an incident to be a misadministration, but it is later classified as such - licensee must comply with requirement to notify NRC Operations Center and all other applicable notification requirements**

ISSUE 6

Definitions of prescribing and referring physician

- **based on a review of:**
  - **Part 35 requirements**
  - **Statements of Consideration for Part 35**
  - **ICRP Publication No. 52**
  - **consultation with ACMUI**
  - **consultation with representatives of AMA and AHA**
  - **consultation with OGC**

ISSUE 6 (Cont'd)

Prescribing physician

- **physician authorized user who prescribes the radiation dose or dosage of byproduct material for a diagnostic or therapeutic procedure**

Referring physician

- **physician who refers the patient to a radiation oncologist, nuclear medicine physician, or other category of authorized user, and requests consultation, treatment, or diagnostic tests for the patient**

- **typically is a specialist, or in some cases, the primary care physician**

QUESTIONS

Are there specific aspects of the Information Notice which the ACMUI believes need further clarification?

Does the ACMUI believe the IN is consistent with NRC's 1979 Medical Policy Statement?

FOR ACMUI MEETING

RADIOPHARMACEUTICAL FINAL RULEMAKING

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