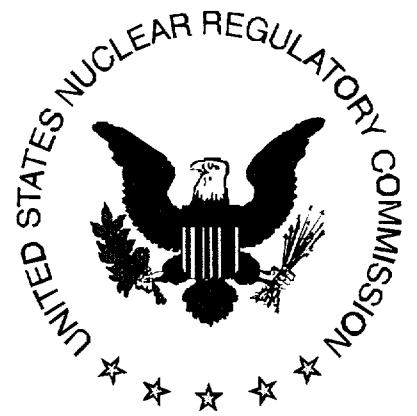

ADVISORY COMMITTEE on the MEDICAL USES of ISOTOPES

Briefing Book

April 18, 2001

Rockville, MD

ACMUI SPEAKERS & PARTICIPATING STAFF
April 18, 2001

Robert Ayres, NMSS/IMNS/MSIB

Frederick Brown, NMSS/IMNS/MSIB

Manuel Cerqueira, ACMUI Chairman

Donald Cool, NMSS/IMNS

Michael Gillin, American Association of Physicists in Medicine

Catherine Haney, NMSS/IMNS/RGB

John Hickey, NMSS/IMNS/MSIB

Donna-Beth Howe, NMSS/IMNS/MSIB

Lucia Lopez, NMSS/IMNS/MSIB

Frederick Sturz, NMSS/IMNS/MSIB

Angela Williamson, NMSS/IMNS/MSIB

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 18, 2001
8:00 am - 5:00 pm

U.S. Nuclear Regulatory Commission
Two White Flint Building-T2B3
Rockville, Maryland

AGENDA

8:00 - 8:15	Opening Remarks - John Hickey, NRC and Dr. Manuel Cerqueira, Chairman, ACMUI
	Award of Appreciation to Dr. Naomi Alazraki - Dr. Donald Cool, NRC
8:15 - 8:30	Follow-up to Items from Previous Meeting (November 8-9, 2000) - Frederick Brown, NRC
8:30 - 8:45	Status of ACMUI Vacancies - Angela Williamson, NRC
8:45 - 9:15	Status of 10 CFR Part 35/Part 35.75 Rulemakings - Catherine Haney, NRC
9:15 - 9:45	10 CFR Part 35 Transition and Implementation Issues - John Hickey, NRC
9:45 - 10:00	**BREAK**
10:00 - 11:00	Recognition of Certification Boards - Robert Ayres, NRC
11:00 - 11:45	Authorization for Brachytherapy Procedures not covered by FDA Approvals - Donna Beth Howe, NRC
11:45 - 1:00	**LUNCH**
1:00 - 2:00	"Physical Presence" issue for new brachytherapy procedures: Presence of Medical Physicist, Cardiologist, etc. - Frederick Sturz, NRC
2:00 - 3:00	Authorization for Broad Licensees to Utilize New Brachytherapy Procedures - John Hickey, NRC
3:00 - 3:15	**BREAK**
3:15 - 3:45	Rejection of Medical Waste by Local Landfills - John Hickey, NRC
3:45 - 4:00	ACMUI Interactions with Staff - Angela Williamson, NRC
4:00 - 4:15	Self-Evaluation Criteria for ACMUI - Angela Williamson, NRC

4:15 - 4:45	Open discussion of next meeting dates and agenda topics
4:45 - 5:00	Summary of Meeting - Dr. Cerqueira, ACMUI Chairman
5:00	**ADJOURN**

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. **Committee's Official Designation**:

Advisory Committee on the Medical Uses of Isotopes

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 Material 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 Material 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. $161,000.00 (includes travel, per diem, and compensation)

b. Total staff-year of support: 1.5 FTE

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

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.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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 applciable 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.

Dated: March 12, 2001.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 01-6615 Filed 3-15-01; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Subcommittee Meeting on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on April 4, 2001, Room T-2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, April 4, 2001—2:30 p.m. until the conclusion of business

The Subcommittee will discuss proposed ACRS activities and related matters. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. 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 Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff person named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

Further information regarding topics to be discussed, the scheduling of sessions open to the public, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted therefor can be obtained by contacting the cognizant ACRS staff person, Dr. John T. Larkins (telephone: 301/415-7360) between 7:30 a.m. and 4:15 p.m. (EST). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: March 9, 2001.

James E. Lyons,

Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 01-6614 Filed 3-15-01; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-247]

License No. DPR-26; Consolidated Edison Company of New York, Inc.; Receipt of Petition for Director's Decision Under 10 CFR 2.206

Notice is hereby given that by Petition dated December 4, 2000, Deborah Katz, Marilyn Elie, Tim Judson, Kyle Rabin, Mark Jacobs, Paul Gunter, and Jim Riccio (petitioners) have requested that the Nuclear Regulatory Commission (NRC) take the following six actions with regard to Indian Point Nuclear Generating Unit No. 2 (IP2): (1) Suspend the license for the IP2 reactor because of the licensee's "persistent and pervasive, negligent management of the reactor," (2) investigate whether the potential misrepresentation of material fact by the utility regarding "significantly insufficient" engineering calculations was due to a lack of rigor and thoroughness or was deliberate, (3) revoke the IP2 operating license if it is found that the licensee deliberately provided insufficient and false information, (4) if the license is not revoked, maintain IP2 on the "list of agency's focus reactors" until management demonstrates it can fulfill its regulatory requirements and commitments, (5) not approve the transfer of the IP2 license until management can demonstrate that the Updated Final Safety Analysis Report (UFSAR), the condition report backlog, and the maintenance requirements are up-to-date and workers have been retrained, and (6) not allow the IP2 reactor to restart until the fundamental breakdown in management is analyzed and corrected.

As a basis for this request, the petitioners state that the NRC inspections and other plant performance measurement processes have uncovered serious weaknesses and inaccuracies in the UFSAR, the Technical Specifications, the design and licensing bases, communications, maintenance, procedures, and worker training which, in the aggregate, point to a systemic mismanagement problem. The petitioners further state that without solid evidence that the licensee has addressed the root causes of systemic mismanagement, brought the reactor within compliance with its licensing and design bases, and established that the material condition of safety-significant reactor components is within safe limits, the licensee is no more prepared to operate IP2 than it was before the two recent operating events.

The Petition has been accepted for review pursuant to 10 CFR 2.206 of the Commission's regulations, and has been referred to the Director of the Office of Nuclear Reactor Regulation (NRR). In accordance with Section 2.206, appropriate action will be taken on this Petition within a reasonable time. The NRR Petition Review Board (PRB) met on December 20, 2000, to consider Requested Action 6, that the NRC prevent the IP2 reactor from restarting. The PRB recommended that the request be denied, and the Director denied it. The Director denied Requested Action 6 because the Petitioners' bases for prohibiting IP2's restart had been previously evaluated individually and in aggregate by the NRC for regulatory and safety significance. The Director found that the issues did not warrant prohibiting the restart of IP2. The petitioners Deborah Katz, Tim Judson, Kyle Rabin, Mark Jacobs, Paul Gunter, and Jim Riccio met with the NRR PRB on January 24, 2001, to discuss the Petition. The results of that discussion were considered in the board's determination regarding the schedule for the review of the Petition. The Petition and the NRC's acknowledgment letter are available in ADAMS for inspection at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and from the ADAMS Public Library component on the NRC's Web site, *http://www.nrc.gov* (the Public Electronic Reading Room) at accession nos. ML010580302 and ML010510218, respectively. Information regarding this Petition can also be found on the Indian Point Unit 2 Event page on the NRC's Web site, *http://www.nrc.gov/NRC/REACTOR/IP/index.html*

Dated at Rockville, Maryland this 9th day of March 2001.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 01-6619 Filed 3-15-01; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision

2. The title of the information collection:

—Final rule, 10 CFR part 35, Medical Use of Byproduct Material

—NRC Form 313, Application for Material License, and Supplemental Forms

NRC Form 313A, Training and Experience, and

NRC Form 313B, Preceptor Statement

3. The form number if applicable: NRC Form 313, 313A and 313B

4. How often the collection is required: Reports of medical events, doses to an embryo/fetus or nursing child, or leaking sources are reportable on occurrence. A certifying entity desiring to be recognized by the NRC must request recognition.

5. Who will be required or asked to report: Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation therefrom to humans for medical use.

6. An estimate of the number of responses: 214,402 (61,182 NRC licensees, 153,220 Agreement State licensees). In addition, 23 organizations are expected to prepare requests for recognition.

NRC Form 313: 7 (2 NRC licensees, 5 Agreement State licensees) applications for new modalities.

7. The estimated number of annual respondents: 5793 (1,655 NRC licensees and 4,138 Agreement State licensees).

8. An estimate of the total number of hours needed annually to complete the requirement or request: Part 35: 889,754 hours (254,059 hours for NRC licensees and 635,695 hours for Agreement State licensees) (an average of 154 hours per licensee). In addition, there is a one-time burden of 368 hours on certifying boards involved in their preparing requests for recognition. NRC Form 313: 673 hours (193 hours for NRC licensees and 480 hours for Agreement State licensees).

9. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Applicable

10. Abstract: 10 CFR Part 35, "Medical Use of Byproduct Material", is being restructured into a more risk-informed, more performance-based regulation. The final rule contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use.

The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the possession and use of byproduct material is in compliance with the license and regulatory requirements.

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. OMB clearance packages are available at the NRC worldwide web site: http://www.nrc.gov/NRC/PUBLIC/OMB/index.html. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by April 16, 2001:

Amy Farrell, Office of Information and Regulatory Affairs (3150–0010, and –0120), NEOB–10202, Office of Management and Budget, Washington DC 20503.

Comments can also be submitted by telephone at (202) 395–7318.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 9th day of March 2001.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–6617 Filed 3–15–01; 8:45 am]

BILLING CODE 7590–01–P

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 April 18, 2001. The meeting will take place at the address provided below. The entire meeting will be open to the public. Topics of discussion will include: (1) status of issuance of the new 10 CFR part 35, Medical Use of Byproduct Material; (2) transition and implementation issues for the new 10 CFR part 35; (3) recognition of certification boards for training and experience qualifications; and (4) licensing issues for brachytherapy.

DATES: The meeting will be held on April 18, 2001, from 8:00 a.m. to 5:00 p.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 reproducible copy to Angela Williamson (address previously listed) by April 11, 2001. Statements 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 and copying for a fee, at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852–2738, telephone (800) 397–4209, on or about May 20, 2001. Minutes of the meeting will be available on or about June 8, 2001.

4. 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 Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations*, Part 7.

ACMUI MEETING
April 18, 2001

Issue: Follow-up to Items from Previous Meeting

NRC Contact: Frederick D. Brown

BACKGROUND: ACMUI made several recommendations to staff as a result of its November 8-9, 2000 meeting. These recommendations were summarized in a memorandum dated February 12, 2001, from the ACMUI Chairman to the Director, IMNS. The recommendations were as follows:

- ❑ Use of 35 CFR 400 for the TheraSphere
- ❑ Development of search engine for NRC website
- ❑ Limit reportability criteria in new 10 CFR 35.75 rulemaking
- ❑ Halt on further rulemaking on exposure to embryo/fetus

Staff will brief the committee on the NRC response to the recommendations, and will also discuss changes in the minutes.

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

February 12, 2001

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

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

SUBJECT: RECOMMENDATIONS FROM NOVEMBER 8-9, 2000, MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

To facilitate the conversation between the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the Division of Industrial and Medical Nuclear Safety, I am providing you with a response and status for each of the recommendations made by ACMUI at the November 8-9, 2000, meeting.

Using 10 CFR 7, "Advisory Committees," and 41 CFR 101, "Federal Advisory Committee Management," we are considering whether a more effective process for interaction between NRC and the ACMUI can be developed. Proposals for the revised process will be discussed with ACMUI at the next meeting scheduled for April 18-19, 2001.

Listed below are the recommendations with the staff's response.

New Medical Technologies:

The ACMUI recommended that a license amendment be required under § 35.400, "Use of sources for brachytherapy," for the TheraSphere®.

Staff response: The staff plans to implement this recommendation when issuing TheraSphere® license amendments under the existing 10 CFR Part 35, "Medical Use of Byproduct Material."

NRC/Agreement State Event Reporting:

The ACMUI recommended that the NRC develop an NRC web site to include a search engine that would enable one to find relevant sections for reporting requirements and that guidance on reporting be organized by type of licensee, e.g., materials, medical, industrial, etc.

Staff response: An extensive effort is underway to improve the NRC web site. This recommendation is consistent with previous input to that effort, and will be considered as part of the agency's ongoing web redesign.

CONTACT: Betty Torres, NMSS/IMNS
(301) 415-0191

Update on Other Rulemaking Activities:

1) The ACMUI recommended that the new risk-informed reporting limit of 5 rem in 10 CFR 35 be limited to reporting of errors made in the release procedure or delivery of instructions to the patient that results in exposures to individuals, other than the patient, in excess of 5 rem.

Staff response: The staff is following the Commission's direction proposing a revision to 10 CFR 35 to require a licensee to notify NRC when it becomes aware that an individual has received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." The staff will include the ACMUI recommendations in the paper transmitting the proposed rule.

2) The ACMUI recommended that no further rulemaking be required for exposure to embryo/fetus because 10 CFR 20, "Standards for Protection against Radiation," already contains reporting requirements for all exposures to the general public.

Staff response: The staff provided the ACMUI recommendations, along with the staff's recommendations, as part of the paper sent to the Commission addressing the issue of embryo/fetus exposure. The staff received Commission approval to terminate any further action on the proposed embryo/fetus rulemaking.

Training Requirements:

Regarding the training requirement in § 35.961, "Training for teletherapy physicist," the ACMUI recommended that exemptions be based on a case-by-case review by the ACMUI Chairman with input from the members.

Staff response: The staff plans to implement the recommendation and review requests, on a case-by-case basis, for exemptions to the training requirement with input from the ACMUI chairman.

ACMUI MEETING
April 18, 2001

Issue: Status of ACMUI Vacancies.

NRC Contact: Angela Williamson

BACKGROUND: Vacant positions require refilling; reappointments pending approval from the Commission. The vacant positions are:

1. Nuclear Medicine Physician
2. Medical Physicist
3. Health Care Administrator

Three reappointments are pending. These are:

1. Manuel Cerquiera, Nuclear Cardiologist and Chairman;
2. Nekita Hobson, Patient Advocate, and
3. Ruth McBurney, State Government Representative

Status Of ACMUI Vacancies

Angela R. Williamson
ACMUI Project Manager

Nuclear Medicine Physician Vacancy

- Forwarded SECY 01-0036
- STATUS: Awaiting Applications

Health Care Administrator Vacancy

- Forwarded SECY 00-0225 to post Federal Register notice
- Forwarded SECY 01-0036 to appoint Screening Panel member
- STATUS: Awaiting Commission Approval of Screening Panel Candidate

Medical Physics (Nuclear Medicine) Vacancy

- Forwarded SECY 00-0225 to post Federal Register notice
- Forwarded SECY 01-0036 to appoint Screening Panel member
- STATUS: Awaiting Commission Approval of Screening Panel Candidate

Questions?

Status of 10 CFR Part 35

Cathy Haney
301-415-6825
Email: cxh@nrc.gov

Status of 10 CFR Part 35

- Week of March 12, 2001 — Rule and OMB Supporting Statement transmitted to OMB for approval of record keeping and reporting requirements
- March 16, 2001 — FRN announced comment period on NRC submittal to OMB (66 FR 15300)
- April 16, 2001 — Comment period expired

Status of 10 CFR Part 35

- Staff available to respond to questions from OMB
- Website for rule and OMB package:

www.nrc.gov/NRC/PUBLIC/OMB/index.html

Status of 10 CFR Part 35

January 3, 2001 — Received petition for rulemaking: ACNP/SNM requested that the Commission, in part

Revoke all of Part 35, except for specifically identified requirements

Status of 10 CFR Part 35

- April 13, 2001 — Commission denied petition (SRM SECY 01-0150) for the following reasons:
  - Commission approved the final rule addressing the issues in the petition after an unprecedented level of enhanced stakeholder and public participation
  - Commission believes ACNP/SNM had many opportunites to present their concerns and suggestions
  - Petition does not appear to present any significant new information or recommendations not already considered.

Notification Requirement

Associated with § 35.75

- Commission direction — SRM SECY 00-0118
  - Require licensee to notify NRC no later than the next calendar day after licensee becomes aware that an individual received or is estimated to have received a dose exceeding 50 mSv (5 rem) from a patient released under § 35.75
  - Require licensee to submit a written report within 15 days after discovery of the event

Notification Requirement

Associated with § 35.75

- Licensee believes the basis of the release may have been incorrect or release instructions may have been inadequate, OR
- Licensee learns, through voluntary means, that the patient did not follow the physician's instructions

Notification Requirement

Associated with § 35.75

- Commission position:
  - NRC does not intend to enforce a patient's compliance with the licensee's instructions
  - The licensee is not responsible for ensuring compliance by patients once they are released from the licensee's facility

Notification Requirement

Associated with § 35.75

- ACMUI recommendation: November 8 - 9, 2000
  - Risk-informed reporting limit of 5 rem should be limited to
    - Reporting of errors made in the release of the patient
    - Reporting of errors made in delivery of instructions to the patient

Notification Requirement

Associated with § 35.75

- Questions
  - What are the implications of requiring reporting of all events where an individual receives a dose greater than 50 mSv (5 rem) from a released patient?
  - Would the ACMUI limit reporting to errors?
  - How would define "error"?

Notification Requirement

Associated with § 35.75

- Questions
  - Could you provide some examples of "real-life" situations which could lead to an individual receiving a dose in excess of 50 mSv (5 rem) from a released patient?
  - What are the number of reports expected per year?

NOTE TO: ALL CONCERNED

SUBJECT: TEXT OF NEW PART 3-PARTIAL

The text of the new Part 35 contained in this document is partial. To view the new Part 35 in its entirety, please see:

http://www.nrc.gov/NRC/Public/OMB/index.html.

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision

2. The title of the information collection:

—Final rule, 10 CFR part 35, Medical Use of Byproduct Material

—NRC Form 313, Application for Material License, and Supplemental Forms

NRC Form 313A, Training and Experience, and

NRC Form 313B, Preceptor Statement

3. The form number if applicable: NRC Form 313, 313A and 313B

4. How often the collection is required: Reports of medical events, doses to an embryo/fetus or nursing child, or leaking sources are reportable on occurrence. A certifying entity desiring to be recognized by the NRC must request recognition.

5. Who will be required or asked to report: Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation therefrom to humans for medical use.

6. An estimate of the number of responses: 214,402 (61,182 NRC licensees, 153,220 Agreement State licensees). In addition, 23 organizations are expected to prepare requests for recognition.

NRC Form 313: 7 (2 NRC licensees, 5 Agreement State licensees) applications for new modalities.

7. The estimated number of annual respondents: 5793 (1,655 NRC licensees and 4,138 Agreement State licensees).

8. An estimate of the total number of hours needed annually to complete the requirement or request: Part 35: 889,754 hours (254,059 hours for NRC licensees and 635,695 hours for Agreement State licensees) (an average of 154 hours per licensee). In addition, there is a one-time burden of 368 hours on certifying boards involved in their preparing requests for recognition. NRC Form 313: 673 hours (193 hours for NRC licensees and 480 hours for Agreement State licensees).

9. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Applicable

10. Abstract: 10 CFR Part 35, "Medical Use of Byproduct Material", is being restructured into a more risk-informed, more performance-based regulation. The final rule contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use.

The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the possession and use of byproduct material is in compliance with the license and regulatory requirements.

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F23, Rockville, MD 20852. OMB clearance packages are available at the NRC worldwide web site: http://www.nrc.gov/NRC/PUBLIC/OMB/index.html. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by April 16, 2001:

Amy Farrell, Office of Information and Regulatory Affairs (3150–0010, and –0120), NEOB–10202, Office of Management and Budget, Washington DC 20503.

Comments can also be submitted by telephone at (202) 395–7318.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 9th day of March 2001.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–6617 Filed 3–15–01; 8:45 am]

BILLING CODE 7590–01–P

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 April 18, 2001. The meeting will take place at the address provided below. The entire meeting will be open to the public. Topics of discussion will include: (1) status of issuance of the new 10 CFR part 35, Medical Use of Byproduct Material; (2) transition and implementation issues for the new 10 CFR part 35; (3) recognition of certification boards for training and experience qualifications; and (4) licensing issues for brachytherapy.

DATES: The meeting will be held on April 18, 2001, from 8:00 a.m. to 5:00 p.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 reproducible copy to Angela Williamson (address previously listed) by April 11, 2001. Statements 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 and copying for a fee, at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852–2738, telephone (800) 397–4209, on or about May 20, 2001. Minutes of the meeting will be available on or about June 8, 2001.

4. 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 Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations*, Part 7.

OMB TEXT, 3/16/01

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

Subpart D--	**Unsealed Byproduct Material - Written Directive Not Required**
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
35.190	Training for uptake, dilution, and excretion studies.
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
35.204	Permissible molybdenum-99 concentration.
35.290	Training for imaging and localization studies.
Subpart E--	**Unsealed Byproduct Material -Written Directive Required**
35.300	Use of unsealed byproduct material for which a written directive is required.
35.310	Safety instruction.
35.315	Safety precautions.
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).
35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).
Subpart F--	**Manual Brachytherapy**
35.400	Use of sources for manual brachytherapy.
35.404	Surveys after source implant and removal.
35.406	Brachytherapy sources accountability.
35.410	Safety instruction.
35.415	Safety precautions.
35.432	Calibration measurements of brachytherapy sources.
35.433	Decay of strontium-90 sources for ophthalmic treatments.
35.457	Therapy-related computer systems.
35.490	Training for use of manual brachytherapy sources.
35.491	Training for ophthalmic use of strontium-90.
Subpart G--	**Sealed Sources for Diagnosis**
35.500	Use of sealed sources for diagnosis.
35.590	Training for use of sealed sources for diagnosis.
Subpart H--	**Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**
35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
35.604	Surveys of patients and human research subjects treated with a remote afterloader unit.
35.605	Installation, maintenance, adjustment, and repair.
35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.630	Dosimetry equipment.

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A--General Information

§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

Authorized medical physicist means an individual who --

(1) Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on --

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who --

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on --

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on --

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Brachytherapy means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

Brachytherapy source means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

High dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy, as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

Medical event means an event that meets the criteria in § 35.3045(a).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented --

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means --

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader, as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but --

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who --

(1) Meets the requirements in §§ 35.50(a) and 35.59; or

(2) Is identified as a Radiation Safety Officer on --

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary job site means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

Therapeutic dosage means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

Unit dosage means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original, a reproduced copy, or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing

a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research --

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the license shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research --

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310,

35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 35.12, NRC Form 313, including NRC Forms 313A and 313B, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

§ 35.10 Implementation.

(a) A licensee shall implement the provisions in this part on or before [insert date 6 months from publication of the Final Rule].

(b) If a license condition exempted a licensee from a provision of Part 35 on [insert date 6 months from publication of the Final Rule], then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(c) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(d) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

§ 35.11 License required.

(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b)(1) or (b)(2) of this section.

(b) A specific license is not needed for an individual who--

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by --

(1) Filing an original and one copy of NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by --

(1) Submitting an original and one copy of either --

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter requesting the amendment or renewal; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on --

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment --

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;

(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except --

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a)and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist --

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(e) Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200;

(f) Before it changes the address(es) of use identified in the application or on the license; and

(g) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety.

§ 35.14 Notifications.

(a) A licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, or the permit issued by a Commission master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).

(b) A licensee shall notify the Commission by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee's mailing address changes;

(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or

(4) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33, is exempt from --

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

(c) The provisions of § 35.13(e) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;

(f) The provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200.

(g) The provisions of § 35.49(a).

§ 35.18 License issuance.

(a) The Commission shall issue a license for the medical use of byproduct material if --

(1) The applicant has filed NRC Form 313 "Application for Material License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing --

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee

has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if --

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall --

(1) In addition to the requirements in § 19.12, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

§ 35.41 Procedures for administrations requiring a written directive.

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material--

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

§ 35.49 Suppliers for sealed sources or devices for medical use.

For medical use, a licensee may only use --

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices noncommercially transferred from a Part 35 licensee; or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;
(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
(C) Securing and controlling byproduct material;
(D) Using administrative controls to avoid mistakes in the administration of byproduct material;
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(F) Using emergency procedures to control byproduct material; and
(G) Disposing of byproduct material; and
(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, 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 Radiation Safety Officer for a medical use licensee; or
(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

§ 35.51 Training for an authorized medical physicist.

The licensee shall require the authorized medical physicist to be an individual who --
(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or
(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and
(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --
(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or
(b)(1) Has completed 700 hours in a structured educational program consisting of both:
(i) Didactic training in the following areas --

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(ii) Supervised practical experience in a nuclear pharmacy involving --
(A) Shipping, receiving, and performing related radiation surveys;
(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
(D) Using administrative controls to avoid medical events in the administration of byproduct material; and
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or master material license permit or by a master material license permittee of broad scope before [insert date 6 months from publication of the Final Rule] need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.
(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before [insert date 6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H.

§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, and H must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart C--General Technical Requirements

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall --

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by--

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by --

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(c) For other than unit dosages, this determination must be made by--

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

§ 35.65 Authorization for calibration, transmission, and reference sources.

Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

(a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations.

(b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(c) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(d) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

(e) Technetium-99m in amounts as needed.

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall --

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall --

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all

such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include --

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

§ 35.80 Provision of mobile medical service.

(a) A licensee providing mobile medical service shall --

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[1] NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it --

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Subpart D--Unsealed Byproduct Material - Written Directive Not Required

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies; the training and experience must include --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

(c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with § 35.2204.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies; the training and experience must include, at a minimum, --

(i) Classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

Subpart E--Unsealed Byproduct Material - Written Directive Required

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is --

(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;
(3) Contamination control;
(4) Waste control; and
(5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.
(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.315 Safety precautions.

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall --
(1) Quarter the patient or the human research subject either in --
(i) A private room with a private sanitary facility; or
(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;
(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.
(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and
(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.
(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who --
(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or
(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include --
(i) Classroom and laboratory training in the following areas --
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience

in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[2];

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

§ 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).

Except as provided in § 35.57, the licensee shall require an authorized user 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), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

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[2]Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve --
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and
(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

Subpart F-- Manual Brachytherapy

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:
(a) As approved in the Sealed Source and Device Registry; or
(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.
(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research

subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall --

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after [insert date 6 months from publication of the Final Rule], a licensee shall have –

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

§ 35.457 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who --

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy; the training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve --

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Subpart G--Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device; the training must include --

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

Subpart H-- Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall --

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include --

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of --

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in --

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency

response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position; and

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

§ 35.632 Full calibration measurements on teletherapy units.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit --

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within +/- 5 percent;

(2) Source positioning accuracy to within +/- 1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions --

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --

(1) The output within +/-3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of --

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of --

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of --

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall--

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --

(1) Assure proper operation of --

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine --

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of --

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

(a) A licensee providing mobile remote afterloader service shall --

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of --

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who --

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes --

(i) 200 hours of classroom and laboratory training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving --

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Subpart I -- [Reserved]

Subpart J -- [Reserved]

Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if --

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L-- Records

§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

§ 35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive

A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2061 Records of radiation survey instrument calibrations.

A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument,

the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain--

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by --

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

§ 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

§ 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include --

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include --

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include--

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under § 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include --

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include --

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642 (b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include --

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include --

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include --

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit.

(b) The record must contain --

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

Subpart M--Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in --

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following –

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include --

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may

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[3]The commercial telephone number of the NRC Operations Center is (301) 951-0550.

not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the individual who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that --

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include --

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or

(b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(a) Name of the pregnant individual or the nursing child who is the subject of the event; and

(b) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

§ 35.3067 Report of a leaking source.

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Subpart N--Enforcement

§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of --

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of --

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002 .5454

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

April 10, 2001

Angela R. Williamson
Office of Nuclear Material Safety and safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 0555-0001

Re: Materials for ACMUI meeting, April 18, 2001

Dear Ms. Williamson:

Pursuant to the notice of the ACMUI meeting published in the Federal Register on March 16, 2001, I am submitting herewith a Memorandum and supporting documents from the Presidents of the Society of Nuclear Medicine and American College of Nuclear Physicians. While we have sent each of the members of the ACMUI these materials, I am providing them to you for inclusion in the packets and materials for the meeting on April 18.

If you have any questions, please feel free to contact me at 703-708-9773 or by email wuffelman@snm.org.

Thank you for your consideration.

Sincerely,

William R. Uffelman
General Counsel and Director of Public Affairs

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SOCIETY OF NUCLEAR MEDICINE
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MEMORANDUM

To: Members, Advisory Committee on the Medical Uses of Isotopes
From: Sue Abreu, MD, President
American College of Nuclear Physicians

Jonathan Links, PhD, President
Society of Nuclear Medicine

Date: April 10, 2001
Re: NRC Part 35

It is our understanding that at your meeting on April 18, 2001, you will be briefed by NRC staff on the status of 10 CFR Part 35, Medical Uses of Byproduct Material. During the briefing we would like you to bear in mind that ACNP and SNM have petitioned the NRC Commissioners to reduce the regulation of diagnostic nuclear medicine to a level consistent with the risks presented. It is our position that the level of regulation of diagnostic nuclear medicine embodied in the revisions of Part 35 is excessive and unnecessarily burdensome.

Recently we submitted a cost analysis to the Office of Management and Budget, commenting on the impact on nuclear medicine of the revisions of 10 CFR Part 35. When we considered the impact analysis submitted by the NRC staff, we determined that it grossly underestimated the first year costs of implementing the revisions and also underestimated the cost of ongoing compliance with the revisions. Our analysis leads us to believe that the first year cost of compliance for all licensees is over $494 million and annual recurring costs for all licensees are $127 million. To put these costs in perspective, they are the equivalent of 247 dedicated PET scanners in the first year and 63 additional scanners in each succeeding year.

In the past, the ACMUI joined the NAS-IOM in calling for diagnostic nuclear medicine regulation to be "de-emphasized". We ask that you now renew that call and that you urge the NRC Commissioners to give the ACNP/SNM Petition fair consideration and to dramatically modify the revisions to 10 CFR Part 35.

Copies of the documents submitted by ACNP and SNM are attached for your review.

Dr. Gary Dillehay, ACNP President-elect, will be attending your April 18 meeting and will answer any questions that you may have about this important matter.

Society of
Nuclear Medicine

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PRESS RELEASE

For Release
January 4, 2001 12 noon

Contact: William Uffelman
703-708-9773
Karen Lubieniecki
703-683-0357

New Nuclear Medicine Regulations Protested

January 4, 2001..Reston, Virginia...The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) today filed a petition with the Nuclear Regulatory Commission in Washington, DC asking it to develop a regulatory program that is better suited to the risks presented by diagnostic Nuclear Medicine and to rescind approval of portions of the proposed revisions to 10 CFR Part 35. Part 35 covers the use of byproduct material in diagnostic nuclear medicine.

Nuclear byproduct materials are used to produce some of the tracer elements injected into patients to conduct many potentially life-saving nuclear medicine procedures such as cardiac stress tests to analyze heart function, lung scans to verify blood clots, bone scans to diagnose orthopedic injuries, and to determine if cancer has metastasized. Currently, the NRC does not regulate x-rays or machine produced radioisotopes such as those used in positron emission tomography, (PET). Approximately 13 million nuclear medicine procedures are performed on patients each year, and the average American receives 3.8 nuclear medicine procedures during his lifetime.

In their petition, SNM and ACNP noted that instead of realistically reforming the regulatory burden in Part 35, the NRC has left the regulations virtually unchanged and instituted increased use of "license conditions" to impose requirements that do not appear in its regulations. SNM and ACNP noted that the NRC's new, supposedly "risk-informed" regulations, in fact mark a step backward and not forward, and one that will potentially cost the US healthcare system between $500 million to $1 billion in dual regulations and meaningless compliance costs.

In a letter signed by Jonathan Links, President of the SNM and Donald A. Podoloff, President of the ACNP, they noted that "We are not asking that diagnostic nuclear medicine be 'deregulated.' Instead, we are asking for the creation of a regulatory proposal that bears some meaningful relationship to the minimal risks presented by diagnostic nuclear medicine."

ACNP and SNM noted that the NRC completely ignored the advice of the National Academy of Science-Institute of Medicine, the agency with which it had contracted to make recommendations on how to reform the regulation of nuclear medicine. In its report the Academy stated: "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 by 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." Further, the NAS/IOM Report 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.

In the petition, SNM and ACNP asked the Commission to refocus its regulatory emphasis on ensuring the safety and health of patients and individuals working in the field. They asked the NRC to revoke

> "all of Part 35, except for requirements concerning comprehensive education, training, and experience of Authorized Users, coupled with a new provision that would require evidence of mastery of basic nuclear and radiation sciences by passage of an examination given in this field by a board certified by the American Board of Medical Specialties or a single alternate examination equivalent in scope and depth to that covered in the certified boards and approved by the ACMUI."

"We find it ironic that at a time when the emphasis should be on reducing patient costs and unnecessary paperwork, NRC is making it even more costly for Americans to access one of the safest group of procedures available to it," stated Links and Podoloff, who went on to write, "if we were truly cynical, we would see a direct connection with our increased licensing requirement with the fact that NRC raises all its operating funds through license fees."

In its petition SNM and ACNP pointed out the discipline's unparalleled safety record, with NO deaths in the past 40 years. It also noted that diagnostic nuclear medicine's safety record far surpassed those of other common medical procedures, many of which are far more hazardous.

Medical Modality	Death Rate
Non-Radioactive Drugs	10-40/10,000
Parenteral Contrast Media	0.25/10,000
Pulmonary Angiography	25/10,000
Penicillin	2/10,000
Heparin	9.5/10,000
Antineoplastics(Chemotherapy Drugs)	58/10,000
Blood Transfusions	0.03/10,000
Radiopharmaceuticals	**0.0004/10,000**[1]

In addressing the issue of patient and worker safety the petition noted that most workers in the field are exposed to radiation absorbed doses below 10 percent of the legal maximum, an average of 68 mrem per year. The general public undergoing a typical nuclear medicine procedure actually receives a radiation dose of 440 mrem, which is less than the background radiation in the city of Denver, Colorado (530) and only slightly higher than the average background radiation in the rest of the United States (300 mrem).

The Society of Nuclear Medicine is an international scientific and professional organization of more than 13,000 members dedicated to promoting the science, technology, and practical

application of nuclear medicine. The American College of Nuclear Physicians represents the socio-economic interests of the nuclear medicine community. SNM and ACNP are based in Reston, Virginia. For more information, visit the SNM web site at www.snm.org.

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[1] Based on one proven death from radiation dose error with Au-198 and allergic or drug reaction deaths in 11 other cases in the course of administering 333 million nuclear medicine doses.

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

January 3, 2001

Richard A. Meserve
Chairman
Nuclear Regulatory Commission
One White Flint North Building 11555 Rockville Pike
Room 17D1
Rockville, MD 20852

Dear Chairman Meserve:

The Society of Nuclear Medicine and the American College of Nuclear Physicians have today filed a petition which asks you to rescind your approval of the staff's proposed revisions to 10 C.F.R. Part 35 and to institute a new rulemaking proceeding to adopt a regulatory system for the use of byproduct material in diagnostic nuclear medicine which reflects the discipline's unparalleled and undisputed safety record. The petition, a copy of which is attached, was filed with the Secretary to the Commission.

The revisions to Part 35 adopted by the Commission on October 23, 2000 offer little meaningful change from the existing regulations. Just as the Commission disregarded the recommendations of the National Academy of Sciences-Institute of Medicine, the Commission staff appears to have overlooked every significant recommendation that was not in their preconceived parameters of what the rule should be. Combined with the Commission's increased use 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.

We are not asking that diagnostic nuclear medicine be "deregulated." Instead, we are asking for the creation of a regulatory proposal that bears some meaningful relationship to the minimal risks presented by diagnostic nuclear medicine. Furthermore, we request that the Commissioners assign the review and evaluation of this petition to staff members who were not

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on the Part 35 revision in order to minimize the impact of pride of authorship on a balanced review of the petition's merits.

We look forward to working with the Commission to continue to provide the public with safe, effective and reasonably priced diagnostic nuclear medicine procedures.

Very truly yours,

Donald A. Podoloff, MD
President
American College of Nuclear Physicians

Jonathan M. Links, PhD
President
Society of Nuclear Medicine

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

January 3, 2001

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Rulemakings and Ajudications Staff

PETITION FOR RULEMAKING

Pursuant to the provisions of 10 C.F.R. § 2.802, the undersigned Society of Nuclear Medicine and American College of Nuclear Physicians hereby petition the Commission to rescind its approval of the staff's proposed revisions to 10 C.F.R. Part 35 and, instead, to institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine which reflects the discipline's unparalleled and undisputed safety record.

I. INTRODUCTION AND SUMMARY OF PETITION

> "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).

The Society of Nuclear Medicine (the Society) and the American College of Nuclear Physicians (the College) hereby petition the Commissioners of the Nuclear Regulatory Commission (NRC) to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine which reflects the discipline's unparalleled and undisputed safety record. Irrationally, the NRC regulations applicable to diagnostic nuclear medicine eclipse by a wide margin the regulatory controls imposed on other dramatically more dangerous medical products and procedures. The goal of this petition is to end that unsupportable and extraordinarily expensive program. Our proposed regulatory scheme, which would assure the continued extremely safe use of diagnostic nuclear medicine products and procedures while saving the Nation millions of dollars a year, is discussed in detail in Section II, below.

The Society and the College, representing 14,000 nuclear medicine physicians, nuclear pharmacists, nuclear medicine technologists, nuclear and medical physicists, radiochemists,

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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. The revised Part 35 was to be an enlightened, "risk-informed" regulatory scheme that recognized the minimal risk of diagnostic nuclear medicine. In fact, the revisions to Part 35 adopted by the Commission on October 23, 2000 offer little meaningful change from the existing regulations. 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 use 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 has adopted 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 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.

II. ACTION REQUESTED

In order to more accurately match the regulatory scheme to the minimal risks presented, the Society and the College petition the Commission to regulate the use of byproduct material in diagnostic nuclear medicine solely by:

1. Protecting workers, the general public, and the environment through the radiation protection standards of 10 C.F.R. Part 20;

2. Ensuring the protection of patients, workers, the public, and the environment by enforcing comprehensive education, training and experience requirements for the use and possession of byproduct materials;

3. Relying on health care professionals with the required education, training, and experience in nuclear medicine, nuclear pharmacy, and basic nuclear and radiation science to protect the health and safety of their patients under the supervision of their respective State Medicine and Pharmacy Boards;

4. Revoking all of Part 35, except for requirements concerning comprehensive education, training, and experience of Authorized Users, coupled with a new

provision that would require evidence of mastery of basic nuclear and radiation sciences by passage of an examination given in this field by a board certified by the American Board of Medical Specialties or a single alternate examination equivalent in scope and depth to that covered in the certified boards and approved by the ACMUI;

5. Ceasing the subdivision of diagnostic nuclear medicine into smaller and smaller fragments. After completing comprehensive education, training, and experience in basic nuclear and radiation sciences, and passing an appropriate comprehensive examination in these areas, as defined in (4), above, an Authorized User may subspecialize in any portion of diagnostic nuclear medicine he/she wishes without further Commission restriction;

6. Removing all license conditions except for simple identification. This includes the name, address, e-mail address, telephone, and fax numbers of the institution, the responsible administrator, and the RSO. The license should simply state, "This license permits the possession, use, transport, and disposal of any byproduct material, in any physical or chemical form, in any quantity, for diagnostic nuclear medicine use including clinical use, research, quality control, teaching, and related diagnostic nuclear medicine professional activities." In the case of presently limited licenses, such as in nuclear cardiology, "diagnostic nuclear cardiology" should replace "diagnostic nuclear medicine." The license should also state that, "This license does not cover diagnostic uses of radiopharmaceuticals containing more than 30 microcuries of I-131."

7. Inspecting diagnostic medical licensees only in those rare situations of likely overexposures of workers, the general public, or the environment. The routine inspections now being conducted are an invitation to document meaningless paperwork "deviations" and which impose substantial unnecessary costs on licensees. As far as patients are concerned, cases of possible malpractice will be handled under existing State law by the Boards of Medicine and/or Pharmacy and the courts, without NRC involvement unless specifically requested by the Board or the Court.

8. Decreasing the size of the staff assigned to the medical use program to adequately reflect the limited role the Commission plays in assuring diagnostic nuclear medicine safety. This staff adjustment has been long overdue. As the number of NRC medical licensees decreases because of the increase in Agreement States, the number of employees assigned to the medical program paradoxically increases. Because Congress requires that the NRC recover its costs from licensees, fewer and fewer licensees are supporting an increasingly bloated NRC program. A properly sized staff alone would dramatically reduce the escalating cost of holding an NRC license.

Adoption of this proposal would assure radiation protection of patients, workers, the public, and the environment by focusing on the competence of practitioners in the basic nuclear and radiation sciences, eliminate requirements that negatively impact patient care, and end unnecessary dual regulation and meaningless paperwork and regulatory compliance costs estimated at $500 million to $1 billion annually.

We are not asking for a "deregulation" of diagnostic nuclear medicine in the usual meaning of the word, which implies a decrease in safety standards.[1] We are asking that the safety standards in 10 C.F.R. Part 20 ***continue to apply unchanged***. Instead, we are asking the NRC to remove the prescriptive regulations and license conditions that purport to tell highly qualified individuals how to achieve those safety standards. Qualified professional Authorized Users have significantly more training and real-life experience than regulators in providing the highest level of protection and safety to their patients and others. Complying with the NRC's onerous, yet ultimately unnecessary, regulations has become such an onerous task that the NAS-IOM condemned NRC's medical program in its entirety. The Society and the College believe that the recent Part 35 rewrite is ample evidence of the staff's inability to make meaningful changes to a program upon which they depend for their jobs. Accordingly, the Society and the College request that the Commissioners assign the review and evaluation of this Petition to staff members who have no vested interest in the continuation of the existing program.

III. STATEMENT OF GROUNDS

The Society and the College believe that the unparalleled history of the safe use of diagnostic nuclear medicine products and procedures is, in itself, more than adequate support for the action requested by this Petition. That history is summarized below. For additional background, the Commission is respectfully referred to the report of its own contractor, the National Academy of Sciences-Institute of Medicine, RADIATION IN MEDICINE - A NEED FOR REGULATORY REFORM (1996), which meticulously documented the utter lack of connection between the Commission's regulatory scheme and any benefit to patients or the public.

A. Nuclear medicine

Diagnostic nuclear medicine is a medical specialty that uses extremely safe radioactive drugs (tracers) to gain information about health and disease, often using modern imaging techniques. As an integral part of patient care, diagnostic nuclear medicine is used in the diagnosis, management, and prevention of serious disease. Nuclear medicine imaging procedures often identify abnormalities very early in the progression of a disease, before these medical problems are apparent with other diagnostic tests. This early detection allows for prompt treatment when the prognosis may well be much better than if the disease were allowed

[1] Although this petition deals solely with diagnostic nuclear medicine, the Society and the College believe that essentially the same arguments can be made to reduce the burden on the practice of therapeutic nuclear medicine.

to progress. Each year in the United States, over 13 million nuclear medicine procedures are performed on patients. Common diagnostic nuclear medicine procedures include radiopharmaceutical cardiac stress tests to analyze heart function, bone scans to diagnose orthopedic injuries or cancer which has spread from other organs, tumor imaging, staging of cancer, lung scans for blood clots, and liver and gall bladder procedures to diagnose abnormal function or blockages.

Diagnostic nuclear medicine procedures are among the safest patient diagnostic tests available, considering adverse drug reactions, vascular complications, anatomical disruption by foreign bodies, anoxic tissue complications, and radiation. The amount of radiation in a diagnostic nuclear medicine procedure averages 440 mrem effective dose equivalent (ede), according to NRCP Commentary No. 7, published Oct. 1, 1991 and paid for by the NRC using medical licensee User Fee money. (This number is somewhat lower today, due to significant replacement of Ga-67 citrate and In-111-white blood cell imaging by Tc-99m-HMPAO-white blood cell imaging, and a rise in the use of Tc-99m labeled cardiac tracers significantly replacing Tl-201 chloride use.) This compares with a United States average of 300 mrem natural background per year, 530 mrem in Denver, 600-700 mrem/year in Colorado ski areas, and 100 mrem/year for every 100,000 miles flown in an airplane. None of these radiation absorbed doses are dangerous and none are regulated by anyone, nor should they be.

Nuclear medicine is practiced only by state-licensed physicians who are assisted by technologists and are supported by specially trained physicists and pharmacists. Nuclear medicine combines chemistry, physics, mathematics, computer technology, and medicine in using radioactivity to diagnose and treat disease. Physicians certified by the American Board of Nuclear Medicine first must receive a medical degree and have one or more years of training in a medical specialty other than nuclear medicine. A further two years of training in nuclear medicine is then required during which special instruction is given in physics, radiopharmacy and radiation biology, as well as patient evaluation, radionuclide therapy and diagnostic studies. After successful completion of at least three years of post-doctoral training, a physician may take certifying examinations.

Nationally approved training programs for nuclear medicine technologists have been in existence for many years. These include training in radiation safety, the correct handling of radioactive materials, and techniques of performing nuclear medicine examinations.

In addition, radiopharmacy companies, universities and teaching hospitals provide specialized training to state-licensed pharmacists who specialize in compounding reliable and safe radiopharmaceuticals for patient examinations. Nuclear pharmacy is a board certifiable subspecialty of pharmacy.

B. The History of Nuclear Medicine Regulation

The entire predicate of the NRC's regulation of diagnostic nuclear medicine appears to be that radiation from byproduct materials poses significant risks to patients, workers and the public. That predicate is demonstrably untrue. In fact, diagnostic nuclear medicine is extremely safe, and its use by properly trained health care professionals poses no undue risks. Accordingly, as the NAS-IOM concluded, the regulatory structure imposed on diagnostic nuclear medicine by the NRC is a costly and unnecessary burden that yields no benefit to patients, workers, or the public.

In the 64-year history of nuclear medicine in the United States, about ***one-third of a billion*** radiopharmaceutical doses have been administered. Since imaging devices were invented in the early 1950's, far more diagnosis has been performed than therapy. In recent decades, 99.5% of nuclear medicine is diagnostic. There has been one case, in the 1950's, of a radiation death due to a diagnostic radiopharmaceutical. This happened when the patient accidentally was given 1000 times the activity ordered by the physician. The tracer, Au-198 colloid, has not been used in diagnostic nuclear medicine in this country for about 40 years. This event also occurred before there was board certification in nuclear medicine, nuclear pharmacy, and nuclear medicine technology. The mistake, due to human error, would not have been avoided through any of NRC's present regulations and license conditions in any case. NRC's "Quality Management" Rule was shown recently *by the NRC* not to improve quality at all, as the number of human errors did not change with this rule in place (Secy-97-037).

A spectacular safety record like this is unknown in the rest of medicine, and reflects the intrinsic safety of the tracers in the hands of well-educated, trained, and experienced professionals. NRC regulation is not the reason nuclear medicine is safe. From 1936-1975, accelerator-produced radiopharmaceuticals were prepared for patient use solely under the authority of State Boards of Pharmacy and Medicine. FDA did not begin regulating radiopharmaceuticals until 1975, after intense insistence by the Atomic Energy Commission/Nuclear Regulatory Commission, which at the time (and wisely) did not want to regulate byproduct (reactor-produced) radiopharmaceuticals and human research any longer. Some States had put some radiation regulations in place by the 1950's and 1960's, but these were relatively benign. ***Nonetheless, nothing bad happened.*** To this day, there is no federal regulator of professionals who use accelerator-produced radiopharmaceuticals for patient care; state regulation is adequate. This, in a sense, is the "control" experiment of what would happen without NRC. Indeed, P-32 and I-131, two of the more dangerous therapeutic radionuclides used in nuclear medicine, were made by accelerator for many years before they were made by reactor. There is no evidence that there were any problems when these drugs were accelerator-produced and used without a federal (or even a State, in the early days) regulator.

Under Section 81 of the Atomic Energy Act (the AEA), the NRC regulates the medical use of reactor-generated radioactive materials to protect the public health. 42 U.S.C. § 2111.

The NRC's responsibilities include the regulation of radiopharmaceuticals and sealed sources. The NRC does not regulate machine-produced x-rays nor naturally occurring or accelerator-produced radioisotopes (such as those used in positron emission tomography).

Congress amended the AEA in 1954 to promote civilian uses of the atom, protect the public health and safety, and promote the common defense. Congress promoted civilian uses of the atom by funding isotope production and basic research using radioactive material, while public health and safety were accomplished by carefully licensing the use of radioactive material.

About 20 years later, Congress dissolved the Atomic Energy Commission, and two federal agencies took over and divided the duties previously carried out by the AEC. 42 U.S.C. §§ 5814 & 5841. The Energy Research and Development Agency (precursor to the U.S. Department of Energy) became the promoter of civilian uses of the atom, while the safety oversight authority (licensing and regulatory functions) of the AEC was assigned to the NRC. At approximately this time, FDA, under intense AEC pressure, announced that it was resuming its statutorily authorized practice of licensing and approving radiopharmaceuticals for sale in interstate commerce. Until this time, the FDA deferred to AEC/NRC licensing and regulation of radiopharmaceuticals. 40 FED. REG. 31298 (July 25, 1975).

The States have broad regulatory authority over the general public health and safety of their residents, including authority over all sources of ionizing radiation (except for any authority preempted by the Federal government). The AEA permits States to obtain authority to regulate by-product material by becoming an Agreement State. The NRC formally will relinquish its regulatory authority to an Agreement State based on the NRC's determination that the State's program is adequate and compatible with NRC's. 42 U.S.C. § 2021(b). One problem of late is that "adequacy" and "compatibility" are constantly moving targets, with increasing NRC demands that an Agreement State's medical program (including nuclear pharmacy and medical research) look more and more like NRC's. Twenty years ago, no adequacy and compatibility was expected other than with 10 CFR Part 20, the basic radiation safety standard of the United States. The fact that the number of staff members in the medical and academic program have gone ***up*** as the number of licensees has gone ***down***, reflects poorly on the Commission. In addition, the decision by Congress to require that NRC earn virtually all its operating funds through User Fees has put a huge burden on medical licensees. When they finance no additional benefit to patients or the public, User Fees are especially distasteful.

The use of radioactive material has been a highly regulated activity. All uses and possession of radioactive material are prohibited, except those uses and possessions that are authorized by an individual license. As medical uses of radioactive materials expanded with the development of new technologies, the licensure process quickly became complex, often involving lengthy documents with little consistency from one license to another license. In the late 1970's, the NRC moved to take all common license conditions and place them into regulations. This regulatory action was the NRC's attempt to simplify the licensing process and to allow greater consistency in uses and possession of radioactive materials.

In response to a 1976 report of multiple patient overexposures involving radiation oncology, an entirely different and separate medical specialty, at a Columbus, Ohio hospital, the NRC began to incidentally increase its regulation of nuclear medicine as well.[2/] On February 2, 1979, the NRC adopted a Medical Policy Statement on medical uses of radioisotopes. *See* 44 FED. REG. 8,242 (Feb. 9, 1979). In summary, the Medical Policy Statement provides that:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public;

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate; and

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

Medical Policy Statement, p. 1. In discussing the Medical Policy Statement, the NRC stated that regulations involving patient safety clearly were within the NRC's power, but that, "[t]he central question is a question of *policy* not *authority*." *Id.* at p. 2. The NRC also stated that:

> [f]rom the standpoint of *policy,* these limits [on physician discretion] depend on how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more the NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

Id. Further, the NRC explained that:

> [t]he second part of NRC's policy statement indicates that the NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with those standards, are inadequate. . . .
>
> NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal and State agencies or well administered professional standards. Whenever

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2/ Radiation oncology is not a branch of nuclear medicine. Instead, it uses radiation generated by a sealed source or implanted seeds to treat disease.

possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners exposure.

Id.

Thus, it is clear that the language in the Medical Policy Statement states that the NRC would become involved in regulating patient safety *only when* justified by the risk *and* where voluntary standards are inadequate. Nevertheless, for over 20 years, the NRC steadily has increased its regulation of nuclear medicine despite minimal changes in the materials used, their applications in medicine, and the absence of any evidence of significant problems. The NRC's increased regulation of nuclear medicine has been the source of ongoing tension between the NRC and members of the regulated medical community and the cause of needless expenditure of limited resources. Refusal of the Health Care Financing Administration (HCFA) to reimburse for NRC compliance costs, and a tightening up of healthcare reimbursement generally, have made NRC's requirements untenable, especially with the new and much more expensive regulations and licensing conditions coming out shortly.

In response to the failure of a therapeutic nuclear medicine device, the NRC in 1994 contracted with the Institute of Medicine (the "IOM") of the National Academy of Sciences ("NAS") to conduct the required external review, including a review of the NRC's regulations, policies, practices, and procedures. The NRC set three goals for the NAS/IOM study: 1) examination of the overall risk associated with the use of ionizing radiation in medicine; 2) examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical use of byproduct material. Further, the NRC sought specific recommendations on two major issues. First, the NRC requested recommendations from NAS/IOM on 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 to human beings should be allocated among Federal Government agencies and between the Federal and State governments. Second, the NRC requested recommendations from NAS/IOM on appropriate criteria to measure the effectiveness of regulatory programs needed to protect public health and safety.

In March 1996, the IOM provided the NRC with a final report entitled RADIATION IN MEDICINE - A NEED FOR REGULATORY REFORM (the NAS/IOM Report). The NAS/IOM Report concluded that the NRC's regulations have proven to be unjustifiably intense and burdensome, may compromise the availability of the benefits of nuclear medicine and do not decrease the already negligible risks of medical use of ionizing radiation in any meaningful way. *Id.* at 173.

Specifically, the NAS/IOM Report stated that "[c]ompared 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 do not seem to result in even a

marginal decrease in risk to providers, patients, or members of the public." *Id.* at 171. Further, the NAS/IOM Report 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.

Id. The NAS/IOM report labeled the NRC's current regulatory framework as "illogical" and "counterproductive" and stated that the NRC's regulation of the medical use of reactor generated byproduct material had "outlived its original logic." *Id.* at 175. Finally, the NAS/IOM Report argued for the need to remove regulatory authority for use of by-product material in medicine from the NRC and to replace it with a broader and more appropriate system for the regulation of all ionizing radiation in medicine. *Id.* at 174

During the time when the NAS/IOM Report was being completed, another significant event took place that impacted on the NRC's regulation of nuclear medicine. In August 1995, the NRC commenced a Strategic Assessment and Rebaselining Project intended to reassess the basic nature of the NRC's function and the means by which this function is accomplished. As part of this project, the NRC defined broad categories of Direction Setting Issues (the "DSIs") that effect NRC management philosophy and principles. A total of sixteen (16) DSIs were issued by the NRC. Strategic Assessment Issue Papers discussed details of each DSI and allowed interested parties and the public to comment on the issues proposed by the NRC in each DSI.

The NRC released a Strategic Assessment Issue Paper in September 1996 regarding DSI 7 - Materials/Medical Oversight (the "DSI 7 Paper"). The DSI 7 Paper was issued after the NAS/IOM report and was intended to evaluate the level of control and regulation needed to oversee the NRC's Nuclear Materials Program, and in particular, the NRC's regulation of Nuclear Medicine.

Subsequently, in Staff Requirements Memorandum (SRM) - SECY-96-057, Materials/Medical Oversight (DSI 7), dated March 20, 1997, the Commission directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement. Further, the SRM stated that:

> With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities

> (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.
>
> With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. *The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.*

SECY-96-057, p. 1 (Emphasis added).

In addition, the SECY-96-057 states that NRC staff must submit a program that should "describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99." *Id.* In developing the program, the SRM urges the NRC to focus on certain issues, including:

(1) Focusing Part 35 on those procedures that pose the highest risk.

(2) For diagnostic procedures, *staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.*

Id. at p. 2 (emphasis added).

As a result of the Commission's request, in a June 5, 1997 Rulemaking Issue, (SECY-97-115) NRC staff requested approval of certain procedures that the staff planned to follow in order to best respond to SECY-96-057 and provide the NRC with an alternative program for the revision of Part 35 and associated documents. However, after a subsequent June 13, 1997 meeting between the staff and the Commission, the Commission requested that the staff supplement SECY-97-115 with additional information. Accordingly, the staff issued a June 20, 1997 Rulemaking Issue, (SECY-97-131) that revised the staff's proposal and recommended that revisions to Part 35 be broken down by modality and develop a set of requirements that are based on risk and specific to each modality. In SECY-97-135, the staff suggested that the following seven (7) modalities be addressed:

1. low-dose unsealed materials (diagnostic nuclear medicine);

2. high-dose unsealed materials (nuclear medicine therapy);

3. low-dose sealed source applications;

4. teletherapy;

5. high-dose-rate remote afterloaders;

6. gamma stereotactic surgery; and

7. emerging technologies.

In a subsequent June 30, 1997 SRM, the Commission informed the NRC staff of the Commission's approval, with comments, of the program that the NRC staff proposed in SECY-97-131.

While the NRC has elected to disregard the NAS/IOM Report, and has refused to review the huge body of material substantiating its conclusions, the NRC has stated that it recognized the need for regulatory reform. However, regulatory reform will be beneficial to the medical community and patients only if the NRC elects to regulate nuclear medicine in direct proportion to the risks associated with nuclear medicine.

C. Safety of nuclear medicine

The safety record of the use of byproduct material in diagnostic nuclear medicine is exceptional:

- The nature of the activities performed in diagnostic nuclear medicine and nuclear pharmacy permit easy compliance with worker radiation absorbed dose limits. Most workers in this field are exposed to radiation absorbed doses below 10 percent of the legal maximum. *The NRC has no evidence that suggests otherwise.*

- Members of the general public receive either no or very low radiation doses incident to the practice of diagnostic nuclear medicine. These doses (if any) are well within legal limits and have never been a cause for concern. *The NRC has no evidence that suggests otherwise.*

- Radioactive drugs are prepared in closed systems to assure sterility, thus minimizing airborne environmental contamination. Accordingly, environmental contamination has been minimal and well below legal limits. EPA examined this issue exhaustively and could not find a single example of noncompliance by any medical or academic facility, any manufacturer of radiopharmaceuticals, or any nuclear pharmacy. This included therapeutic as well as diagnostic nuclear medicine, research as well as clinical use. *The NRC has no evidence that suggests otherwise.*

- The number of misadministrations to patients is essentially at the rate of irreducible human error and regulatory attempts to reduce it, such as the Quality Management rule, produce no results. (The only way the number could be reduced is by changing the definition of a "misadministration." The NRC defines as a "misadministration" many events that no one else would.) *The NRC has no evidence that suggests otherwise.*

Because of the small amount of radioactivity required and subsequently low radiation dose, nuclear medicine diagnostic procedures pose little risk to the patient. The amount of time a radiopharmaceutical (radionuclide) remains in the body is determined by both the physical and biological half-life of the radiopharmaceutical. The physical half-life is the time it takes for a radioactive substance to reach one-half of its original strength. The half-lives of medical use radioisotopes vary from mere seconds to thousands of years and a radioisotope with short half-life (seconds or minutes) will cease to be radioactive within a day. Tc-99m, the radioisotope most commonly used in nuclear medicine, has a physical half-life of 6 hours. Biological half-life is the time it takes for a radiopharmaceutical to be eliminated from the body. Accordingly, even though a radioisotope may have a long physical half-life, the time it takes for the radiopharmaceutical to leave the body may be a matter of just minutes or hours.

The greatest risk to a patient in diagnostic nuclear medicine is for the medical professional to perform something other than the best procedure or to fail to tailor the right procedure to a particular patient's needs. Additionally, the patient may be at risk if the medical professional fails to make a diagnosis or makes the wrong diagnosis. However, the radiation dose is unimportant. For example, the average radiation dose equivalent to a patient from diagnostic nuclear medicine is 440 mrem. A dose of 440 mrem is between the yearly average background radiation in the United States (300 mrem) and the background radiation in the city of Denver, Colorado (530 mrem). Based on film badge data, the average annual exposure to workers in nuclear medicine is about 68 mrem ede (NCRP Report No. 101, 1989). It is important to note that humans continually are exposed to radiation from natural and man-made sources. For most people, natural background radiation from space, rocks, soil, and carbon and potassium atoms in his or her own body account for 85 percent of their annual exposure to radiation. Additional exposure is received from consumer products such as household smoke detectors, color television sets, and luminous dial clocks. The remainder is from x-rays and radioactive materials used for medical diagnosis and therapy. The average exposure from human activities involving radiation is 63 mrem/person/year in the United States (NCRP Report No. 93, 1987).

With most nuclear medicine procedures, the patient receives about the same amount of radiation as that acquired during the course of a year of normal living. Table 1 contains a summary of dosage levels associated with several common diagnostic nuclear medicine procedures.

TABLE 1

Dosage Levels Associated With Several Common Diagnostic Nuclear Medicine Procedures[3/]

Type of study and Radioactive Agent	Effective Dose[4/] (mrem)
Cardiac	
Tc-99m -Sestamibi	750 mrem
Bone	
^{99m}Tc-methyldiphosphonate	440 mrem
Brain	
Tc-99m-HMPAO	910 mrem
Infection	
Tc-99m-HMPAO-white blood cells	630 mrem
Hepatobiliary	
^{99m}Tc-DISIDA	330 mrem
Kidney	
^{99m}Tc-DTPA	230 mrem
^{99m}Tc-MAG3	250 mrem
Liver	
^{99m}Tc-sulfur colloid	260 mrem
Lung	
^{99m}Tc-macroaggregate	220 mrem
^{99m}Tc-DTPA aerosol	120 mrem
^{133}Xe gas (5 min rebreathing)	44 mrem
Thyroid	

3/ Dosimetry data from NCRP Commentary no. 7 (1991), ICRP Report No. 53 (1987), ICRP Report No. 62(1991), and FDA-approved Package Inserts.

4/ Effective dose (E) calculated using effective dose equivalent data from ICRP, (1987), *i.e.* effective dose (E) and effective dose equivalent are assumed to be equivalent for the purpose of this table. This column added by the NCRP Ad Hoc Committee.

Type of study and Radioactive Agent	Effective Dose[4/] (mrem)
^{123}I-sodium iodide (25% uptake and scan)	110 mrem
^{131}I-sodium iodide (25% uptake; no scan)	220 mrem
^{99m}Tc-sodium pertechnetate (scan)	40 mrem

D. Safety of nuclear medicine compared to other modalities

No medical activity, process or procedure is completely free of risk. Accordingly, in addition to the strict general regulation of the practice of medicine and pharmacy, many specific medical procedures are subject to increased regulation by specific federal and state regulatory bodies. However, in most cases, the level of regulation has some rational relation to the risks associated with the specific medical activity, process or procedure. Table 2 presents a summary of the risk of death associated with several other medical modalities.

TABLE 2

Comparative Death Rates of Selected Medical Modalities

Medical Modality	Death Rate
Non-Radioactive Drugs	10-40/10,000
Parenteral Contrast Media	0.25/10,000
Pulmonary Angiography	25/10,000
Penicillin	2/10,000
Heparin	9.5/10,000
Antineoplastics(Chemotherapy Drugs)	58/10,000
Blood Transfusions	0.03/10,000
Radiopharmaceuticals	0.0004/10,000[5]

The low risk of nuclear medicine procedures is put into sharp focus by the risks posed by the use of prescription drugs. According to the Food and Drug Administration, adverse drug reactions may occur in 20 percent of ambulatory patients and 2 to 5 percent of hospital admissions are attributed to drug-related illness. 60 FED. REG. 44182, 44187 (Aug. 24, 1995). Further, FDA cites a study which indicates that the case/fatality rate from drug-induced disease in hospitalized patients is 2 percent to 12 percent. *Id.*

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[5] Based on one proven death from radiation dose error with Au-198 and allergic or drug reaction deaths in 11 other cases in the course of administering 333 million nuclear medicine doses.

Similarly, although the NAS/IOM Report states that exact data regarding the risks of anesthesia are difficult to quantify, the NAS/IOM Report states that "[a]ccording to an ECRI technology assessment, more than 2,000 healthy Americans die each year during general anesthesia; an estimated 50 percent of these deaths are preventable. Derrington and Smith estimate the mortality rate from the use of anesthesia at 1:5,000 to 1:10,000 patients/procedures." *Id.* at 123 (citations omitted).

Finally, the NAS/IOM Report provides specific information regarding the risk of death associated with blood transfusions:

> More than 12 million units of red blood cells, 5 million units of platelets, and 2 million units of plasma are administered to patients in the United States each year. Adverse reactions are estimated to be as high as 20 percent. Hemolytic blood transfusion reactions occur as often as 1 in 7,000 red blood cell transfusions and carry a mortality rate of 10 percent.

Id. Accordingly, the risk of death associated with red blood cell transfusions is as high as 1 in 70,000 transfusions.

E. Safety of nuclear medicine compared to level of NRC regulation

It is a common, but sad, joke among those in nuclear medicine that the level of regulation imposed by the NRC is more appropriate to the construction and operation of a nuclear power plant than to a medical procedure. A system failure in a nuclear power plant can lead to catastrophic consequences. The NRC can probably rightly claim that the level of regulation it imposes on power reactors is the reason there have been so few significant nuclear accidents in the United States.

In the field of diagnostic nuclear medicine, however, there is virtually no risk from which protection is needed. As virtually every careful observer has noted, the level of regulation imposed by the NRC is wholly out of proportion to the risks of the procedure. Despite the consistency of this conclusion, the NRC continues to impose unnecessary and expensive requirements. The NRC's 1979 Medical Policy Statement clearly intended to rely on the professionalism of health care professionals to protect patients. As the NRC increasingly ignored it own policy and imposed new and additional requirements, increasingly imposing on the practice of medicine, it has now revised the Medical Policy Statement to support imposition of needless regulations and licensing requirements instead of revising its regulations to accurately reflect the intent of the 1979 Medical Policy Statement. The NRC has also suddenly discovered that the Atomic Energy Commission and the public misinterpreted Section 104 of the Atomic Energy Act incorrectly for nearly fifty years, and that the caveat to make "minimal regulation" in medicine applied to reactors and special nuclear material ***only***, and not to regulations involving byproduct materials. That is, the staff now believes that Congress decided that the direct exposure of patients to nuclear reactor radiation, and the use of U-235 and Pu-238

in medicines, should be "minimally" regulated, while the use of virtually harmless diagnostic agents using byproduct material may be regulated without regard to this Congressional injunction. *See* 63 FED. REG. 43583-84 (Aug. 13, 1998). This new NRC interpretation is preposterous, and shows the lengths the staff will go to justify its regulatory approach. The Commissioners should renounce this absurd pronouncement.

F. Costs to society of unnecessary regulation

On October 21, 1998, the Society and the College presented a preliminary cost estimate of the impact of the proposed revisions to Part 35 to the NRC at a public meeting. The analysis, entitled "Preliminary Estimate of the Cost of the Proposed Part 35 for a Typical Hospital Nuclear Medicine Service; Spread Sheet Analysis," was prepared by Mark Rotman, a former Visiting Medical Fellow at NRC. The analysis did not include the costs of most of Part 20, Part 19, NUREG 1559 Volume 9 (the new licensing NUREG for nuclear medicine), typical license conditions, radioactive waste disposal, User Fees, or any costs at all to any Agreement State nuclear medicine licensees. The total costs of the NRC regulatory scheme alone came to just over $100,000,000/year. Assuming that Agreement States will be forced by NRC to have similar programs, which is indeed happening now, the cost, including Agreement State licensees, is $500,000,000. When one adds all of the other costs, it is easy to reach $1 billion /year , even with the uncertainties. The Society and the College asked the NRC to discard its own severely flawed cost analysis, which was sent to OMB, and to work with the Society and the College to produce a realistic cost estimate. The Commission has not only refused to do so, it has refused to even recognize the existence of the analysis produced by the Society and the College, refusing to discuss it, comment on it, or address the issues in it in any manner.

If this Petition is approved, most of these costs would disappear. In addition, it is likely that nuclear pharmacy costs would also decrease and, therefore, radiopharmaceutical costs would decrease somewhat as well. At present, about 80 percent of radiopharmaceutical doses are obtained unit dose from centralized nuclear pharmacies.

G. Benefits to the public from the actions sought by the Petition

The public would benefit in two ways if the Commission grants the action requested by this Petition. First, substantial requirements for physician education, training, and experience, and appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. This would assure a broader scope of nuclear medicine services and procedures, with optimization of procedures for individual patients and a generally higher medical quality of procedure. Radiation safety itself would remain the same, because the standards would be unchanged. Radiation safety is not now, and never has been, an issue with diagnostic nuclear medicine practiced by competent professionals.

Second, costs to the health care system would decrease without any decrease in safety. As this petition has demonstrated, the level of regulation imposed by the Commission on nuclear

medicine bears no relationship whatsoever to the extremely low level of risk posed by diagnostic nuclear medicine procedures. The abolition of needless levels of regulation would free up scarce resources in the health care system, resources that could be used to positively impact patient care.

IV. CONCLUSIONS

In order to assure the same level high level of continued protection to patients and the public at a reasonable regulatory cost, the Commission should revoke Part 35, both as it exists today and as the Commission has voted to revise it, and all license conditions for diagnostic nuclear medicine, with the exception of substantial education, training, and experience requirements for Authorized User physicians and pharmacists, as evidenced by board certification or equivalent testing, and identification information about the licensee, as described in more detail in Section II of this Petition.

The Society and the College would welcome an opportunity to meet with the Commission to discuss this Petition and to recommend appropriate education, training, and experience requirements for practicing nuclear medicine.

Respectfully submitted,

Donald A. Podoloff, MD
President
American College of Nuclear Physicians

Jonathan M. Links, PhD
President
Society of Nuclear Medicine

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

January 12, 2001

Jonathon M. Links, PhD
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Dr. Links:

This letter is in reference to the petition for rulemaking that you and Dr. Podoloff, President, American College of Nuclear Physicians, filed with the Commission on January 3, 2001. You request that the Commission rescind its approval of the staff's proposed revisions to 10 CFR Part 35 and institute a new rulemaking that would adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the unparalleled and undisputed safety record of that discipline.

Your letter has been docketed as a petition for rulemaking under 10 CFR 2.802 and assigned Docket Number PRM-35-16. We will inform you of the status of your petition as staff action on it progresses.

You may direct any questions you may have concerning the status of your petition to me on (301) 415-7163, e-mail MTL@NRC.GOV.

Sincerely,

Michael T. Lesar, Acting Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration

Uffelman William

From: Uffelman William
Sent: Wednesday, March 28, 2001 2:26 PM
To: 'afarrell@omb.eop.gov'
Subject: NRC Part 35 analysis

March 28, 2001

Amy Farrell
NRC Desk Officer
Office of Management and Budget

Re: NRC Part 35

Dear Ms. Farrell:

I am writing to follow up on our earlier conversation concerning the amendments to Part 35 that the NRC recently submitted to OMB for review. As I told you, and as we have previously written, the Society of Nuclear Medicine and the American College of Nuclear Physicians believe that the NRC has grossly underestimated the cost to licensees of implementing the new regulations, both during the first year and in the long term. Attached is a spreadsheet comparing NRC's estimate of costs with SNM/ACNP's estimate. As you can see, there are significant differences. Our estimate of the first year total costs of implementing Part 35 is over $494 million with recurring annual costs of almost $127 million.

Analysis of the Costs

The NRC's cost analysis is mainly focused on the record keeping and reporting requirements of the new Part 35. This is the focus of OMB review. However, the NRC has failed to include any time to read the 652 page typewritten regulation or the guidance documents associated with it. Further, the fact that many of the requirements of old Part 35 were transferred to Part 20 does not really reduce the cost of compliance for licensees under the new Part 35. They also do not include time to actually implement the regulations. NRC only includes the time to complete the forms, record surveys and generate reports. The NRC has analyzed the directly regulated states (NRC licensees) separately from the Agreement States. The NRC says that there are about 1,655 NRC licensees directly affected by Part 35 and about 4,138 Agreement State medical licensees for a total of 5793 affected licensees. (On the accompanying spreadsheet this separate analysis by the NRC is maintained.) In the SNM/ACNP analysis we determined that there were 1684 direct NRC licensees and calculated the impact using that number. In the SNM/ACNP estimate for Agreement State licensee impact, we used 4109 licensees to maintain the same total number of licensees (5793) as the NRC. The figures in the Agreement State analysis were extrapolated from our calculated direct NRC licensee figures. The SNM/ACNP calculation uses the same $143 composite hourly salary rate used by the NRC. Finally in comparing the activities included in the SNM/ACNP "implementing" category, we determined that there were some overlaps with the NRC's "record keeping" and "reporting" activities. To eliminate any double counting the SNM/ACNP numbers were reduced by 50% in arriving at the total First Year Cost of compliance of more than $494 million.

Since the time of SNM/ACNP's original economic impact analysis that I described in our phone conversation, the NRC has changed the rule significantly. Some of the requirements have been moved out of the regulation and into regulatory guidance. They have also added some record keeping and reporting requirements. We have now recalculated our original estimate to reflect these changes. As mentioned earlier, the NRC did not include any time for actually reading the regulation and guidance documents -- we have included that time. We have also included time for actually implementing the requirements, time which the NRC ignored in its analysis. Included in the cost of implementing the new regulation are writing the procedures to comply with the Part 35 requirements and the necessary cross-references to Part 20. For example, under 35.24, the time needed to write the procedure must also include the time necessary to comply with the Radiation Protection Program in Section 20.1101. Similarly, under 35.70 the time for compliance with 20.1301 and NUREG 1556 must be included.

With respect to recurring annual costs, only "record keeping" and "reporting" are included as the

requirements are only "implemented" once.

In sum, the SNM/ACNP estimates the first year cost of compliance for all NRC and Agreement State licensees at over $494 million. The recurring annual costs for these licensees are almost $127 million. To put hese costs in perspective, the first year costs are the equivalent of 247 dedicated PET scanners and the recurring costs would buy an additional 63 dedicated PET scanners each year, thus making this new and promising diagnostic technology available to more patients throughout the United States.

Earlier we sent you a copy of the SNM/ACNP Petition asking the NRC to amend Part 35 and to develop a regulatory scheme for diagnostic nuclear medicine that is more closely related to the very low risks presented. Several groups, including the National Academy of Science-Institute of Medicine and the Advisory Committee on Medical Uses of Isotopes have called for diagnostic nuclear medicine regulation to be "de-emphasized". NRC even suggested this during their strategic re-base lining initiative in 1997-98. The NRC Commissioner's original SRM on Part 35 directed staff to develop regulations for diagnostic nuclear medicine commensurate with its low risk. Even though some of the record keeping and reporting requirements have been moved to Part 20 or into guidance documents, the requirements of the new Part 35 as presented to OMB continue the unnecessary reporting and record keeping that do not reflect the safe nature of diagnostic nuclear medicine, but rather the NRC continues to regulate the field by prescriptive and unnecessary regulation. It is our opinion that the new Part 35 regulations lack the "practical utility" that is required of under 5 CFR 1320.5.

5 CFR 1320.5(d)(1)(i) requires the NRC to demonstrate "...that it has taken every reasonable step to ensure that the proposed collection of information ... is the least burdensome necessary for the proper performance of the agency's function...". It appears as though the NRC would have licensees spend more time complying by compiling unnecessary reports and records and conforming to prescriptive regulations to make the NRC inspection job easier, rather than making it the "least burdensome" as possible for the licensees. This does nothing to ensure the public's health and welfare as called for by the Atomic Energy Act, but does drive up the cost of practicing nuclear medicine and the cost of health care to patients.

5 CFR 1320.5(e) requires OMB to determine whether the collection of information proposed by the agency "...is necessary for the proper performance of the agency's functions." It has been our experience that when NRC inspectors are doing their compliance inspections, they often do not look at the content of the records and reports, but rather spend their time looking at whether there are any records or reports that were not done in a timely fashion. The addition of more unnecessary reports and records can only compound this problem.

If you have any questions concerning our analysis of NRC Part 35 or any other matters related to this rule, please let me know. We would be happy to meet with you at your convenience to further discuss this important matter.

Thank you for your consideration.

Sincerely,

William Uffelman
General Counsel and Director of Public Affairs
Society of Nuclear Medicine and American College of Nuclear Physicians


Part 35-Cost of Compliance Sum...


Part 35-Cost AnalysisRev1.xls

Cost of Compliance for Medical Licensees Under the new Part 35

First Year Cost			
Reading Part 35 & Guidance documents ([76,678 hr. + 187,094 hr.] x $143/hr)	$	37,719,396	Notes 1 and 2
Implementing Part 35 ([1,339,019 hr. + 3,267,206 hr.] x .5 x $143)		329,345,088	Notes 2 and 3
New Equipment Purchases (per NRC)		371,000	
Complying with Recordkeeping Requirements ([240,072 hr. + 595,706 hr.] x $143)		119,516,254	Note 2
Complying with Reporting Requirements ([14,868 hr. + 37,232 hr.] x $143)		7,450,300	Note 2
Total First Year Cost	**$**	**494,402,038**	
Recurring Annual Costs			
Complying with Recordkeeping Requirements [240,072 hr. + 595,706 hr.] x $143)	$	119,516,254	Note 2
Complying with Reporting Requirements [14,868 hr. + 37,232 hr.] x $143]		7,450,300	Note 2
Total Recurring Annual Cost	**$**	**126,966,554**	

Notes

1 Total number of licensees per NRC is 5793 or 3.44 times larger than the number of licensees used in SNM/ACNP calculation

2 $143 composite hourly salary rate for licensees per NRC

3 In comparing what activities are included in the SNM/ACNP "Implementing" category to the activities in the NRC's "record keeping" and "reporting" numbers, we determined that there are some overlaps. Ultimately we determined that it was appropriate to reduce the SNM/ACNP "implement" numbers by 50% to eliminate any possible double counting

COMPARISON OF RECORDKEEPING, REPORTING, READING & IMPLEMENTING REQUIREMENTS (hrs.) - NRC vs. SNM

Section	NRC Estimate for NRC Licenses			NRC Estimate for Agree. St. Lic.			SNM Estimate for NRC Licenses			SNM Estimate for Agree. St. Lic.		
	# Licenses	Rcrdkping	Reporting	# Licenses	Rcrdkping	Reporting	# Licenses	Reading	Implement	# Licenses	Reading	Implement
Entire rule							1684	20040		4109	48898	
State of Consid							1684	15577		4109	38008	
NUREG 1556							1684	40921		4109	99847	
35.2							1684	140		4109	342	
35.5							1684		118	4109		288
35.6(b)	164		656	410		1640	1684		51	4109		124
35.6(c)	41		164	103		412						
35.14(a) &9b)	414		104	1035		259	1684		202	4109		493
35.19	2		2	5		5						
35.24							1684		71828	4109		175260
35.24(a)	1655	4138		4138	10345		1684		6392	4109		15596
35.24(c)	336		336	840		840	1684		421	4109		1027
35.24(d)							1684		2526	4109		6163
35.24(e)							1684		2103	4109		5131
35.24(f)	810	405		2025	1013		1684		561	4109		1369
35.26(a)(3 & (4)	1655	828		4138	2069		1684		2526	4109		6163
35.27(a)	1655	1655		4138	4138		1684		12630	4109		30817
35.27(b)	1434	1434		3585	3585							
35.40(a)(1)	1166	2915		2915	5101		1684		63150	4109		154086
35.40(c)(1)	1166	2915		2915	7288							
35.41(a)	1166	583		2915	1458		1684		34103	4109		83211
35.50							1684		2105	4109		5136
35.51							1684		982	4109		2396
35.55							1684		982	4109		2396
35.60							1684		63600	4109		155184
35.61(a)(3)	1655	50		4138	124		1684		15577	4109		38008
35.63							1684		789796	4109		1927102
35.69	1478	62845		3695	157111		1684		87537	4109		213590

	NRC Estimate for NRC Licenses			NRC Estimate for Agree. St. Lic.			SNM Estimate for NRC Licenses			SNM Estimate for Agree. St. Lic.		
Section	# Licenses	Rcrdkping	Reporting	# Licenses	Rcrdkping	Reporting	# Licenses	Reading	Implement	# Licenses	Reading	Implement
35.70							1684		98859	4109		241216
35.75(b)	974		3974	2435		9935	1684		7504	4109		18310
35.80(a)(1)	44	880		110	2200							
35.92							1684		47650	4109		116266
35.204							1684		2890	4109		7052
35.310(a)	841	841		2103	2103		1684		1401	4109		3418
35.315(a)(3)	841	1514		2103	3785		1684		9119	4109		22250
35.315(b)	16		16	40		40						
35.410(a)	421	421		1053	1053							
35.415(a)(3)	421	758		1053	1895							
35.415(c)	73		73	183		183						
35.610(a)(4)	190	190		475	475							
35.610(b)	190	6		475	14							
35.610(c)	190	95		475	238							
35.610(d)	190	190		475	475							
35.610(e)	190	95		475	238							
35.615(f)(4)	20		20	50		50						
35.642(b)	17	68		43	172							
35.642(c)	17	51	51	43	129	129						
35.643(b)	125	500		313	1252							
35.643(c)	125	8125	8125	313	20345	20345						
35.645(b)(1)	15	60		38	152							
35.645(b)(2)	15	975	975	38	2470	2470						
35.1000							1684		3503	4109		8547
35.2024(a)	1655	2069		4138	5173		1684		280	4109		683
35.2024(b)	1655	132		4138	331							
35.2026	1655	414		4138	1035		1684		140	4109		342
35.2040	1166	2507		2915	6267		1684		2097	4109		5117
35.2041	1166	58		2915	146							
35.2045							1684		0	4109		0
35.2060	1478	11824		3695	29560		1684		699	4109		1706
35.2061	1655	621		4138	1552		1684		140	4109		342
35.2063	1478	62845		3695	157111		1684		1677	4109		4092

	NRC Estimate for NRC Licenses			NRC Estimate for Agree. St. Lic.			SNM Estimate for NRC Licenses			SNM Estimate for Agree. St. Lic.		
Section	**# Licenses**	**Rcrdkping**	**Reporting**	**# Licenses**	**Rcrdkping**	**Reporting**	**# Licenses**	**Reading**	**Implement**	**# Licenses**	**Reading**	**Implement**
35.2067(a)	1655	298		4138	745							
35.2067(b)	1655	199		4138	497							
35.2070	974	604		2435	1510		1684		1817	4109		4433
35.2075(a)	974	1403		2435	745		1684		2096	4109		5114
35.2075(b)	974	497		2435	1242							
35.2080(a)	44	26		110	66							
35.2080(b)	44	1144		110	2860							
35.2092	1655	1721		4138	4304		1684		1677	4109		4092
35.2204	591	2459		1478	6148		1684		140	4109		342
35.2310	1127	113		2818	282		1684		140	4109		342
35.2404	580	336		1450	841							
35.2406	584	2920		1460	7300							
35.2432	584	2920		1460	7300							
35.2433	20	8570		50	21425							
35.2605	157	1570		393	3930							
35.2610	190	19		475	48							
35.2630	190	95		475	238							
35.2632	190	1140		475	2850							
35.2642(a)	17	102		43	258							
35.2642(c)	17	1		43	2							
35.2643(a)	125	32500		313	81380							
35.2643(c)	125	6		313	16							
35.2645(a)	15	7800		38	19760							
35.2645(c)	15	1		38	2							
35.2647	4	520		10	1300							
35.2652	190	95		475	238							
35.2655	32	6		80	16							
35.3045(c)	30		15	75		38	1684		0	4109		0
35.3045(d)	30		240	75		600						
35.3045(e)	30		60	75		150						
35.3045(g)	30		15	75		38						
35.3047(c)	3		2	7		4						
35.3047(d)	3		24	7		56						

Section	NRC Estimate for NRC Licenses			NRC Estimate for Agree. St. Lic.			SNM Estimate for NRC Licenses			SNM Estimate for Agree. St. Lic.		
	# Licenses	Rcrdkping	Reporting	# Licenses	Rcrdkping	Reporting	# Licenses	Reading	Implement	# Licenses	Reading	Implement
35.3047(e)	3		6	7		14						
35.3047(f)	3		2	7		4						
35.3067	2		8	10		20						
											187094	3267206
TOTALS		240072	14868		595706	37232		76678	1339019			

NRC Estimate for Recordkeeping & Reporting			
NRC License		Agre. St. Lic.	
254,940 hrs		632,938 hr	

SNM Estimate for Reading & Implementing			
NRC Licenses		Agre. St. Lic.	
1,415,697 hrs.		3,454,300 hrs	

10 CFR PART 35 TRANSITION & IMPLEMENTATION ISSUES:

NO HANDOUT PROVIDED

Board Recognitions

ACMUI Meeting

April 18, 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

Status of Previously Discussed Board Submissions

- Boards reporting as meeting qualifications for NRC recognition:
  - American Board of Nuclear Medicine – 35.190, 35.290, 35.390, 35.392, & 35.394
  - Board of Pharmaceutical Specialties – 35.50 & 35.55
- The three remaining Boards reported either problems with meeting qualifications or were requesting clarification on selected NRC Requirements

New Board Submissions

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

American Board of Nuclear Medicine

- Letter from the Board, dated 11/29/2000
- Addendum to previous submission requesting recognition of board diplomates under 35.50

American Board of Radiology

- Letter from the Board – dated 12/26/2000
- 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

ABR Issues to be Resolved - 1

- Satisfying the 500 hrs of work experience in 35.392, 35.394, 35.490, and 35.690
  - Are 500 hours of separate work experience for **each** therapeutic modality for which Board recognition is sought?
  - No – but work experience for each of the tasks listed under b(1)(ii) for each medical use authorization must be shown

ABR Issues to be Resolved - 2

- Can clinical training of a medical physicist be recognized for 35.50 authorization as an RSO? Yes, provided:
  - At least one year of this training is under the supervision of an RSO
  - Signed preceptor statement is obtained

Alternate Pathway for RSO Authorization

- Alternate pathway for recognition
  - 35.50(c) – authorized medical physicist, authorized user, or authorized nuclear pharmacist who has experience in the radiation safety aspects of using similar types of byproduct materials can be an RSO
  - Applicable to all authorized users, authorized medical physicists, and authorized nuclear pharmacists named on the license
  - Not applicable to those board certifications that do not result in authorized user status, such as,:
    - ABR Board Certification in Medical Nuclear Physics
    - ABSNM Board Certification in Nuclear Medicine Science

Certification Board of Nuclear Cardiology

- Letter from the Board – dated 11/09/2000
- Requests recognition of the board diplomats under 35.290
- Note: Would also be expected to meet the requirements of 35.50(c)

American Board of Science in Nuclear Medicine

- Letter from the Board – dated 12/06/2000
- Requests recognition of the board diplomates for 35.50
  - Appears to lack:
    - the 1 year full-time radiation experience
    - RSO preceptor statement
  - Would not qualify under 35.50(c)

Board	50	51	55	190	290	390	392	394	490	491	590	690
ABHP	x											
ABNM	x			x	x	x	x	x				
AOBNM												
AOBR												
BPS	x		x									
ABMP	x	x										
ABR	x	x				x	x	x	x	x		x
RCPSC	x											
BNC						x						
ABSNM	x											
CNM					x							

Options for Board Recognitions

- Fully meets all stated requirements in the Rule – Recognized
- Partially meets the Rule requirements:
  - Partial recognition (*e.g.* afterloading brachytherapy and teletherapy under 35.600 but not gamma stereotactic radiosurgury)
  - No recognition
- Does not meet the Rule requirements:
  - No recognition
  - Licensees must submit proof that individuals seeking authorized user status meet all applicable T&E requirements set forth in the Rule

Discussion?

American Association of Physicists in Medicine (AAPM)

4,000 plus members, mostly in the United States
The majority of AAPM members practice Radiation Oncology Physics

Michael Gillin, Ph.D.
Chair, Professional Council, AAPM
(Also board member, American Board of Medical Physics)

The AAPM is grateful for the opportunity to address the ACMUI regarding its concerns over the training and experience requirements in the new 10 CFR 35.51 for authorized medical physicists. The AAPM has been and remains generally supportive of the new Part 35 and is pleased that this regulation has introduced the concept of an "Authorized Medical Physicist" (AMP), which emphasizes the importance of the medical physicist's role in the safe and effective delivery of radiation therapy with byproduct materials. The AAPM has explicit concerns about Para. 35.51 and Para. 35.71.

Byproduct Treatment Modalities

1. Teletherapy Units T&E addressed in current Part 35
2. Gamma Knife Units Not previously addressed
3. High Dose Rate Remote Afterloading Units Not previously addressed

Observations

1. There is substantial overlap between the three byproduct material modalities relative to radiation safety, calibration, and quality assurance activities. Thus, a teletherapy trained and experienced medical physicist is well positioned to deal with either HDR or gamma knife therapies. The basic emergency concepts are similar. Radiation decay is radiation decay. Measurement techniques, which involve ionization chambers and radiographic film, are similar.

2. There is substantial overlap between byproduct material modalities and non-byproduct material modalities relative to radiation safety, calibration, and quality assurance activities. Linear accelerators are significantly more complex than Co-60 teletherapy units. Thus a qualified medical physicist is well positioned to become an AMP for teletherapy. The external calibration protocols, which are published by the AAPM, include both accelerators and Co-60 units in the same protocol. With one notable addition relative to Co-60 units, the radiation safety concerns for external beam treatments are similar. The calculation of treatment times follows the same approach for teletherapy units and accelerators.

Concerns – Philosophical

1. An unintended consequence of the new criteria to become an AMP might be to reduce the importance of board certification within the medical physics community. The board examination process does not require experience with specific byproduct material technologies. The focus of the board examination process is to determine if a particular candidate has sufficient knowledge and judgment to practice medical physics independently. There are limited opportunities for medical physicists to obtain training, prior to taking board examinations, with Co-60 teletherapy units or with gamma knifes.

The American Association of Physicists in Medicine, the American College of Medical Physics, and the American College of Radiology have similar definitions for a qualified medical physicist. All the definitions include board certification and continued medical physics education as the essential elements of their definition of a qualified medical physicist.

One argument for a young physicist to go through the expense and effort of taking the board certification examination was that it was an easier path to be named on an NRC license (using the old Part 35.)

Concerns - Practical

1. If a large enough pool of currently authorized medical physicists is not fully grandfathered as AMPs, a shortage of NRC-qualified physicists will result, which will negatively impact on patient care, as there will not be enough AMPs to deliver the needed services.

2. With an inadequate number of grandfathered AMPs, the initial capacity of the NRC's preceptor-based system will be severely constrained, exacerbating the shortage of AMPs and negatively impacting on patient care. It appears from the response to the Public Comments that only currently licensed teletherapy or gamma knife or HDR physicists will be allowed to precept trainees in teletherapy or gamma knife or HDR, respectively. Especially for teletherapy units and gamma knifes, there are relatively few institutions and physicists to oversee and certify this training.

3. The tuition cost to receive vendor-endorsed gamma knife training is $5,000 for one week. The cost for the preceptor-based system may be substantial, given the limited number of opportunities to obtain this training and experience.

ossible Solutions

1. Revise 35.51 to make board certification in therapeutic radiological or radiation oncology physics a sufficient condition to serve as an AMP.

2. Interpret 10 CFR 35.57 broadly, which would create a grandfathered population of AMPs authorized to practice clinical physics for any 35.400 or 35.600 modality and to perform the preceptor function regardless of the current modalities authorized in the license.

3. Define a classification of AMPs who are authorized to manage the licensee's physics and safety commitments for selected byproduct material modalities. The current wording for the new Part 35 appears to require training and experience in all modalities, as opposed to a subset of the modalities.

Thank you for considering these concerns and possible solutions. The AAPM believes that these concerns are very important to insure that the new Part 35 can be implemented successfully and that patients can continue to receive therapeutic benefits from byproduct materials in a safe and effective manner. The AAPM is prepared to work with the NRC staff as staff develops regulatory guides and enforcement manuals for the new Part 35 to insure arification of these concerns.

It is AAPM's understanding of the new part 35 that board certification essentially makes no difference. The new Part 35 requires that the AMP be either certified by a board "whose certification process includes all of the training and experience requirements of paragraph (b), which boards will be very reluctant to agree to, or have THE SAME experience and NOT be certified. If the current understanding of the AAPM is correct, then it is the opinion of the AAPM that the new Part 35 poses a long term, negative public health issue by having the qualifications of medical physicists being defined one way by professional organizations and another way by regulatory agencies.

Even if the AAPM's understanding is not correct, it is important for the ACMUI to understand that the AAPM has this concern, which is based upon the current wording of the new Part 35.

ACMUI MEETING

April 18, 2001

Issue: Authorizations for Brachytherapy Procedures not covered by FDA approvals.

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

BACKGROUND: FDA has several approval mechanisms for approving brachytherapy devices (e.g., 510(k) substantially equivalent determinations, Pre-Market Application approvals, Humanitarian Device Exemptions). Documents submitted to FDA may include very specific indications for use [e.g., "in the radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC)" or "in-stent restenosis of native coronary arteries"] and others may not specify any indications for use. NRC currently specifies fairly broad brachytherapy uses such as "interstitial treatment of cancer."

The question is should NRC's licensing authorizations for use include only those specific uses approved or accepted by FDA or should they be stated in more general terms. This question is specifically for those brachtherapy sources and devices that are not presently included in 10 CFR 35.400.

POINTS FOR DISCUSSION:

- Application of the Medical Policy Statement
- Applicability of 10 CFR 35.7, " FDA, other Federal, and State requirements.
- Lessons learned from the Radiopharmacy Rule
- FDA approvals and the "Practice of Medicine"

Authorization for Brachytherapy Procedures and Devices not Covered by FDA Approvals

ACMUI MEETING
April 18, 2001

Donna-Beth Howe. Ph.D.

Authorization for Brachytherapy Procedures and Devices not Covered by FDA Approvals

ISSUE:

Should Brachytherapy Licensing Authorizations strictly follow the FDA-approved Indications for use

In the last meeting the ACMUI generally supported broader authorizations

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

Medical Use Policy Statement

1. NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.

2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

Medical Use Policy Statement

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

Results from the 1994 "Radiopharmacy Rule"

NRC Authorizarions for radioactive drugs were not limited to FDA-approved uses

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

- **35.7 FDA, other Federal, and State requirements.**
  - Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

Traditional Brachytherapy Source and Device Approval Sequence

- FDA 510 (k) process
- NRC \ Agreement State Sealed Source and Device Registry

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

FDA 510 (k) process - "substantially equivalent" determination

- Proposed use may be general
- Proposed use might not be addressed

Authorization for Brachytherapy Procedures not Covered by FDA Approvals

What is Different Today

Very Specific FDA Indications for Use

- Clinical Trials prior to 510(k) submission
- FDA Pre-Market Approval
- FDA Humanitarian Device Exemption
  - Outside the indication for use requires new HDE

Authorization for Brachytherapy Procedures and Devices not Covered by FDA Approvals

§§35.400, 35.500 and 35.600 Uses

NRC broadly describes Uses

- Routine clinical use
- Research uses
  - Investigational use
  - Approved devices for research uses

Authorization for Brachytherapy Procedures and Devices not Covered by FDA Approvals

NRC's Licensing Approach

- Initially approve uses requested by licensees limited to the FDA approved indications for use
- Broader use authorizations are still under review
- Additional comments from the ACMUI?

If we are allowed to speak, I would offer some brief opening remarks and then turn to Dr. Ian Crocker of Emory University, a Radiation Oncologist, who will offer some specific information about how certain NRC regulatory practices affect patient care. Please call me at 202-986-8059 if there are any questions. I would appreciate knowing as soon as possible if oral presentations will be permitted on April 18, since necessary travel arrangements will need to be made for Dr. Crocker and other Novoste personnel.

Very truly yours,

Martin G. Malsch

Attorney for Novoste Corporation

Enclosure

STATEMENT OF NOVOSTE CORPORATION BEFORE THE NRC ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 18, 2001

This statement is prepared by Novoste Corporation ("Novoste") for consideration by the NRC Advisory Committee on the Medical Uses of Isotopes ("ACMUI") at its meeting scheduled for April 18, 2001 (see 66 Fed. Reg. 15300, March 16, 2001). In particular, this statement addresses one item on the ACMUI agenda, "Authorization for Brachytherapy Procedures not covered by FDA Approvals."

Novoste has invested about $175 million in establishing the safety and efficacy of a manually-controlled intra vascular brachytherapy device, known as the Beta-Cath system, which uses beta radiation from by-product material to treat in-stent restenosis in coronary arteries. The Beta-Cath model approved by FDA includes four principal components: the source train; the delivery catheter; the transfer device; and system accessories. The device uses sealed sources, each consisting of a Sr-90 ceramic matrix contained within a very small stainless steel tube with laser-welded steel lids at each end. The source train, which consists of multiple sealed sources with a non-radioactive opaque marker seed at each end, provides a beta radiation dose along a defined treatment length. The source train is designed

to easily navigate within a delivery catheter and, when not in use, is stored within the transfer device

The Beta-Cath System has been the subject of extensive research and clinical trials, approved by the Food and Drug Administration ("FDA") for routine use, reviewed and approved by Agreement State (Georgia) officials, and placed in the NRC's Sealed Source and Device Registry ("SSDR") maintained pursuant to 10 C.F.R. §32.210. Among other things, the Beta-Cath system is not only safe and effective for patients but, since it uses beta as opposed to photon emitting isotopes, it represents a major advance in assuring that radiation exposures to medical personnel are ALARA, as required by 10 C.F.R. § 35.20.

Novoste is committed to the protection of the health and safety of patients, medical personnel, and the public in the use of its Beta-Cath System, and wants to do all that is necessary to support a sound NRC framework for the licensing of the device. However, while licenses for the use of the Beta-Cath system have been issued in both Agreement and Non-Agreement States, Novoste is still pursuing some licensing issues with the NRC Staff.[1] In particular, as relevant to the cited item on the ACMUI agenda, NRC Staff has instructed its regions (which are responsible for issuance of 10 C.F.R. Part 35 materials licenses in Non-Agreement States) that individual licensees who wish to use the device must

[1]To preserve its right to judicial review, Novoste filed a petition with the U.S. Court of Appeals for the D.C. Circuit for review of NRC Staff's February 5, 2001 instruction to its regions on licensing of Novoste's Beta-Cath system (No. 01-1162).

accept a condition in their license that the Beta-Cath system can be used only for "the treatment of coronary arteries for in-stent restenosis lesions (treatable with a 20 millimeter balloon)." The NRC Staff has thereby sought to prohibit individual physicians from using the Beta-Cath system for any purpose or for any indication other than the precise one addressed in the FDA approval, whatever the physician's best medical judgment might otherwise dictate. We think this instruction is both bad policy and contrary to law, and have urged NRC Staff to change it.

This kind of restrictive condition on use of the device by individual licensees is contrary to NRC policy on the licensing and regulation of radiation medicine. Many years ago, NRC sought to apply FDA limitations directed at distribution and advertising of devices containing Atomic Energy Act materials to the actual practice of medicine by physicians who used those materials, but NRC policy has changed substantially since then.

In 1990 NRC completed rule making that specifically authorized its licensees and authorized users "to depart from the FDA approved instructions to obtain diagnostic or therapeutic medical results not otherwise obtainable or to reduce medical risks to particular patients because of their medical condition." 55 Fed. Reg, 34513, August 23, 1990. This was based on the essential NRC regulatory premises that "physicians have the primary responsibility for the protection of their patients," and that "basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are

traditionally considered to be part of the practice of medicine." Id. More recently, in its "Medical Use Of Byproduct Material; Policy Statement, Revision," 65 Fed. Reg. 47654, August 3, 2000 (2000 Policy Statement), NRC stated specifically that its policy "is not to intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public," and that "the focus of NRC regulation to protect the patients health and safety is primarily to ensure that the authorized user physician's directions are followed."

Accordingly, consistent with the 1990 rule making, the regulations in 10 C.F.R. § 35.400 on the use of sources for brachytherapy include only very general limitations on indications (e.g., "for interstitial treatment of cancer"). Moreover, the revised 10 C.F.R. Part 35 Notice of Rule Making, that NRC has approved but is not yet published, would not only eliminate even these very general restrictions, but would also reiterate that "NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients," and state that "the NRC does not intend to develop requirements that are redundant with those of the FDA." The Notice of Rule Making also provides that a deviation from the terms of an FDA approval by an individual NRC licensee does not necessarily require a license amendment, so long as the conditions of the SSDR registration are satisfied and the device was properly

distributed under 10 C.F.R. § 32.74. See draft Notice of Rule Making at page 183.

There is no reason why the NRC Staff must interfere in the exercise of medical judgment by physicians using the Beta-Cath System because of the health and safety of workers or the general public. Given this, it is contrary to NRC policy as explained above to restrict uses of the System to the particular indications in the FDA approval. To impose such a restriction would produce the very result sought to be avoided by the 1990 rule making and the 2000 Policy Statement. It would prevent authorized user physicians from exercising their best medical judgment in circumstances where a departure from the exact terms of the FDA approval are required for therapeutic results that are not otherwise obtainable or to reduce patient risk.

Moreover, as a general matter, this kind of NRC Staff initiative is contrary to law. There is no requirement in the Atomic Energy Act ("AEA") that NRC apply FDA requirements to its licensees. Instead, NRC requirements are to be based on NRC's own safety judgment as an independent regulatory agency. In an analogous situation, the courts have warned parties before another independent regulatory commission that a sister federal agency's recommendations do not absolve the commission from exercising its own judgment, even in cases where the statute itself requires consideration of the sister agency's recommendation. *See, e.g., National Wildlife Federation v. Federal Energy Regulatory Commission*, 912 F.2d 1471, 1480 (D.C.

Cir. 1990). The AEA makes no specific mention of FDA recommendations. Moreover, when Congress wanted NRC to enforce another agency's rules or requirements, or even to take account of another agency's regulatory action, it knew precisely how to do so and spelled this out in the law (for example, section 275 of the AEA). So if Congress had wanted NRC to adopt and enforce FDA requirements, it would have said so.

Finally we believe that this kind of condition, which deprives physicians of their ability to exercise sound medical judgment on patients' behalf, is contrary to sound risk informed regulation. We believe that there are two complementary principles that need to be followed in developing a risk-informed regulatory framework for radiation medicine. First, NRC should target only risk-significant activities, identified from the best available scientific information, for if the NRC and the regulated community spend safety resources on small risks, the inevitable result will be that larger risks will not receive the attention they deserve, and public health and safety will suffer. Second, NRC should target only those activities where NRC's regulatory involvement can benefit public health and safety.

This second principle of risk-informed regulation has direct application to restrictive conditions of the kind under discussion here. As stated above, under the AEA these kinds of conditions must be based on NRC's own expert judgment rather than FDA's. But, while NRC has substantial expertise in radiation

safety principles and related fields, such as health physics, it cannot (even with ACMUI's assistance) possibly acquire or maintain the kind of expertise that would be required to assess the safety or efficacy of the full range of possible treatment options associated with all medical devices and other materials subject to NRC regulation. NRC involvement in controlling individual physician medical judgments could even raise a serious constitutional question whether NRC power under the AEA could extend so far. And even if NRC had such resources, and the constitutional question is put aside, construction of a regulatory framework, which would allow timely patient treatment decisions to be second-guessed on a case basis by NRC, would be impossible. As a result, NRC could as a practical matter only deal with such patient safety matters generically, by instructions of the sort issued for the Beta-Cath system, with the result the regulatory second-guessing of individual physician judgments would be made without any consideration of any of the particular facts or circumstances of individual patient need.

For these reasons, NRC cannot second guess decisions by qualified physicians using materials subject to AEA regulation without running a grave risk that it would do more harm than good. If NRC's regulatory involvement would more likely add risk rather than lesson it, then NRC's involvement in contrary to sound, risk informed regulation.

The NRC Commission made a wise decision in the new Part 35 rulemaking when it said, as it had said before over a decade earlier, that NRC regulation is premised on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of patients. It should stick with that judgement here.

ACMUI MEETING
April 18, 2001

ISSUE: "Physical Presence" for new intravascular brachytherapy procedures: Presence of the Authorized User, Medical Physicist, and Cardiologist.

NRC Contact: Fritz Sturz

BACKGROUND:

Following the patient death in Indiana, PA in November 1992, NRC BULLETIN 92-03 was issued. It required, in part, that:

> *"The Licensee shall assure that appropriate staff and equipment are available immediately, at the location that the HDR procedure is performed, to implement the written emergency procedures."*

Subsequently, Policy and Guidance Directive FC 86-4 was issued that included, in part, that:

> *"During all patient treatments using medium or high dose rate after loading device, both the authorized user and either the medical physicist or radiation safety officer must be physically present....within audible range of normal human speech."*

The New Part 35.615 (f), codifies these requirements that are currently imposed by license conditions:

> *(2) For high dose-rate remote afterloader units, require --*
> *(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and*
> *(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.*

"PHYSICAL PRESENCE" OF TREATMENT TEAM DURING INTRAVASCULAR BRACHYTHERAPY PROCEDURES

ACMUI MEETING
U.S. Nuclear Regulatory Commission
April 18, 2001

Fritz Sturz, NRC

1

NEW IVB TREATMENTS FOR IN-STENT RESTENOSIS

1. Ir-192 seeds in nylon ribbons
2. Sr-90 seeds in hydraulically driven device

FDA premarket approval (PMA) for both in Nov. 2000

2

FOR DISCUSSION

IDENTIFY MEDICAL PERSONNEL (TEAM) TO BE PRESENT DURING NEW INTRAVASCULAR BRACHYTHERAPY TREATMENTS (e.g., IN-STENT RESTENOSIS)

GOAL: PATIENT SAFETY
MEDICAL PERSONNEL SAFETY

3

IVB PROCEDURES

1.	Source Calibration	(Medical Physicist)
2.	Prescribe Dose	(Authorized User)
3.	Patient Preparation	(Interventional Cardiologist)
4.	Dwell Time Calculations	(Medical Physicist/AU)
5.	Introduction of Source Train	(Interventional Cardiologist)
6.	Radiation Treatment Period	
7.	Removal	(Interventional Cardiologist)
8.	Storage/Source Inventory	(Medical Physicist)

4

CODIFICATION OF HDR LICENSE CONDITIONS IN NEW PART 10 CFR 35

High dose-rate remote afterloader units - New Part 35.615 (f)(2) :

1. **Physical presence *during the initiation* of all patient treatments:**
   - **An authorized user (35.690 T&E for 35.600 uses); *and***
   - **An authorized medical physicist (AMP)**

2. ***Continual* physical presence *throughout* the treatment:**
   - **an authorized medical physicist *and either:***
     - **an AU (35.690 training); *or***
     - **a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit**

5

INTERIM NRC STAFF PROPOSAL: PHYSICAL PRESENCE FOR NEW IVB PROCEDURES

Physical Presence of Treatment Team Consisting Of:

- **Authorized User (35.940 T&E For 35.400 Uses);**
- **Interventional Cardiologist; and**
- **Medical Physicist or RSO**

6

MEDICAL SOCIETY RECOMMENDATIONS

1. American College of Radiology (ACC) and Society for Cardiac Angiography and Interventions (SC&I), March 28, 2001:
- IVB for restenosis prevention is a promising modality;
- Techniques are "first generation," significant evolution will occur;
- Committed to developing curriculum and training standards for sealed sources in the vascular system;
- *"In the meantime, the team approach required by the NRC and FDA should continue."*

2. American Society for Therapeutic Radiology and Oncology (ASTRO) and the American College of Radiology (ACR), April 11, 2001
- ASTRO: "Views patient safety as paramount in this procedure...*we feel it is imperative that the team approach remains a requirement of vascular brachytherapy treatment delivery in the future."*

7

POINTS FOR DISCUSSION

1. Important for a properly trained physician to be available at all times to respond to an emergency requiring source removal?
2. Does the inherent risk of high dose-rate IVB (manual or remote) justify both the AU and the AMP to be physically present throughout the treatment period?
3. Appropriate for both the AMP and either an AU or a physician (under the supervision of an AU, who has been trained in the operation and emergency response for the unit) to be present.
4. If not, then either the AU or the AMP?
5. Should the decision of who will be physically present be the responsibility of the AU?

8

ACMUI MEETING
April 18, 2001

Issue: Authorizations for broad licensees to utilize new brachytherapy procedures.

NRC Contact: John Hickey

BACKGROUND: By definition, broad medical licensees have broad flexibility to conduct medical procedures. For example, they can use brachytherapy sources for purposes other those specifically listed in 10 CFR 35.400.

Some new brachytherapy procedures utilize gas, liquid, or microspheres, instead of sealed sources. This raises the question of how the requirement to prepare a written directive applies to broad licensees. The current Part 35 definition of a written directive for brachytherapy is:

(1) Prior to implantation: the radioisotope, number of sources, and source strengths; and
(2) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose)

The new Part 35 definition is:

(i) Before implantation: treatment site, the radionuclide, and dose; and
(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

The definition of the written directive is important in determining whether a misadministrations has occurred.

POINTS FOR DISCUSSION:

–Should broad licensees be required to obtain prior approval from NRC regarding modified definition of the written directive.

–Should the treatment site be specified in advance?

–A gas, liquid, or microsphere dose may be viewed as a "single source".

Issue 1

- Part 20 exposure limits apply to all types of radiations, not just to those generated by by-product materials
- Many physicians perform nuclear medicine procedures and fluoroscopy interventions
- EDE is impossible to measure
- How does NRC and agreement States apply limits to individuals who mix exposures?
- Need reform in methods of occupational risk assessment and enforcement because basing violation-type enforcement on mixed EDE is impractical
- Fallout----violation-enforced regulation discourages faithful risk monitoring
- Need to develop techniques that reward good practices of risk monitoring.

Recommendation: NRC should review rules on occupational dose limitation to:

A. Determine whether NRC has legal authority to incorporate risk from non-by-product material into their regulations.
B. Investigate risk-informed methods of regulation based not on dose limits but on practice of risk assessment and an informed workforce.

Issue 2

- Conditions for licensing are specified by licensing agency and are listed on license
- Regulations state that Agency may require conditions to ensure safety
- Conditions are regulations that are not subject to public review

But

- Who in Agency decides on conditions?
- What guidance is followed to ensure uniformity?
- Are the conditions risk-based?

Recommendation:

- NRC review its policies on creating licensing conditions and make modifications as necessary to:

1. Define criteria under which conditions are necessary (use not covered in rules or repeat violations, etc.)
2. Assure that conditions are risk-based
3. Assure uniformity and fairness in requiring licensing conditions.

A S T R O
The American Society
For Therapeutic Radiology and Oncology, Inc.

April 11, 2001

Ms. Angela R. Williamson
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, Maryland 20852-2738

Dear Ms.Williamson:

The American Society for Therapeutic Radiology and Oncology (ASTRO) and the American College of Radiology (ACR) appreciates the opportunity to submit a written statement to the ACMUI regarding the practice of vascular brachytherapy.

As you know, the FDA implemented a requirement (pre-market approval) that a team of professionals, including a cardiologist, radiation oncologist and medical physicist, be involved in the delivery of vascular brachytherapy. This team approach has remained a requirement after market approval and is indicated on the labelling of brachytherapy devices.

ASTRO believes strongly that the proven effectiveness of vascular brachytherapy to date is due to this team approach. Moreover, ASTRO views patient safety as paramount in this procedure, and considers the low incidence of errors with this treatment delivery to be directly related to the team approach. For these reasons, we feel it is imperative that the team approach remains a requirement of vascular brachytherapy treatment delivery in the future.

ASTRO is committed to collaborating with other organizations, providing educational tools and offering assistance wherever possible to ensure access to all patients needing vascular brachytherapy, while maintaining the highest standards in quality and radiation safety.

If you have any questions, please contact me at (703) 227-0145.

Sincerely,

Nancy R. Daly

Nancy R. Daly, MS, MPH
Director, Government Relations

ASTRO
The American Society
For Therapeutic Radiology and Oncology, Inc.

Written statement submitted to the ACMUI for the April 18, 2001 meeting by The American Society for Therapeutic Radiology and Oncology (ASTRO) and the American College of Radiology (ACR).

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12500 Fair Lakes Circle, Suite 375 Fairfax, VA 22033-3882 (800) 962-7876 (703) 502-1550 Fax: (703) 502-7852

ACMUI MEETING
April 18, 2001

ISSUE: Disposal of radioactive medical waste at local landfills

NRC Contact: John Hickey

BACKGROUND: There are several methods whereby medical licensees can dispose of slightly contaminated radioactive waste as normal trash. This waste is routinely sent to local landfills.

Many landfills have installed radiation alarms, and will reject or investigate any waste which triggers the alarms.

POINTS FOR DISCUSSION:

–There are many ways that radioactive substances can reach a local landfill.

–If radioactive waste is determined to be from a hospital, it is not always easy to tell whether the disposal was authorized or unauthorized.

–NRC does not regulate landfills, and cannot dictate how they monitor incoming waste.

–There is no way to establish a "standard" monitoring method. Some authorized waste materials are more radioactive than unauthorized materials.

–In December 1999, NRC issued a Notice to all medical licensees discussing this issue, but we continue to receive frequent reports of radiation alarms at landfills.

ACMUI MEETING
April 18, 2001

Issues: Changes in Staff Interactions with ACMUI and Review of Abnormal Occurrences

NRC Contact: Angela Williamson

BACKGROUND: Staff proposes several changes to improve interaction with ACMUI. These changes involve the points listed below.

✓ Staff follow-up to Committee recommendations. A summary memorandum will be prepared for inclusion in the meeting minutes.

✓ Administrative matters

✓

-Distribution of briefing books prior to the meeting
-More efficient processing of travel and professional service vouchers

BACKGROUND: In response to the draft SRM SECY 01-0030, staff has proposed that ACMUI review abnormal occurrences that result from the use of radioactive materials. The purpose of this review is to advise NRC whether certain medical events may warrant additional NRC regulatory oversight. The medical events in question are those that involve failures in the quality assurance associated with the medical uses of radioactive materials.

Staff Interactions w/ACMUI

Angela R. Williamson
ACMUI Project Manager

Recent Procedural Changes

- Recommendations to ACMUI
  - answered by IMNS Division Director
  - forwarded to Committee
- Briefing Books
  - indicate desire for advance copy
- Travel Voucher Procedures
- Professional Voucher Procedures
- ACMUI Review of Abnormal Occurrences

Travel Voucher Procedures

- Complete travel voucher worksheet
- Use travel voucher worksheet to complete voucher to the extent possible
- Sign voucher
- Leave voucher with ACMUI Project Manager
- Forward receipts for expenses over $75 to Project Manager
  - original receipt for hotel

Professional Voucher Procedures

- Complete on NRC premises
- Sign and date
- Leave with ACMUI Project Manager

Review of Abnormal Occurrences

Review of Abnormal Occurrences

- Commission-directed action
- Proposed in SRM SECY 01-0030

ACMUI's Role

- When medical events are classified as A.O.s, advise NRC whether revisions to regulatory oversight are warranted
- Medical events: limited to those that occur due to lack of quality management of RAM use

QUESTIONS?

ACMUI Self-evaluation Criteria

1. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the Committee?
2. Do the Committee members clearly define issues for the staff and provide timely, useful, objective information to the staff when requested?
3. Does the Committee provide critical review and oversight of issues?
4. Does the committee provide expertise/advice which is not available from within the Agency?
5. Does the Committee meet frequently enough to address issues in a timely manner?
6. Do committee members bring issues from all elements of the medical community to the attention of NRC staff?
7. Does the committee facilitate/foster communication between the public/medical community and NRC?
8. Does the Committee consider resource constraints of the NRC when recommending new or enhanced regulatory programs?
9. Does the Committee make effective use of subcommittees to assist the staff on specific tasks or projects?
10. Does the scope and size of the Committee meet the current needs of NRC?

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

MEMORANDUM TO: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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

SUBJECT: SELF-EVALUATION OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) initiated a self evaluation at the October, 1999, committee meeting. The draft evaluation was provided to Committee members for review and comment. Attached is the completed self-evaluation of the ACMUI for your use.

Manuel D. Cerqueira, M.D., Chairman

5/2/00
Date

Attachment: ACMUI self-evaluation

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

SELF-EVALUATION

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 communicate openly and effectively. The ACMUI typically conducts a Spring and Fall meeting. The NRC ACMUI Coordinator or the Designated Federal Official (DFO) for the ACMUI contacts the members to keep them informed of issues that will be brought to the Committee's attention. The Committee is provided with background information on issues that will be discussed at the meetings in advance of scheduled meetings. ACMUI members have also identified issues for Commission consideration. In this situation, the members contact either the ACMUI Coordinator or the DFO and request that the issue be placed on the meeting agendas.

The ACMUI and staff have developed a process that provides for open discussion between staff and ACMUI members. During ACMUI meetings, staff typically opens discussion on a specific issue with a formal presentation. Staff will focus the Committee on the key issues for discussion. The topic is then opened for discussion by ACMUI members. Members of the public attending the meeting are frequently given the opportunity to make a statement on the issue. Following these discussions, an ACMUI member will make a formal recommendation which is then voted on by committee members. This recommendation is placed in the meeting minutes. Staff will then provide ACMUI members with updates on how the recommendation is incorporated into the NRC regulatory program.

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

Yes — Committee members clearly define issues for the staff and provide timely, useful, and objective recommendation. The Committee is comprised of individuals representing the various uses of byproduct material in medicine - clinical use, radiation safety, health care administration, and patients rights. This diversity allows the Committee to discuss each issue from many different perspectives. As a result, the Committee is able to clearly define issues and to identify the implications of their recommendations. Communicating not only through committee and subcommittee meetings, but also through the use of alternative methods of communication, such as telephone, email and facsimile, the Committee provides timely, useful information to the requests made by the staff.

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

Yes — The primary focus of the Committee is the safe use of medical byproduct material. The diversity of the medical disciplines represented by the Committee enhances the Committee's ability to recognize issues that need to be addressed, and ensures that each issue is critically reviewed, thus providing better oversight.

4. **Does the Committee provide expertise/advice which is not available from within the Agency?**

Yes — Committee members provide expertise that is not always available from the NRC staff. Committee members are able to provide staff with first-hand information on the clinical and research use and handling of byproduct material. Committee members provide staff advice on the clinical uses of byproduct material; use and preparation of radiopharmaceuticals; interests and rights of patients and human research subjects; radiation safety issues associated with use of byproduct material in academic and clinical settings; Agreement State issues; and health care administration.

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

Yes — The ACMUI typically meets twice a year. This allows for timely discussion on issues relating to the use of byproduct material in medicine. More frequent meetings of the full Committee and ad hoc subcommittees are scheduled when issues arise that warrant face-to-face interaction between the Committee and NRC staff. This flexibility afforded staff is beneficial in allowing for timely discussions on regulatory issues, such as the revision of 10 CFR Part 35, "Medical Use of Byproduct Material".

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

Yes — Committee members frequently bring issues raised by their colleagues to NRC's attention. In addition, members are involved in routine activities involving use of radioactive material in medicine and as such, are able to bring "real-life" issues to NRC's attention. Given the expertise of the Committee members, NRC is presented with many different types of issues involving the use of radioactive material in medicine.

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

Yes — The Committee encourages communication among the public, medical, and regulatory communities. All meetings are announced in the Federal Register. Members of the public and professional organizations frequently attend the meetings and present information for Committee consideration. In addition, Committee members typically bring issues from their respective professional organization to the NRC for information and consideration. Also, when appropriate, Committee members are able to provide status reports on the NRC regulatory program to their professional organizations. This "two-way" communication provides the opportunity for the NRC and the stakeholders to exchange information in an open forum.

8. Does the Committee consider resource constraints of the NRC when recommending new or enhanced regulatory programs?

Yes — The Committee does consider resource constraints of the NRC when recommending new or enhanced regulatory programs. It also considers resource implications of new or revised regulatory programs on the regulated community. For example, the ACMUI discussed the implications of requiring an examination as one element of the training and experience criteria for authorized users, Radiation Safety Officers, authorized medical physicists, and authorized nuclear pharmacists. One of the reasons that the Committee withdrew the proposal was an understanding that a review of exam programs would have been resource-intensive for the NRC.

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

Yes — On several occasions, subcommittees have been used to assist staff. Most recently, two subcommittees were formed to assist with the revision of Part 35. One subcommittee focused on issues associated with use of unsealed byproduct material while the other focused on use of sealed sources. It has been our experience that at subcommittee meetings both the ACMUI members and NRC staff are able to discuss issues in more detail and to identify those issues that should be discussed by the full Committee. The Committee encourages further use of subcommittees.

10. Does the scope and size of the Committee meet the current needs of NRC?

Yes — The current positions on the ACMUI are as follows:

1. Nuclear medicine physician
2. Nuclear cardiologist
3. Nuclear pharmacist
4. Radiation oncologist (two positions to represent diverse high-risk modalities)
5. Medical physicist (nuclear medicine)
6. Medical physicist (therapy physics)
7. Radiation safety officer
8. Health care administrator
9. Patients' rights and care advocate
10. State or local government representative
11. Food and Drug Administration representative

It is very important that all these disciplines be represented on the Committee because of the diverse use of byproduct material in medicine. As new uses of byproduct material evolve, it is recommended that NRC consider revising the Committee composition to allow for representation by individuals who are familiar with the new technology. Also, it is important that vacancies be filled in a timely manner. Committee members recommend that vacancies be announced well in advance, giving a more effective lead time for filling the positions.

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April 2001

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NOTE: Dr. Wagner's term as medical physicist expired on September 30, 2000. He is retained as a consultant, but the medical physicist position is currently vacant.