

**SPEAKERS and PARTICIPATING NRC STAFF
ACMUI MEETING
APRIL 25-26, 2006**

Lydia Chang, NMSS/IMNS/RGB

Michael Curter, North American Scientific

David A. Diamond, MD, ACMUI

Douglas F. Eggli, MD, ACMUI

Thomas H. Essig, NMSS/IMNS/MSIB, Designated Federal Official

Cynthia M. Flannery, NMSS/IMNS/MSIB

Donna-Beth Howe, PhD, NMSS/IMNS/MSIB

Leon S. Malmud, MD, ACMUI Chairman

Charles L. Miller, PhD, NMSS/IMNS

Mohammad S. Saba, NMSS/IMNS/MSIB

Sami Sherbini, PhD, NMSS/IMNS/MSIB

Ronald Zelac, PhD, NMSS/IMNS/MSIB

Robert O'Connell, NMSS/IMNS/MSIB

**ACMUI MEETING
APRIL 25-26, 2006**

**TUESDAY, APRIL 25, 2006 BALCONY B, NATIONAL INSTITUTE OF HEALTH (NIH), NATCHER
CONFERENCE CENTER, 45 CENTER DRIVE, BETHESDA, MARYLAND**

- 1) 8:00 – 8:05 Opening Remarks (Closed Session) (Presenter: Thomas Essig, NRC)
Mr. Essig will formally open the closed session meeting.
- 2) 8:05 – 8:15 Opening Remarks (Closed Session) (Presenter: Charles Miller, PhD, NRC)
Dr. Miller will provide an update on the status of ACMUI/ Presenter interactions, and will also provide an outline of the topics to be discussed during the closed session.
- 3) 8:15 – 9:15 Amendments to the ACMUI's Bylaws (Closed Session) (Cindy Flannery, NRC)
Ms. Flannery will discuss the proposed amendments to the bylaws and the committee members will discuss the changes.
- 4) 9:15 – 10:15 Training and Experience Requirements in Residency Programs (Closed Session) (Presenter: NRC staff)
NRC staff will discuss the minimum number of hours of training and experience required in residency training programs.

NOTE: The above sessions may be closed pursuant to 5 U.S.C. 552b(c)(2), (6) and (9)(B) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute."

10:15 – 10:30 *BREAK*****

- 5) 10:30 – 10:35 Opening Remarks (Open Session) (Presenter: Thomas Essig, NRC)
Mr. Essig will formally open the open session meeting.
- 6) 10:35 – 10:45 Opening Remarks (Open Session) (Presenter: Charles Miller, PhD, NRC)
Dr. Miller will provide opening remarks.
- 7) 10:45 – 11:30 RIS on Visitor Dose Limits (Open Session) (Presenter: Sami Sherbini, PhD, NRC)
Dr. Sherbini will present the draft RIS on rapidly granting exemptions from regulatory dose limits for certain caregivers.
- 8) 11:30 – 12:30 Updates on Proposed Regulations to Include Discrete Radium Sources and Accelerator-Produced Radioactive Materials in 10 CFR 35 (Open Session)(Presenter: Lydia Chang, NRC)

Ms. Chang will update the ACMUI on naturally occurring accelerator-produced radioactive materials (NARM) rulemaking.

12:30 – 1:30

*****LUNCH*****

9) 1:30 – 1:45

CORAR's Assessment of the New NRC Draft Rulemaking to Implement the Energy Policy Act(Open Session)(Presenter: Roy Brown, CORAR)
Mr. Brown will present CORAR's views Proposed Regulations to Include Accelerator-Produced Radioactive Materials in 10 CFR 35.

10) 1:45 – 2:45

Part 35 Training and Experience (Open Session)
Status of Board Applications (Presenters: Cindy Flannery, NRC; Donna-Beth Howe, PhD, NRC; Ronald Zelac, PhD, NRC)
NRC staff will present the status of applications submitted for recognition by the various Specialty Boards.
Training and Experience Rule Change for an Authorized User Seeking RSO Status. (Presenter: Ronald Zelac, PhD, NRC)
The NRC staff will explain the training and experience rule change in 10 CFR 35.

2:45 – 3:00

*****BREAK*****

11) 3:00 – 6:15

Training and Experience for Use of Microspheres for Therapy (Open Session) (Presenter: Douglas F. Eggli, MD, ACMUI; David Diamond, MD, ACMUI)
Dr. Eggli and Dr. Diamond will provide their points of view with regard to the licensing guidance currently posted on NRC's website on the training and experience requirements for Y-90 microspheres.

12) 6:15 – 6:45

Proposed Breast Brachytherapy Using I-125 Seeds (Open Session)(Presenter: Michael Cutrer, North American Scientific)
Mr. Cutrer will present to the ACMUI the proposed breast brachytherapy using I-125 and the associated shielding issues.

6:45

ADJOURN

**WEDNESDAY, APRIL 26, 2006 ROOM E1/E2, NIH, NATCHER CONFERENCE CENTER,
45 CENTER DRIVE, BETHESDA, MARYLAND**

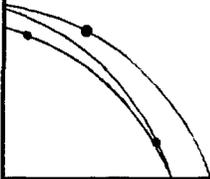
- 13) 8:00 – 8:45 ACMUI Review of Medical Events Involving I-131 (Open Session)
(Presenter: Douglas Eggli, MD, ACMUI)
Dr. Eggli, Chair of the I-131 Event Review Subcommittee, will provide the NRC staff with the subcommittee's advice and insights regarding the cause of medical events where diagnostic administrations were intended, but therapeutic administrations occurred. Ways to reduce these types of events will be recommended.
- 14 8:45 – 9:00 Status of Medical Events (Open Session) (Presenter: Donna-Beth Howe, PhD, NRC)
Dr. Howe will provide a summary of recent medical events and will seek ACMUI advice, recommendations, and insights.
- 15) 9:00 – 10:00 Potential Changes to 10 CFR 35 (Open Session)
(Presenter: Donna-Beth Howe, PhD, NRC)
Dr. Howe will present the proposed changes to the ACMUI and seeks its recommendations.
- 10:00 – 10:15 *****BREAK*****
- 16) 10:15 – 11:15 Commission Briefing Preparation
(Open Session)(Presenter: Ralph Lieto, ACMUI)
Mr. Lieto will use this time to discuss the briefing to the Commission regarding the Energy Policy Act in May 15, 2006.
- 17) 11:15 – 12:00 Administrative Closing/Action Item Review (Open Session)
(Presenter: Mohammad Saba, NRC)
The NRC staff and the ACMUI will discuss miscellaneous items of interest arising from the October 25-26, 2005 meeting; will review action items arising from this meeting, will discuss other non-sensitive administrative matters related to committee business, if any; and will discuss proposed meeting dates for the Fall 2006 meeting.
- 12:00 **ADJOURN**

(Closed Session)
NO HANDOUT

(Closed Session)
NO HANDOUT

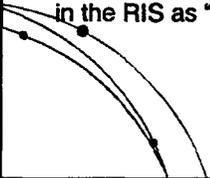
(Open Session)
NO HANDOUT

RIS ON VISITOR DOSE LIMITS



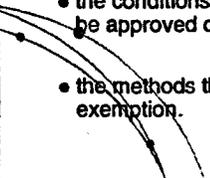
SUBJECT OF THE RIS

- Exemption from NRC's dose limit of 1 mSv per year for members of the public for a certain subgroup of the public referred to in the RIS as "caregivers"



PURPOSE OF THE RIS

- To inform licensees of :
 - the availability of this option.
 - the conditions under which this exemption will be approved on very short notice.
 - the methods that may be used to obtain this exemption.



WHO IS A CAREGIVER

- A person involved in the care of a hospitalized patient, and
- One whose services in this capacity are deemed by the medical staff at the hospital to be necessary for the patient's welfare, and
- One who accepts the risks involved in receiving radiation doses that may be significantly higher than the limits applicable to members of the public, and in some cases, possibly to occupationally exposed personnel.

CONDITIONS FOR GRANTING THE EXEMPTION

- Formal approval of the medical staff at the hospital.
- Formal acceptance by the caregiver.
- Initiation of an enhanced radiation monitoring program for the caregiver, the necessary elements of which are described in the RIS.
- Approval by NRC following application for the exemption. A default provisional limit of 20 mSv will be used, to be changed if deemed necessary.

HOW IS EXEMPTION TO BE OBTAINED

- Generally, a telephone call to the appropriate NRC regional staff, followed by mailed, e-mailed, or faxed description of the program that implements the guidance in the RIS.
- In an emergency, outside normal working hours, notification of the NRC Operations Center of initiation of the caregiver option, with concurrent faxing of the required documentation to the regional office. To be followed by regional contact during working hours.

**HOW DOES THIS DIFFER FROM
THE NORMAL EXEMPTION
PROCEDURES**

- The conditions under which the exemption will be granted are pre-determined and known to licensees.
- Satisfaction of these conditions constitutes a sufficient condition for granting the exemption.
- The exemption may be granted on the same day as requested.

WHY A 20 mSv DOSE LIMIT

- A limit is required to avoid an open-ended exposure situation.
- Experience has shown this dose level to be adequate for nearly all caregiver cases.
- The limit may be raised if conditions warrant such an action.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555
June XX, 2006

**NRC REGULATORY ISSUE SUMMARY 2006-XX REQUESTING
EXEMPTION FROM THE PUBLIC DOSE LIMITS FOR CERTAIN
CAREGIVERS OF HOSPITAL PATIENTS**

ADDRESSEES

All NRC medical licensees.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide guidance on the procedures that may be used to request an exemption from the dose limits normally applicable to members of the public for certain caregivers of hospitalized patients.

BACKGROUND

Patients undergoing medical diagnostic or therapeutic procedures involving the use of radioactive materials may be released from the hospital, even though they represent sources of potential radiation exposure to members of the public, if they meet certain release criteria. These criteria are specified in 10 CFR 35.75. Patients who do not meet these release criteria must remain in the hospital until they do satisfy them. Other circumstances, aside from failure to meet release criteria, may also require patients with administered or implanted radioactive materials to remain in the hospital, for ongoing diagnosis or treatment that require continued presence there. Such patients are usually visited in the hospital by family and friends, and these visitors are considered members of the public, subject to the dose limits specified in 10 CFR 20.1301 for members of the public. These limits, normally 1 mSv (0.1 rem), and in some case 5 mSv (0.5 rem), are adequate and are easily observed for the vast majority of visitors.

In some cases, however, the applicable dose limits are insufficient to accommodate situations in which a member of the public, who will be referred to in this RIS as a caregiver, is directly involved in the care of a patient containing radioactive material. Caregivers are usually members of the patient's family, or someone close to the family or the patient, but this is not a necessary characteristic of a caregiver. They do not include the hospital staff, who are considered to be occupationally exposed individuals subject to occupational dose limits, which are much higher than those for members of the public. The role of caregiver often involves close contact with the patient, sometimes for prolonged periods of time, with the result that the

MLXXXXXXXX

radiation doses they receive may be much higher than the dose limit that would normally apply to them. To address this situation, the NRC staff proposed to the Commission that dose limits for caregivers be waived, and that their doses be limited only by the demands of their caregiving functions and the needs of the patient, provided, of course, that the dose not be permitted to be high enough as to present an immediate danger to the health of the caregiver or to increase the risks long-term from radiation exposure to unacceptable levels. The rationale behind this approach is that dose limits are normally imposed for the protection of persons who are exposed either involuntarily, as in the case of exposures to members of the public in unrestricted areas, or who are exposed as a result of their occupations, such as hospital staffs and others whose occupations necessarily involve exposure to radiation. The caregiver situation is different in that it involves a voluntary and deliberate decision, by the caregiver, with the approval of attendant medical staff, to incur radiation exposures, and its attendant risks, as an incidental consequence of the need to perform the caregiving function in the interest of the patient. A notable parallel to this situation is exposure of patients to radiation doses during radiation diagnostic procedures or radiation treatments; although the doses resulting from such activities may be subject to guidance, they are not subject to regulatory limits.

The Commission approved the staff's proposal, and directed that a graded approach be used in controlling doses to caregivers. This approach would initially approve a default limit that experience has indicated would be adequate for most caregiver situations. The limit may subsequently be increased if it proves too low for a particular case. This RIS provides guidance for NRC licensees who may encounter such caregiving situations at their facilities and who may wish to apply for exemption from the dose limits in 10 CFR 20.1301. The guidance assumes that licensees will in most cases anticipate the development of the situation requiring such an exemption and will allow sufficient time for the request to be submitted to the appropriate NRC regional office using normal procedures. However, the guidance also addresses situations in which the need for an exemption arises with little opportunity to anticipate its development.

SUMMARY OF ISSUES

Licensees have always been permitted to request exemption from any part of the regulations by applying to the NRC and providing adequate justification to support the request. Such exemptions are granted if the NRC considers the reasons provided to be sufficient to justify the exemptions. Exemption of a caregiver from the dose limits applicable to members of the public may also be treated in the same manner as any other exemption, and such exemptions have been approved in the past. However, some characteristics of the caregiver situation make it different from most other exemption requests, and one of the most important is that the need to invoke a caregiver situation is identified and justified by the responsible medical staff and the caregiver rather than by the regulatory agency, namely the NRC or the Agreement State. In this case, the role of the agency will not be to approve the justification but rather to ensure that the justification was provided by the appropriate responsible staff. The agency will also ensure that the licensee will implement radiation safety measures that are adequate to monitor and control radiation exposures to the caregiver at all times.

Another characteristic that may make the caregiver situation unique is that it may involve an unanticipated situation requiring rapid approval to accommodate the evolving needs of the patient. For example, the patient's condition may change in a manner that may require

additional testing using radioactive materials, or the unanticipated initiation or continuation of the use of radioactive materials in treatment or therapy. Caregivers may at that time elect to involve themselves directly in the care of the patient, and medical considerations may also indicate that such direct involvement may be beneficial, or even essential, to the patient. Hence the need for rapid waiver of the public dose limit that may have been enforced up to that point.

This RIS provides guidance to licensees on the means that they may use to obtain an exemption for the caregiver situation, whether there is ample time to follow routine application procedures or there is a need for a quick exemption. To ensure that the information needed by the NRC staff is available at the time of the exemption request, and that the regulatory conditions that are likely to accompany an exemption are known beforehand to the licensee, this RIS provides a list of the information that should accompany the exemption request, and provides a discussion of the control measures that are likely to be a condition for approval of the exemption request. These conditions have been reviewed by NRC's regional staff, who considered them adequate as a basis to issue the exemption, at least on a provisional basis pending a more thorough review or on-site inspection if necessary. The exemption request becomes, in essence, a request by the licensee to initiate the pre-approved conditions upon acceptance by the NRC of the pre-approved list of information that would be considered sufficient to justify immediate issuance of the exemption without further discussions.

It should be emphasized that exemption from a pre-established regulatory dose limit for caregivers does not in any way imply that radiation safety and control of dose is no longer necessary. Quite the contrary. The potential that a caregiver may receive doses much higher than those normally permitted for members of the public, or possibly for occupationally exposed persons, and also that doses may be accumulated at a rate that is much higher than normally encountered in radiation exposure situations, points to the need for a very carefully planned and executed radiation monitoring and control program, and this is an essential condition underlying the approach to the caregiver exemption described in this RIS.

APPLYING FOR THE EXEMPTION

Licensees may apply for the exemption by calling the regional office that issued the license, and in particular the Licensing Branch if feasible. Most licensees, as a result of previous contacts with the regional staff during licensing and inspection, will know the NRC staff who inspect or conduct licensing activities for their facility, and contacting one of these persons may be one approach to initiate the request. Other persons who may be contacted, if there is some urgency in the request, include the Branch Chief of the inspector's or license reviewer's branch, or the Director of that Division. The licensee should ensure that the necessary telephone numbers are available for use when needed, as well as the appropriate fax numbers to permit transmitting the licensee's request to the region in written form. It is possible, however, that conditions may develop that require an exemption during periods when the NRC staff is not available, such as during the night or outside normal working hours, on weekends, or during holidays. If this occurs, licensees may proceed as though the exemption has been approved, provided that the pre-established conditions described in this RIS are put into effect, and the NRC Operations Center is immediately notified of the action. The telephone number of the NRC Operations Center is (301) 816-5100. Attempts should be made to contact the NRC regional staff as soon as possible during normal working hours, and in any case, a written request should be forwarded to the regional office within 24 hours of Operations Center

notification. The same approach may be used if the licensee finds that the limit approved in a previous exemption proves to be insufficient for a particular case and that a higher caregiver dose limit is needed. In any case, the request for the exemption should be accompanied by documentation provided to the region that describes the manner in which the elements of the caregiver protection program, as described in this RIS, are to be implemented. A rapid method of transmittal, such as fax or e-mail, will ensure prompt attention and approval of the request. It should be noted that the caregiver limits referred to in this discussion are in fact controls imposed on the caregiver's radiation exposure to avoid accumulating high doses at rapid rates without adequate and carefully considered justification, and that the dose that the caregiver is ultimately permitted to receive is determined by the patient's needs and the caregiver's informed willingness to incur the resulting radiation risks.

INFORMATION THAT SHOULD ACCOMPANY THE EXEMPTION REQUEST

The following may be considered the minimum information to be provided to NRC's regional staff to permit them to evaluate the merits of the request and on which to base the decision to grant the exemption. The information should be as complete as possible to make it unnecessary for the staff to request additional information and hence delay approval. The list below is not exhaustive, and the licensee should provide any additional information that may help clarify the situation and explain the justification for the request. The NRC Regional offices will issue the exemption on the basis of the licensee's statement that these conditions have been put in place, and the adequacy of implementation will be verified during subsequent NRC reviews or inspections.

1. The name of the licensee, the license number, the authorized user involved, and any other identifying information, and the names of the physicians and other staff who made the determination that a caregiver situation should be invoked.
2. Name and telephone number of a contact person or persons in case the NRC needs additional information, and for notification of approval or denial of the request. Any written exemption requests should be signed by a person authorized to represent the institution in matters pertaining to the NRC license.
3. A brief description of the medical situation that necessitates the request, the radioisotope, form, and activity of radioactive material administered to the patient, and the anticipated number of caregivers.
4. The expected duration of the requested exemption, and the needed starting date for the exemption.
5. The expected dose that may be incurred, and the proposed control limit to be imposed on the caregiver. It is suggested that a limit of 20 mSv (2 rem) be requested initially, to be raised via a second exemption request if the need arises. Experience with care giver situations has demonstrated that virtually all such cases can be accommodated within this initial limit.
6. A description of the control program that will be implemented to meet the requirements described in the section below on exposure controls.

CONTROL MEASURES THAT SHOULD BE IMPLEMENTED

An exemption from any dose limits for the caregiver does not mean that no controls on the dose received will be required. The exemption simply means that the dose that the caregiver will be permitted to receive will be determined by the needs of the situation rather than beforehand by the regulatory agency, as is the case with all other dose limits. Therefore, the exemption must be accompanied by a control program designed to minimize the dose received by the caregiver and to ensure that the selected dose limit be observed unless it proves impossible to do so under the prevailing conditions. The general control measures that should be implemented are listed below, but the details will depend on the facility and the local conditions. These details should also be provided with the exemption request, in addition to items 1 through 6 in the section above.

7. The organization that will be in place, including the names and positions of personnel who will be responsible for ensuring that the conditions of the exemption will be implemented.
8. The training and instruction to be given to the caregivers on the risks of radiation exposure, the applicable dose limit, and ways to minimize exposures. Information on the relationship of the caregivers to the patient and their ages should also be provided.
9. Any consent forms to be signed by the caregiver and the responsible licensee personnel. The caregiver should also sign a declaration that she is not pregnant or, if pregnant, that she is aware of the risks to the embryo/fetus arising from radiation exposure. Otherwise, a description of hospital policy regarding radiation exposure of pregnant women and minors should be provided.
10. The radiation protection organization and personnel who will be responsible for maintaining control of the caregiver exposures and who will monitor doses on a real-time basis.
11. The methods that will be used to monitor the dose to the caregiver on a real-time basis to ensure that it does not exceed the limit and that will provide adequate warning if the dose is accumulating at a rate that is higher than anticipated, or that the dose received, given current trends, is likely to exceed the approved limit.
12. The measures to be used to keep the dose to the care giver as low as is reasonably achievable (ALARA).

It should be noted that the above controls will generally require careful consideration and planning to determine the specific approaches suited for the licensee's facility, such as, for example, the types of monitoring equipment that is available to monitor caregiver dose or, if necessary, the types that should be acquired to serve that function. Since design of such a control program is unlikely to be successfully completed under pressing emergency conditions, licensees who anticipate any possibility of the need to invoke a caregiver situation should plan

their control programs ahead of time, and acquire any instruments and develop any procedures that may be needed if such a situation develops.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational, and does not represent a departure from current regulatory requirements.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

The information collections contained in the appendix to this Regulatory Issue Summary are covered by the requirements of 10 CFR Parts 20 and 35, which were approved by the Office of Management and Budget, approval numbers 3150-0014 and 3150-0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

This RIS requires no specific action or written response. If you have questions about the information in this summary, please contact one of the technical contacts listed below, or the appropriate regional office.

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: "List of Recently Issued NMSS
Generic Communications"

Technical Contacts:

Sami Sherbini, NMSS
(301) 415-7853
E-mail: sxs2@nrc.gov

Joseph E. DeCicco, NMSS
(301) 415-7833
E-mail: jxd@nrc.gov

Thomas H. Essig, NMSS
(301) 415-7231
E-mail: the@nrc.gov

NARM Rulemaking

Lydia Chang
U.S. Nuclear Regulatory
Commission

NARM Rulemaking Efforts

- Energy Policy Act of 2005
- Waiver
- Rulemaking Approach
- Rulemaking Strategy
- Current Status/Schedule
- Draft Proposed Rule Summary
- Implementation Considerations
- Next Steps

2

Energy Policy Act of 2005

- Signed into law on August 8, 2005
- Section 651(e) of the Energy Policy Act:
 - Amends definition of byproduct material in AEA Section 11e.
 - Amends AEA Section 274b. to include newly added byproduct material for agreements with States
 - Amends AEA Section 81 to provide other disposal options for the newly added byproduct material
 - Requires NRC to issue final regulation within 18 months from the date of enactment
 - Allow NRC to grant time-limited waiver

3

Energy Policy Act (Cont.)

- Section 651(e) amends the definition of byproduct material in Section 11e of the Atomic Energy Act to include:
 - Discrete sources of Ra-226
 - Material made radioactive by use of a particle accelerator (or accelerator-produced radioactive material)
 - Discrete sources of naturally occurring radioactive material, other than source material, that NRC determines, in consultation with EPA, DOE & DHS, pose a threat similar to Ra-226
- Limited to materials
 - Produced, extracted or converted after extraction before, on, or after August 8, 2005
 - Used for commercial, medical, or research activities

4

Waiver

- Energy Policy Act allows the Commission to grant waivers allowing current programs to continue for the newly added byproduct materials (NARM)
- Waiver published on August 31, 2005 (70 FR 51581)
- Allows persons engaged in activities involving NARM to continue with their activities
- Allows States to continue to regulated NARM
- Effective through August 7, 2006 for import/export of NARM
- Effective through August 7, 2009 for other NARM activities
- NRC may terminate sooner

5

Rulemaking Approach

- NARM Rulemaking Working Group
 - NRC HQ, Regions, and States
- Steering Committee
 - NRC HQ, Region, and States
- Stakeholder Participation
 - Public meeting
 - Meetings with other Federal agencies
 - Website
 - Draft rulemaking documents

6

Roundtable Public Meeting

- Held on November 9, 2005, at NRC
- More than 70 people attended
- Stakeholders included: Federal agencies, State regulators, professional organizations, advisory committee, and industry, research, and medical groups
- Shared background information and received valuable insights and areas of concern
- Prepared and posted meeting summary and transcript

7

Rulemaking Website

- Established on November 16, 2005
- Availability published on January 3, 2006 (71 FR 29)
- Website address:
<http://ruleforum.llnl.gov>
 - Select "Other Rulemaking-Related Comment Requests"
 - Once published, select "Proposed Rule"

8

NARM Rulemaking

- Energy Policy Act requires NRC to:
 - Issue final rule within 18 months
 - Consult with States and other stakeholder
 - Cooperate with States and use model State standards to the maximum extent practicable
 - Consider impact on the availability of radiopharmaceuticals to physicians and patients

9

NARM Rulemaking Strategy

- Use existing NRC regulatory framework
- Use the Suggested State Regulations for Control of Radiation (SSRs) as model State standards to the maximum extent practicable
- Proposed to regulate all radioactive material from production accelerators (PET cyclotron)
- Proposed NOT to regulate activated material from nonproduction accelerators (radiation therapy linac)

10

NARM Rulemaking Strategy (Cont.)

- Add other provisions to supplement SSRs
- Develop requirements for radium-226
- Provide certain grandfather provisions
- Recognize certain FDA and State programs
- Allow certain flexibilities

11

Current Status/Schedule

- January 3, 2006 – Draft proposed rule sent to States and ACMUI for review and comment
- March 27, 2006 – SECY-06-0069 signed forwarding the draft proposed rule package to the Commission
- April 6, 2006 – SECY-06-0069 and its enclosed draft proposed rule package made public and posted on NRC website
- February 7, 2007 – Required by the Energy Policy Act to issue final rule

12

Draft Proposed Rule – Definition

- Amend definitions for:
 - Authorized nuclear pharmacist, authorized user, byproduct material, low-level radioactive waste, waste (Part 61)
- Add definitions for:
 - Accelerator-produced radioactive material, cyclotron, discrete source, particle accelerator, positron emission tomography (PET) radionuclide production facility, waste (Part 20)

13

Draft Proposed Rule – Definition (Cont.)

- Definition of a "Discrete source"
 - *A source with physical boundaries, which is separate and distinct from the radiation present in nature, and in which the radionuclide concentration has been increased by human processes with the intent that the concentrated material will be used for its radiological properties*

14

Draft Proposed Rule – General provisions

- Recognize certain general licenses and exempt distribution licenses issued by States for NARM
- Add certain NARM radionuclides to existing provisions for certain specific exemptions and for certain general license
- Add 13 NARM radionuclides to Schedule B – exempt quantities (Cs-129, Co-57, Ga-67, Ge-68, Au-195, In-111, I-123, Fe-52, K-43, Rb-81, Na-22, Y-87, Y-88)
- Add radium-226 to Schedule C – consideration of the need for emergency plan

15

Draft Proposed Rule – General License for Radium-226

- Products included:
 - Antiquities
 - Luminous items installed in aircraft
 - ≤ 100 luminous items not installed in aircraft
 - ≤ 50 other luminous items (hands and dials) not installed in timepiece
 - Small sources containing ≤ 1 μ Ci
- Specific requirements:
 - Shall notify NRC of possible damage
 - Shall not abandon
 - Shall not export
 - Shall dispose of in accordance with regulation
 - shall respond written request from NRC

16

Draft Proposed Rule – Medical Use

- Non-PET radionuclides/drugs - No rule text changes needed
- PET radionuclides/drugs
 - Only minor rule text changes to 32.72 and Part 35
 - Recognize registered PET facilities
 - Allow noncommercial distribution between medical use licensees
 - Regulate all radionuclide production using accelerator (including cyclotrons) under Part 30 and under Part 32 if for commercial distribution
 - Grandfather certain individuals currently engaged in activities involving accelerator-produced radioactive material uses from certain regulatory requirements (e.g. Authorized Users and nuclear pharmacist from new training and experience requirements)

17

Implementation Strategy

- Effective date: 60 days from the date of publication of the final rule for Federal facilities
- Special provisions: Authorized by rule to allow continued use of NARM if comply with other requirements
- License amendment: Submit within 6 months from the effective date or waiver termination
- New license application: Submit within 1 year from the effective date or waiver termination
- Waiver termination: Sooner and in batches

18

Transition Plan Integration

- NRC is required to prepare and publish a transition plan to facilitate orderly transition of regulatory authority for NARM
 - Non-Agreement States
 - Agreement States
- Waiver is in effect through August 7, 2009; however, NRC plans to terminate sooner
- NRC plans to include waiver termination process in the transition plan

19

Next Steps

- Commission decision on SECY-06-0069
- Revise proposed rule per Commission direction in Staff Requirements Memo
- Publish the proposed rule in the *Federal Register* for a 45-day comment period
- Plan for a public meeting during public comment period

20

CORAR's Initial Thoughts on NRC's Draft NARM Rulemaking

ACMUI Meeting
April 25, 2006

Roy W. Brown
Senior Director, Federal Affairs
Council on Radionuclides & Radiopharmaceuticals



Background on CORAR

- CORAR is the North American Trade Association for the manufacturers and distributors of radionuclides & radiopharmaceuticals
- All of the major manufacturers are members of CORAR
- Members utilize radionuclides to produce the radiopharmaceuticals for medical diagnosis and therapy & medical radionuclides for life science research
- CORAR has initial thoughts on rulemaking



Positive Aspects of Draft NARM Rulemaking

- NRC's classification of accelerators into three categories seems to be workable
- Uniformity of regulation regardless of method of production (i.e. Co-57 produced in cyclotron vs. reactor) is best way to deal with these radionuclides
- Grandfathering of qualified AUs, ANPs and RSOs is very helpful
- CORAR does not believe the emergency planning or decommissioning funding provisions in Part 30 will be triggered by most of the PET facilities covered under the draft regulations
- NRC's waiver will allow operations to continue until new rules take effect



Concerns With the Draft NARM Rulemaking

- NRC has not addressed CORAR's major concern of non-uniformity of regulations
 - There is no plan to get new NARM radiopharmaceuticals into the states any faster than the current cumbersome process
 - There is no plan to address state-specific product approval and labeling requirements
 - Differing approaches to level of detail and approval in sealed source/device registry
 - The level of compatibility needs to be higher (Category B) in all areas of the new, and existing rule to promote more uniformity
- Regrettably, the regulated community had no interaction with the Steering Committee, the NMSS EPAct Task Force, or NARM Working Group
- The new fee structure in Part 170 will negatively impact facilities located in non-Agreement states that will now be under NRC's jurisdiction



Suggestions for the Draft NARM Rulemaking

- Create a higher level of compatibility for new and existing regulations for the use of radionuclides in medicine
- NRC needs to clarify how they intend to regulate incidentally produced materials on accelerators
- Although NRC promoted the use of CRCPD's SSR, CORAR would like to see strict adherence to them to create greater uniformity among states
- Special provisions could be developed for decommissioning lower energy PET cyclotrons (<10 MeV) which are typically self-shielded
- CORAR would like to see at least one more workshop to work out some of the problems in the draft rulemaking





STATUS OF SPECIALTY BOARD RECOGNITION

April 25, 2006

Cindy Flannery
Donna-Beth Howe, Ph.D.
Mohammad Saba
Ronald Zelac, Ph.D.

Recognition of Specialty Boards

Approved Formal letter of approval sent to Board and the Board is listed on NRC's website

Under review Information provided by the Specialty Board is being reviewed by NRC staff

Awaiting Input NRC staff is waiting for additional informational that was requested of Boards before review can be continued

Specialty Board:	Status:
Board of Pharmaceutical Specialties	Approved for 35.55
American Board of Nuclear Medicine	Approved for 35.190, 35.290 & 35.390
Certification Board of Nuclear Cardiology	Approved for 35.290
American Board of Health Physics	Approved for 35.50
American Board of Science in Nuclear Medicine	Approved for 35.50
American Board of Radiology (Radiation Oncology)	Approved for 35.390, 35.490, 35.690
American Board of Radiology (Diagnostic Radiology)	Under Review
American Board of Radiology (Radiologic Physics)	Awaiting Input
American Osteopathic Board of Radiology (Radiation Onc.)	Awaiting Input
American Osteopathic Board of Radiology (Diag. Radiology)	Awaiting Input
American Osteopathic Board of Nuclear Medicine	Awaiting Input
American Board of Medical Physicians	Awaiting Input


[Index](#) | [Site Map](#) | [FAQ](#) | [Help](#) | [Glossary](#) | [Contact Us](#)

[Advanced Search](#)

U.S. Nuclear Regulatory Commission


[Home](#)
[Who We Are](#)
[What We Do](#)
[Nuclear Reactors](#)
[Nuclear Materials](#)
[Radioactive Waste](#)
[Facility Info Finder](#)
[Public Involvement](#)
[Electronic Reading Room](#)

Home > [Nuclear Materials](#) > [Medical, Industrial, and Academic Uses of Nuclear Materials](#) > [Medical Use of By-Product Material](#) > [Specialty Board\(s\) Certification Recognized by NRC Under 10 CFR Part 35](#)

Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35

- §35.50 Training for Radiation Safety Officer
American Board of Health Physics from January 1, 2006 to present.
- American Board of Science in Nuclear Medicine from June 2006 forward for the Nuclear Medicine Physics and Instrumentation Specialty and the Radiation Protection Specialty.**
- §35.51 Training for an authorized medical physicist
 None
- §35.55 Training for an authorized nuclear pharmacist
Board of Pharmaceutical Specialties certification process for Board Certified Nuclear Pharmacist (BCNP) from March 6, 1996 to present.
- §35.190 Training for uptake, dilution, and excretion studies
American Board of Nuclear Medicine certification process from October 20, 2005 to present for all physicians before and after that date issued an ABNM certification with the word "United States" appearing under the certification number.
- §35.290 Training for imaging and localization studies
Certification Board of Nuclear Cardiology certification process from October 29, 2000 to present for certificates issued to physicians residing in the United States.
- American Board of Nuclear Medicine certification process from October 20, 2005 to present for all physicians issued an ABNM certifications before and after that date with the word "United States" appearing under the certification number.**
- §35.390 Training for use of unsealed byproduct material for which a written directive is required
American Board of Nuclear Medicine certification process from October 20, 2005 to present for all physicians before and after that date issued an ABNM certification with the word "United States" appearing under the certification number.
- §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)
 None
- §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)
 None
- §35.490 Training for use of manual brachytherapy sources
 None
- §35.590 Training for use of sealed sources for diagnosis
 None
- §35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
 None

Therapy with Y⁹⁰ Microspheres
A Nuclear Medicine Perspective

Douglas F. Egli, M.D.
ACMUI
Nuclear Medicine Physician

Y⁹⁰ Microspheres

- Y⁹⁰ Microspheres share features of brachytherapy sources and unsealed therapy sources
- Therapeutic Microspheres are currently regulated under subpart 1000, new technology

Brachytherapy Source Features

- Similarities to typical brachytherapy sources
 - Microspheres are registered as brachytherapy sources
 - Y⁹⁰ is sealed in glass beads
- Differences from typical brachytherapy sources
 - Sources do not have serial numbers
 - Sources cannot be counted (too numerous to count)

Unsealed Source Features

- Similarities to unsealed sources
 - Sources are too numerous to count
 - Sources behave like large particles (eg: MAA)
 - Spills have to be handled like unsealed sources
 - Patient distribution and dosimetry studies use nuclear techniques
 - Administration is similar to intra-arterial MAA
- Differences from unsealed sources
 - Registered as brachytherapy sources
 - Y^{90} sealed in microspheres

Training Issues

- Any experienced therapeutic physicians trained for either part 300 or part 400 uses can be trained to safely handle therapeutic microspheres.
 - Nuclear Medicine physicians can learn appropriate dosimetry techniques
 - Radiation Oncologists can be trained to manage administrations and spills similar to unsealed sources

Experience Requirements

- 3 supervised cases may be too few to consider either a part 300 or part 400 user "adequately trained" to handle Y^{90} microspheres
- As risk increases, it is reasonable to increase the experience requirement for independent use.

Training Programs

- Programs should be designed *conjointly* by radiation oncologists and nuclear medicine physicians to train part 300 users in the part 400 use requirements and to train part 400 users in part 300 use requirements.

Possible Additional Training Requirements

- Experience with 10(?) cases for either part 300 or part 400 users (reasonable number to be determined)
- For Radiation oncologists (hours to be determined)
 - Theoretical knowledge of radiation biology, basic physics of radioactivity, and mathematics of radioactivity and radioactive decay are adequate
 - Experience with administration devices
 - Practical experience in radiation safety as applied to unsealed sources, radiopharmacy techniques, use of a dose calibrator, surveying packages for contamination on receipt, and detection, containment, and cleanup of radioactive spills
 - Nuclear Medicine distribution studies

Possible Additional Training Requirements

- For Nuclear Medicine Physicians (hours to be determined)
 - Dosimetry theory, techniques, and calculations.
 - Experience with administration devices

Recommendation

- With appropriate training authorized users for both subpart 300 uses and subpart 400 uses should be able to obtain AU status for therapeutic microspheres
- Appropriate training requirements need to be defined for both classes of users
 - Training requirements should be conjointly developed by appropriate professional organizations (eg: Joint SNM, ACR, ASTRO, & AAPM letter of 2003)
- Appropriate experience levels need to be determined.

**Training & Experience Issues
in the Use of Hepatic Arterial
Microspheres:**

***A Radiation Oncology
Perspective***

David Diamond, MD
Member, NRC ACMUI
April 25, 2006

ACMUI Charge

- ⌘ To provide advice to the NRC Commissioners & Staff on medical & technical issues that arise in regulating the medical use of byproduct materials
- ⌘ Chief concern: public safety
- ⌘ No interest in the "practice of medicine", which is the purview of the medical community

**Microsphere Therapy:
a medical device?**

- ⌘ The manufacturers specifically opted to go through the FDA device, not drug, pathway for approval
- ⌘ This fact (and not radiation safety considerations) was the premise for FDA regulation as a "medical device"

**Microsphere Therapy:
a brachytherapy modality?**

- ⌘ Yes--Physically, they are encapsulated (sealed sources)
- ⌘ But, from a regulatory viewpoint it is problematic to place it under the "Manual Brachytherapy Sources" (35.490) rubric:
 - One, for example, cannot "count" the individual sources
 - (each Sir-Sphere vial contains 40-80 million spheres)
 - Further, the Tc-99m microspheres used for decades in nuclear medicine never have been regulated as such

Current Microsphere Guidance

- ⌘ NRC Staff has placed these agents under the "Emerging Technologies" section (35.1000)
- ⌘ Current NRC guidance recognizes 35.490 (manual brachytherapy) AU's with specific vendor training as authorized for this purpose
- ⌘ Question: Should the guidance be modified to specifically allow nuclear medicine AU's to use this modality?

**Joint SNM, ACR, ASTRO, &
AAPM letter of 2003**

- ⌘ This draft recommended that both physicians certified in nuclear medicine who have met 35.390 training and those certified in radiation oncology who have met 35.490 be authorized for this use

Personal Recommendations

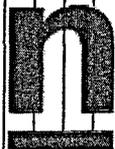
✂ I concur that both nuclear medicine 35.390 AU's and radiation oncology 35.490 AU's have the technical training & experience to safely handle and administer hepatic microspheres

**Personal Recommendations
(Continued)**

- ✂ Though outside the purview of the NRC, I strongly support efforts by the professional societies to develop guidelines which promote optimal patient care through a defined multi-specialty "team approach"
- ✂ Pt. screening & treatment planning are complex
 - ☒ Most patients have been heavily pretreated with chemotherapy and external beam radiotherapy
- ✂ Roles of the
 - ☒ Radiation oncologist
 - ☒ Interventional radiologist
 - ☒ Nuclear medicine physician

north american
SCIENTIFIC

n



NRC Presentation
April 25, 2006

north american
SCIENTIFIC

n

Breast Cancer Statistics

- ACS estimates 211,200 new cases of invasive breast
- 58,400 DCIS
- Estimated that 75%-80% of invasive cases are early stage (T1 or T2)
- Early stage cancers can be treated with Breast Conserving Therapy (BCT)
- ACS "A woman who chooses lumpectomy and radiation will have the same expected long-term survival as if she had chosen mastectomy".
- Yet in some regions as many as 80% choose mastectomy. Why?
 - 6-8 week time course
 - fear of radiation to breast, lungs, heart, and ribs
 - cbst
- Proponents feel this will change based on APBI data

north american
SCIENTIFIC

n

Whole Breast Radiation Therapy (WBRT)

- 6-8 week treatment time with one fraction per day
- Data indicates recurrence rate is or near tumor bed
- Risk of dose to surrounding critical areas
- Cosmetic results
- Delays initiation of chemotherapy
- Remains the Gold Standard for BCT but data suggests APBI as effective

Accelerated Partial Breast Irradiation (APBI)

- Distal disease is same in mastectomy patients as in BCT patients
- 5 RFI studies have show recurrence rates same as whole breast
- Therefore RT has maximum effect on reducing cancer in or near tumor bed
- Similar results for DCIS
- Phase III studies underway
- Reduces treatment time from 6-8 weeks to 5 days
- Minimizes dose to surrounding healthy structures

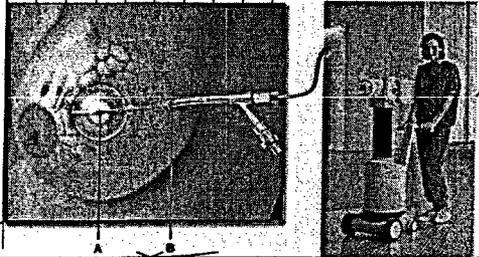
APBI using catheters



Problems with Catheter Treatment

- Invasive
- Not easy to learn
- HDR only. LDR requires 96 hour treatment time
- Skin dose potentially an issue due to breast movement in prior LDR.
- Requires capital investment

APBI using Balloon Catheter

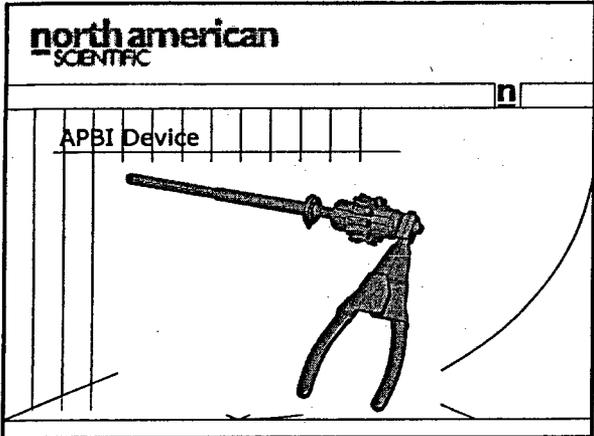


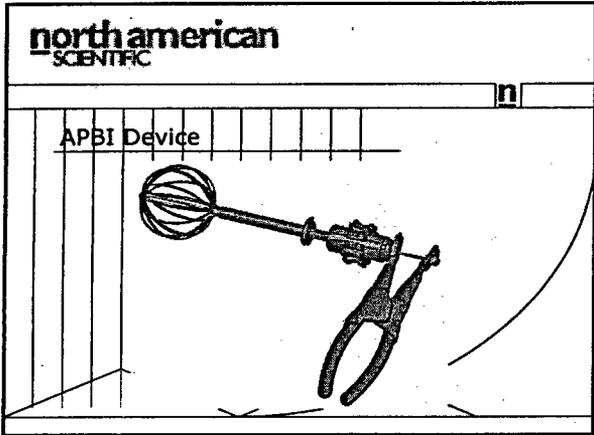
Problems with Balloon Catheter

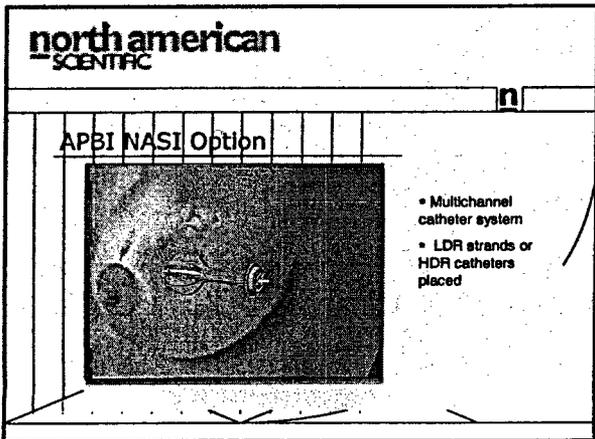
- Non-conformal
- Inflation may cause areas of hypoxia
- Seroma can prevent good deployment
- Balloon rupture possible
- Single lumen reduces options for treatment
- HDR only

NASI Solution

- Single Site Placement
- Multiple channels for dose delivery
- LDR, HDR, or combination therapy
- No possibility of rupture
- Conformal
- No compression

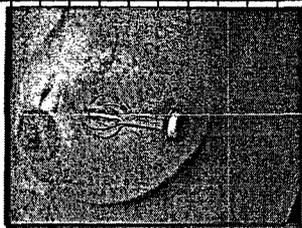








APBI NASI Option



- Patient can go home with shielding for LDR or return daily for HDR
- Adapter for HDR eliminates catheters when not being treated
- Device removed in 4-5 days



APBI Device LDR

- Continuous dosing and improved biological effectiveness
- Reduced dose to healthy tissue
- No shielded facility required
- Convenience
- I.D. on wrist badge and on shielding device
- Patient education prior to release



APBI Device LDR Shielding

- Demron and Leac
- Lightweight
- I.D. Badges
- Patient Information



north american
SCIENTIFIC

n

Timeline

- File 510 K on LDR design March (Complete)
- Establish collaboration with the University of Wisconsin (Complete)
- Anticipate 510K for LDR design in April (Complete)
- File 510 K for HDR design (June)
- Prepare clinical data with UW (Ongoing)
- Seminar planned at ASTRO in November
- Introduction planned at ASTRO and launch
- Introduction OUS planned mid 2007

north american
SCIENTIFIC

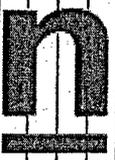
n

Market Drivers

- Data on APBI should drive patients to BCT
- Reduced treatment time should lead to adoption
- Fear of radiation minimized with LDR
- Reimbursement for surgeon and Radiation Oncologist established
- Improvements in design overcome concerns with balloon device
- Ease of use should overcome learning curve for current catheter procedure
- HDR established in EU
- International opportunity for LDR good due to in-patient treatment

north american
SCIENTIFIC

n



CLINICAL EXCELLENCE. PRACTICAL CHOICE

TAB13

**Review of Medical Events
Involving I-131**

ACMUI Subcommittee Report

Douglas Egli
Ralph Lieto
Sally Schwarz
Richard Vetter

Charge

- Review I-131 (NaI) Administration incidents to determine if there are any patterns to the errors
- Determine if there is a way to further reduce iodine administration errors
- Since several of the incidents were initially intended to be less than 30 uCi administrations (not requiring a written directive), but ended up with larger administrations, can any recommendation be made to prevent these incidents

**Event 1
NMED 030987**

The licensee reported that a patient was administered a thyroid uptake dose of 36.26 MBq (0.98 mCi) instead of the prescribed dose of 0.56 MBq (15 uCi). The event occurred due to the prescription order being made incorrectly with no subsequent verification by the technologist.

Analysis

- Dosage was ordered incorrectly
- Assume the dosage was labeled with the activity actually contained in the capsule
- Verification in a dose calibrator would have confirmed a dosage in the range requiring a written directive
 - It would have also confirmed a dosage different than anticipated
- The activity delivered would have required a written directive
 - Seeing the dosage to be administered, the technologist should have located a written directive
 - A dosage of 0.98 mCi without an accompanying written directive should have been a "red flag"

**Event 2
NMED 040073**

The licensee reported that a patient was administered 19.8 MBq (535 uCi) of I-131 instead of the prescribed 0.19 MBq (5 uCi). The verbal order from the authorized user for a 0.19 MBq (5 uCi) dose was misunderstood and an 18.5 MBq (500 uCi) dose was ordered.

Analysis

- Dosage of 500 uCi was ordered incorrectly based on a misunderstood verbal order for 5 uCi
- Technologist should not have accepted a verbal order for a dosage in the range requiring a written directive (the technologist understood the order to be for 500 uCi)
- Technologist administering the dosage knew the dosage was greater than 30 uCi and should not have administered the dosage without reviewing a written directive (technologist should actually see the written directive)
- If either the ordering technologist or the administering technologist had sought out the required written directive for the dosage being administered, the error would have been discovered

Event 3
NMED 040352

The licensee reported that the wrong patient was administered 74 MBq (2 mCi) of I-131 for a thyroid cancer workup instead of the prescribed dose of 7.4 MBq (200 uCi) of I-123 for a thyroid uptake scan. The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was to receive the I-131 dose. The technologist did not follow procedures regarding proper identification of the patient, which requires two separate methods for verifying patient identification.

Analysis

- Proper patient identification procedures were not followed by the administering technologist
- Subcommittee recommends that patient identification procedures similar to blood administration or approaching the rigor of the JCAHO Universal Protocol be required for I-131 dosages greater than 30 uCi
 - Blood administration requires that two individuals must positively identify the patient prior to administration
 - Two identification methods should be employed such as full name and date of birth
 - ▶ The patient should be asked to state their full name and date of birth

Event 4
NMED 040415

The licensee reported that a patient received 33.86 MBq (915 uCi) of I-131 sodium iodide for a thyroid uptake study instead of the intended oral dose of 0.37 MBq (10 uCi). The root cause of the event was the lack of an adequate double check of the I-131 uptake dose prior to administration. A pipette contaminated with 74 MBq (2 mCi) of I-131 was inadvertently used to prepare the uptake dose. The radiopharmacy computer was programmed to detect volume errors but not activity errors, so it accepted the dose and printed the label. The radiopharmacy technologist did not detect the error when she assayed the dose because she assumed that the activity displayed as "0.915 mCi" was "0.15 uCi". The nuclear medicine technologist that double-checked the dose mistook the "0.9 mCi" for "0.9 uCi" on the dose label and administered the dose.

Analysis

- Four errors occurred which combined to produce the erroneous dosage administered
- This is a unique incident, not likely to be repeated.
- The root cause was re-use of a pipette previously used to draw up a far more concentrated iodine solution with residual iodine left in the pipette
- The corrective action which prohibits reuse of pipettes is an adequate corrective action

Event 5 NMED 040441

The licensee reported that a 19-year-old female patient, who was diagnosed with Grave's Disease of the thyroid, was administered 462.5 MBq (12.5 mCi) of I-131 instead of the prescribed dose of 0.444 MBq (12 uCi) of I-131. The intent of the procedure was to ablate the patient's thyroid. The physician wrote "12 uCi" on the prescription, but the technologist ordered "12 mCi" instead. The technologist received 462.5 MBq (12.5 mCi) of I-131 and administered it on 4/7/2004

Analysis

- The physician ordered a dosage 1000 fold smaller than intended (12 uCi when the intended dosage was 12 mCi)
- The technologist actually gave the intended dosage, not the ordered dosage
 - The patient received the correct dosage for the wrong reason
- A procedure to compare the dosage ordered with that received might have detected the error
- Technologist administering the dosage knew the dosage was greater than 30 uCi and should not have administered the dosage without reviewing a written directive

Event 6
NMED 040491

- The licensee reported that a patient was administered 103.6 MBq (2.8 mCi) of I-131 instead of the prescribed 74 MBq (2.0 mCi). The Woman's Hospital had ordered a 74 MBq (2 mCi) capsule of I-131. When the dose was sent it was 103.6 MBq (2.8 mCi). A verbal order was given to administer the dose to the patient

Analysis

- Therapeutic overdosage resulted from an error made by the radiopharmaceutical vendor
- It is likely that the correct dosage was indicated on the capsule label
- The written directive should have been reviewed by the administering technologist
- A verbal order to administer the capsule should not have been accepted
- A procedure to compare the dosage ordered with that received might have detected the error

Event 7
NMED 040610

The licensee reported that a patient received 111 MBq (3 mCi) of I-131 for the assessment of metastatic thyroid disease instead of the prescribed dose of 0.93 MBq (25 uCi). The imaging technologist misunderstood the referring physician's order and the authorized user did not approve the dose.

Analysis

- A dosage of 25 mCi for the evaluation of metastatic thyroid cancer is both inappropriate and ineffective
- No iodine dosage should ever be ordered at the direction of a referring physician without the knowledge and approval of a responsible authorized user
- The dosage actually administered would have required a written directive, which should have been reviewed
- The NMED narrative is inconsistent with standard clinical practice
 - The standard goal of treatment of metastatic thyroid cancer is to render the patient athyroidic
- 3 mCi is an appropriate dosage for evaluating thyroid cancer metastases (assuming an appropriate patient prep using either hormone withdrawal or Thyrogen stimulation)

**Event 8
NMED 040611**

The licensee reported that a patient received 3.7 GBq (100 mCi) of I-131 instead of a prescribed dose of 0.64 GBq (17.3 mCi). Three patients were scheduled for I-131 treatments on the same day. Two outpatients were scheduled to receive less than 0.11 GBq (33 mCi) and one inpatient was scheduled to receive 3.7 GBq (100 mCi). One of the outpatients was given the inpatient dose and allowed to leave the facility without receiving proper instructions. The licensee did not discover the incident until after the patient had left the facility with her children. The authorized user who signed the written directive was at the facility when the dose was administered

Analysis

- Review of the written directive combined with accurate patient identification prior to administration of the therapeutic dosage would have prevented this error
- All I-131 therapy patients, including therapies with less than 33 mCi, should be thoroughly instructed on radiation safety measures and provided with a written copy of safety instructions.
- Patients receiving outpatient I-131 therapies who have children in the household require careful evaluation to determine that the children will not receive excess exposure.

**Event 9
NMED 040326**

The licensee reported that a patient was administered a 0.148 GBq (4mCi) dose of I-131 without a written directive. Several patients were scheduled to receive doses of 0.148 GBq (4mCi) of I-131, but one of the patients did not have a written directive. Due to a change in the written directive for another patient, there was an extra 0.148 GBq (4mCi) dose capsule in the lab. The technologist decided to give this dose to the patient who did not have a written directive and have the prescribing physician complete a written directive later. When asked to sign the written directive, the prescribing physician realized that a mistake had been made. Additional instructions from the patient's physician had directed the administration of 5.55 GBq (150 mCi) of I-131

Analysis

- Administration of 4 mCi of I-131 without a written directive is a clear and willful violation of regulation by the administering technologist
- An unambiguous and enforced policy of requiring the technologist to have a written directive in hand prior to administering I-131 dosages of greater than 30 uCi might have prevented this erroneous administration
 - Well understood and routinely enforced policies are more likely to be followed

**Event 10
NMED 040859**

The licensee reported that a patient scheduled to receive 74 MBq (2mCi) of I-131 was instead administered 555 MBq (15 mCi) of I-131. Previously the patient's thyroid was surgically removed (due to cancer) and the patient also received an ablative dose of I-131. The patient was scheduled to receive 74 MBq (2mCi) of I-131 as a diagnostic procedure to verify effectiveness of previous treatments.

Analysis

- The NMED narrative does not contain enough detail to determine whether a written directive authorizing the dosage existed
- Assuming that a written directive existed and that the dosage was properly labeled with the correct activity, the administering technologist did not review the written directive which would contain an order for the dosage to be administered
- Reviewing the written directive with the responsible authorized user prior to administration would have prevented the error

**Event 11
NMED 040702**

The licensee reported that a patient received 190.9 MBq (5.16 mCi) of I-131 (NaI) instead of the prescribed 74 MBq (2mCi) for a post thyroid treatment follow-up scan. The prescribing physician discovered the error on 9/27/2004 when the patient underwent the scan. A viable follow-up scan was performed even though the error occurred.

Analysis

- The NMED narrative does not contain enough detail to determine whether a written directive authorizing the dosage existed
- Assuming that a written directive existed and that the dosage was properly labeled with the correct activity, the administering technologist did not review the written directive which would contain an order for the dosage to be administered
- Reviewing the written directive with the responsible authorized user prior to administration would have prevented the error

Summary

- There are only 11 iodine incidents in the NMED database during the period being considered
- There are tens of thousands of both diagnostic and therapeutic iodine administrations in the US annually
- Of the 11 incidents reported:
 - Four involved intended therapeutic dosages
 - Two involved dosages intended to be greater than 30 uCi
 - Five involved dosages intended to be less than 30 uCi, not requiring a written directive

Summary

- One case involved an incorrect patient identification
 - The subcommittee's recommendation on patient identification procedures would have prevented this
- In 9 of the 11 cases, the dosages administered were in the range that would have required a written directive
 - Although 5 of the 6 were intended to be administrations under 30 microcuries, there is no reason to believe that the administering technologist was unaware that the dosages were in the range requiring a written directive
 - The subcommittee's recommendation that the written directive must be reviewed with the authorized user by the administering technologist whenever the dosage administered is greater than 30 uCi, would have prevented all nine of these errors

Summary

- In two cases, in spite of erroneous orders, the patients received medically appropriate dosages of radioactive iodine
 - These are none the less iodine administration incidents
- In both cases, the iodine dosages administered were in the range that would have required a written directive
 - Review of a written directive with the authorized user would have permitted correction of the erroneous orders before the iodine was administered
- Absence of a written directive should have been a "red flag" to the administering technologist

Final Conclusion

The ACMUI subcommittee on I-131 administration incidents reaffirms the recommendations made at the April 2005 ACMUI meeting

April 2005 Subcommittee Recommendations

1. It is impossible to entirely eliminate all human errors from any process, however, verification procedures, similar to blood administration (i.e. two people verifying therapeutic dosages), could be considered
2. Verbal orders should not be permitted in any step of the therapeutic dosage administration process from dosage ordering through dosage administration, except as already provided in Part 35 for emergent situations
 - Change "therapeutic dosages" to "dosages greater than 30 mCi"
3. The dosage to be administered must be verified against the written directive prior to dosage administration
4. Communication links between the Authorize User and the individual administering the dosage should be strengthened. The administering technologist should review the treatment plan with the AU prior to dosage administration
5. Re-verifying the therapeutic dosage in a dose calibrator on site prior to dosage administration might have prevented a number of administration errors
6. The documentation of NMED medical events for radiopharmaceuticals needs to be improved

Therapy Medical Events

35.300

2

2 Sodium Iodide I-131

One Capsule left in Vial

Identified 7 - 10 days later

Brachytherapy Medical Events

35.400

5(5)

GYN

1 wrong seed activity selected

1 wrong source-bucket combination

PROSTATE

1 broken source

1 wrong seed activity sent - air kerma vs activity

HDR Medical Events

HDR

4

Error in depth

Unspecified error

Lung Catheter moved

Cap not on end of Catheter

**Y-90 Microsphere Medical
Events**

35.1000

1

Some spillage

40 % remained in V vial

OTHER REPORTED EVENTS

Prior to Patient treatment **1**

Cut Cs-131 source - improper packaging

Patient treatments **3**

I-131 4 mCi no Written Directive

Brachytherapy Strands in bladder

HDR equipment failure - source path

constriction fault once repaired new

problem related to error in assembly

REPORTABLE MEDICAL EVENTS

10 CFR 35.300

NMED Item Number: 050808

Narrative:

Last Updated: 02/16/2006

The licensee reported that a patient was only administered two of three I-131 capsules. The three capsules were transported to the licensee in two small pgs. After the administration, one of the capsules was discovered in a pig, indicating that the patient only received two of the capsules. The patient was prescribed to receive 7.96 GBq (215 mCi), but only received 5.62 GBq (152 mCi). The patient will be notified of the event. Corrective actions taken by the licensee included requiring the authorized user to administer the dosage instead of the technician, requiring the authorized user's signature indicating that the required dosage was administered, verification of the number of pills that make up a dosage, and performing a post administration assay of the containers to ensure that a pill is not still in the container.

Event Date: 12/09/2005 Discovery Date: 12/13/2005 Report Date: 12/13/2005

Licensee/Reporting Party Information:

License Number: 45-09207-01 Name: LEWIS-GALE MEDICAL CENTER
Docket Number: 03003333 City: SALEM, VA

Site of Event:

Site Name: SALEM, VA

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42202	12/14/2005	EVENT NOTIFICATION
LTR060214	02/16/2006	NRC LETTER

NMED Item Number: 060047

Narrative:

Last Updated: 02/21/2006

The licensee reported that a patient prescribed to receive an I-131 therapy dose of 5.6 GBq (150 mCi) in two capsules was only administered one capsule containing 2.8 GBq (75 mCi). The patient was given a vial containing two capsules, upended the vial into his mouth, and took several sips of water. The technologist placed the vial into the lead pig and capped it. It was later determined that the vial still contained one capsule. The patient was notified of the incident. The INL has requested additional information for this event.

Event Date: Discovery Date: Report Date:
01/10/2006 01/17/2006 01/17/2006

Licensee/Reporting Party Information:

License Number: GA-0677-1 Name: GWINETT MEDICAL CENTER
Docket Number: NA City: LAWRENCEVILLE, GA

Site of Event:

Site Name: ATLANTA, GA

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42265	01/23/2006	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
GA-06-003I	02/21/2006	AGREEMENT STATE EVENT REPORT

10 CFR 354.400

NMED Item Number: 060049 CESIUM-137

Narrative:

Last Updated: 03/13/2006

The licensee reported that a patient received 6,474 cGy (rad) instead of the prescribed 4,338 cGy (rad) during a manual brachytherapy treatment. The authorized user's written directive called for a temporary implant tandem and ovoid using Cs-137 sources to deliver the dose over 68 hours. The applicator (Fletcher-Suit-Delclos, model 640 M) was to be loaded with 1.89 GBq (51.1 mCi) in the right ovoid, 1.89 GBq (51.1 mCi) in the left ovoid, and 1.45 GBq (39.2 mCi), 1.89 GBq (51.1 mCi), and 1.45 GBq (39.2 mCi) in the tandem. The medical dosimetrist loaded the tandem and ovoid incorrectly. The applicator was loaded with 1.89 GBq (51.1 mCi) in the right ovoid, 1.89 GBq (51.1 mCi) in the left ovoid, and 1.45 GBq (39.2 mCi), 3.21 GBq (86.8 mCi), and 3.21 GBq (86.8 mCi) in the tandem. The error resulted in a delivered dose 49.2% greater than prescribed. The 1.45 GBq (39.2 mCi) source (model 6502) was manufactured by 3M, the 1.89 GBq (51.1 mCi) sources (model 6503) were manufactured by 3M, and the 3.21 GBq (86.8 mCi) source (model CDC.T1, serial #GG 899 and GG 909) was manufactured by AEA Technology. The patient was notified of the incident on 1/20/2006. The licensee conducted follow-up investigations. Corrective actions taken by the licensee included writing a new procedure.

Event Date: Discovery Date: Report Date:
01/17/2006 01/18/2006 01/18/2006

Licensee/Reporting Party Information:

License Number: NC-060-0014-3 Name: CAROLINAS MEDICAL CENTER
Docket Number: NA City: CHARLOTTE, NC

Site of Event:

Site Name: CHARLOTTE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42270	01/23/2006	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC060004	02/15/2006	AGREEMENT STATE EVENT REPORT
NC060004A	03/13/2006	AGREEMENT STATE EVENT REPORT

NMED Item Number: 060216

Narrative:

Last Updated: 04/04/2006

The licensee reported that a patient received a dose that was less than the prescribed dose by greater than 20%. The patient received a gynecological administration using a manual, low-dose rate brachytherapy device with Cs-137 sources. The device uses hinged hardware (bucket) to properly position the sources within the device. After the administration, it was noted that the bucket was too short for the device. As a result, the sources were not positioned properly in the patient. Review of the x-ray taken to confirm placement during the exam confirmed that a different dose distribution was given to the patient than originally intended. The event occurred because the licensee did not perform a direct physical comparison of the bucket and applicator prior to the procedure. Following the event, the licensee sorted all applicators and buckets to create matched sets. The licensee is considering modifying procedures to include physical comparison of the applicator and bucket in the future. The oncology physician was to inform the patient of the differing dose. The licensee reviewed all of the brachytherapy treatments that were conducted with the brachytherapy device. The licensee identified six additional treatments that involved similar, incorrect source positioning due to the use of buckets that were too short for the brachytherapy device. Based on the licensee's preliminary dose evaluations, none of the additional six treatments resulted in a medical event because the doses delivered did not differ from the prescribed doses by more than 20%.

Event Date:	Discovery Date:	Report Date:
03/29/2006	03/30/2006	03/30/2006

Licensee/Reporting Party Information:

License Number:	13-02752-03	Name: INDIANA UNIVERSITY MEDICAL CENTER
Docket Number:	03001609	City: INDIANAPOLIS, IN

Site of Event:

Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42453	04/03/2006	EVENT NOTIFICATION
ML060930528	04/04/2006	PRELIMINARY NOTIFICATION
PN306008	04/04/2006	PRELIMINARY NOTIFICATION

NMED Item Number: 060219

Narrative:

Last Updated: 04/05/2006

The licensee reported that a patient received a delivered dose of 1,203 cGy (rad) instead of the prescribed dose of 2,500 cGy (rad) using an ovoid applicator. The patient received a gynecological administration using a manual, low-dose rate brachytherapy device with Cs-137 sources. The event was discovered during a review of patient records. Both the referring physician and patient were informed.

Event Date:	Discovery Date:	Report Date:
01/17/2006	04/03/2006	04/03/2006

Licensee/Reporting Party Information:

License Number:	13-02752-03	Name:	INDIANA UNIVERSITY MEDICAL CENTER
Docket Number:	03001609	City:	INDIANAPOLIS, IN

Site of Event:

Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42469	04/04/2006	EVENT NOTIFICATION

NMED Item Number: 060142

PROSTRATE IODINE 125

Narrative:

Last Updated: 02/27/2006

The licensee reported a broken I-125 brachytherapy seed (GE Healthcare Medi-Physics) that occurred during a prostate seed implant procedure. The cartridge jammed in the Mick applicator (model 200-TP) and the seed was ruptured. The seed contained an activity of 17.4 MBq (0.47 mCi). All seed fragments were recovered while rinsing the applicator and no fragments were implanted into the patient. The report stated that 90 seeds were ordered, 74 were implanted, and 16 unused seeds were recovered – one of which had ruptured. The radiation oncologist stated that the applicator jammed several times during the procedure and that he was required to remove seeds from the applicator. The licensee believes that it was at that time that the seed was damaged and loose seeds fell to the table. The medical physicist stated that he identified two loose seeds when going to the operating room to retrieve the unused seeds. One of those seeds was damaged and appeared shorter than the others. A radiological survey indicated that no radioactive contamination was present on instruments or in the implant area. The inner contents of the broken seed were recovered. Thyroid and urine bioassays were performed on the patient, physicist, and RSO. All revealed negative results. All unused seeds were placed in storage for decay. The licensee obtained new applicators and placed them into service. The State of New York is tracking this incident as NY-06-003 (NYS DOH internal tracking number is 421).

Event Date: 11/29/2005 **Discovery Date: 11/29/2005** **Report Date: 02/22/2006**

Licensee/Reporting Party Information:

License Number: NR Name: NR
Docket Number: NA City: NR, NY

Site of Event:

Site Name: NR, NY

Reference Documents:

Reference Document Number:
EN42360

Entry Date:
02/27/2006

Type of Report:
EVENT NOTIFICATION
REPORTED FROM AN
AGREEMENT STATE

10 CFR 35.600

NMED Item Number: 050778

HIGH DOSE RATE AFTERLOADER

Narrative:

Last Updated: 02/13/2006

The licensee reported that a female patient undergoing HDR brachytherapy treatment for cervical cancer received 290 cGy (rad) instead of the prescribed 600 cGy (rad) during the third of five fractions. Each fraction was scheduled to deliver 600 cGy (rad) to the intended treatment site for a total delivered dose of 3000 cGy (rad). The treatment for the third fraction was delivered based on a dose calculation performed to a depth of one centimeter rather than to the prescribed depth of two centimeters. This event was discovered while preparing for the fourth fraction. The source used in the treatment contained Ir-192 with an activity of 253.8 GBq (6.86 Ci). The licensee will stop use of the HDR unit (Nucletron Corporation, model 150.999, serial #31123) upon completion of the remaining treatment fractions for patients currently under treatment. The unit will be placed in storage pending transfer. An NRC inspection conducted on 11/30/2005 determined that the root cause was that the licensee did not have procedures for written directives. The licensee was required to examine all of its previous treatments for similar errors.

Event Date: 11/22/2005 Discovery Date: 11/29/2005 Report Date: 11/29/2005

Licensee/Reporting Party Information:

License Number: 52-118832-02 Name: HOSPITAL ANDRES GRILLASCA, INC.
Docket Number: 03034175 City: PONCE, PR

Site of Event:

Site Name: PONCE, PR

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42174	11/30/2005	EVENT NOTIFICATION
ML053400023	12/19/2005	CONFIRMATORY ACTION LETTER
ML053420668	12/19/2005	CONFIRMATORY ACTION LETTER
LTR060210	02/13/2006	NRC LETTER

NMED Item Number: 060044

Narrative:

Last Updated: 02/23/2006

The licensee reported that a patient received a dose that was 67% less than prescribed while being treated with a high dose rate afterloading brachytherapy system using an Ir-192 source. During the first of three treatments to the pelvic region, the patient received a dose of 233 cGy (rad) rather than the prescribed dose of 700 cGy (rad). The treatment plan specified three fractionated doses of 700 cGy (rad) for a total of 2,100 cGy (rad). The patient ended up receiving four treatments and the fourth fraction was 467 cGy (rad). The licensee stated that no HDR treatments will occur until the manual dose calculations check has been performed. The INL has requested additional information for this event.

Event Date: Discovery Date: Report Date:
01/12/2006 01/12/2006 01/13/2006

Licensee/Reporting Party Information:

License Number: SC-0646 Name: CARE ALLIANCE HEALTH SERVICES ROPER
HOSPITAL
Docket Number: NA City: CHARLESTON, SC

Site of Event:

Site Name: CHARLESTON, SC

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42256	01/18/2006	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
SC060004	02/23/2006	AGREEMENT STATE EVENT REPORT

NMED Item Number: 060046

Narrative:

Last Updated: 02/21/2006

The licensee reported problems with an HDR brachytherapy treatment to a patient using a Varian Medical Systems HDR unit (model VS2000, serial #VS331) and an Ir-192 source with an activity of 0.26 TBq (7.059 Ci). The patient was prescribed to receive a dose of 750 cGy (rad) in a single fraction to a site in the right lung. The patient instead received 750 cGy (rad) to a distance of 1.0 cm beyond the active dwell positions in the right lung. A catheter was inserted in the right bronchus on 11/22/2005 for the treatment. The catheter was marked at the entrance of the nostril and taped to the nose and face. The patient was then taken to CT for the treatment planning. The treatment plan was developed and approved. The patient was treated in a linear accelerator vault. Prior to treatment, a dummy wire was placed into the catheter and a megavoltage portal image was taken to confirm placement of the catheter. The radiation oncologist believed that he had verified the catheter placement from the portal image. The catheter was connected to the HDR unit and the treatment was performed. At the conclusion of the treatment, the prescribing physician and nurse entered the treatment room to remove the catheter from the patient. At that time, it was discovered that the catheter was not fully inserted into the patient's lung. The mark that was put on the catheter during the planning was 15 cm outside of the nose. Apparently the catheter had become loose from the tape. The patient was informed on 11/22/2005. External beam therapy will be used for the missing dose to the lung. Some licensee procedures have been modified to prevent this from recurring. This event is being tracked by the State of Louisiana as event report LA050009.

Event Date: 11/22/2005 **Discovery Date: 11/22/2005** **Report Date: 11/22/2005**

Licensee/Reporting Party Information:

License Number: LA-2651-L01 Name: MARY BIRD PERKINS CANCER CENTER
Docket Number: NA City: BATON ROUGE, LA

Site of Event:

Site Name: BATON ROUGE, LA

Reference Documents:

Reference Document Number: EN42263	Entry Date: 01/23/2006	Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR060215	02/20/2006	AGREEMENT STATE LETTER

NMED Item Number: 060235

Narrative:

Last Updated: 04/07/2006

The licensee reported that a terminally ill lung cancer patient received a high dose rate remote afterloader treatment to the incorrect site. This occurred because the catheter used to carry the source into the patient's body was inserted without a cap on the end. As a result, the source was placed approximately 7 mm higher than originally intended per the physician's written directive. Immediately following the treatment, the error was noted and the physician was informed. This event resulted in the airway above the lung receiving a dose of 500 cGy (rad) rather than the prescribed dose of 200 cGy (rad). Also, the treatment area of the lung received a dose of 200 cGy (rad) rather than the prescribed dose of 500 cGy (rad). This treatment was performed to relieve the patient's symptoms rather than cure the illness. The patient succumbed to the illness approximately two weeks later. During a routine NRC Region III inspection conducted on 4/4/2006, the inspector noted that the event appeared to be a reportable medical event.

Event Date:	Discovery Date:	Report Date:
11/08/2005	04/04/2006	04/05/2006

Licensee/Reporting Party Information:

License Number:	13-06009-01	Name:	COMMUNITY HOSPITALS OF INDIANA
Docket Number:	03001625	City:	INDIANAPOLIS, IN

Site of Event:

Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42474	04/06/2006	EVENT NOTIFICATION

10 CFR 35.1000

NMED Item Number: 060078

Narrative:

Last Updated: 03/21/2006

The licensee reported that a patient received an undertreatment of Y-90 microspheres during treatment for liver cancer. The nuclear medicine physician delivered the microspheres to the patient; however, after the treatment was presumed finished, he noted that some of the fluid remained in the vial. The retention fluid for the microspheres had become backed up from the site of injection (hepatic artery) and some spillage at the surface occurred, which was absorbed with gauze. The patient was prescribed to receive 0.41 GBq (11 mCi), but there was 0.17 GBq (4.5 mCi) left in the vial. The licensed medical physicist is evaluating the incident and making an effort to assess the dose delivered to the patient. Corrective actions taken by the licensee included modifying procedures. The INL has requested additional information for this event.

Event Date: 01/10/2006 Discovery Date: 01/10/2006 Report Date: 01/20/2006

Licensee/Reporting Party Information:

License Number: TX-L00650 Name: MEMORIAL HERMANN HOSPITAL
Docket Number: NA City: HOUSTON, TX

Site of Event:

Site Name: HOUSTON, TX

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
TX060001	02/02/2006	AGREEMENT STATE EVENT REPORT
TX060001A	03/07/2006	AGREEMENT STATE EVENT REPORT
TX060001B	03/21/2006	AGREEMENT STATE EVENT REPORT

OTHER EVENTS OF INTEREST - NOT MEDICAL EVENTS

10 CFR 35.300 NO WRITTEN DIRECTIVE

NMED Item Number: 060035

Narrative:

Last Updated: 01/23/2006

The licensee reported that a patient was administered 151.7 MBq (4.1 mCi) of I-131 for a diagnostic whole body scan without a written directive. The patient had a physician's order to perform the scan, but the technologists over-looked the fact that there was no written directive. The patient got the correct dose of I-131 for his scan. The licensee stated that they were operating under departmental protocol for thyrogen whole body iodine doses. Based on discussions with NRC personnel, the licensee does not consider this to meet the criteria of a medical event. The event was retracted on 1/19/2006.

Event Date: Discovery Date: Report Date:
01/11/2006 01/11/2006 01/12/2006

Licensee/Reporting Party Information:

License Number: 06-02388-01 Name: NEW BRITAIN GENERAL HOSPITAL
Docket Number: 03001250 City: NEW BRITAIN, CT

Site of Event:

Site Name: NEW BRITAIN, CT

Reference Documents:

Reference	Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42253		01/13/2006	1/19/2006	EVENT NOTIFICATION
LTR040603		01/16/2006		NRC LETTER

10 CFR 35.400 PROSTRATE STRANDS

NMED Item Number: 050671

Narrative:

Last Updated: 02/06/2006

The licensee reported a possible medical event involving a patient that was prescribed to have 90 I-125 brachytherapy seeds implanted into his prostate, but 45 of the seeds were inadvertently implanted into his bladder. The seeds were recovered from the bladder prior to completion of the procedure in the operating room. The written directive was revised by the authorized user prior to the completion of the procedure to document the actual number of seeds implanted into the prostate. The licensee stated that this event was similar to a previous event (EN 39586 or NMED Item #030135) that the NRC determined was not a reportable medical event. The NRC NHPP decided to perform an on-site review to assess the circumstances of this event. The licensee has not determined the cause of the event, but will be investigating on 10/13/2005 to determine both the cause and significance of the event. The patient was notified of the event. The licensee retracted the event on 2/3/2006, based on discussions with the NRC Region III Office.

Event Date: Discovery Date: Report Date:
10/03/2005 10/03/2005 10/05/2005

Licensee/Reporting Party Information:

License Number: 03-23853-01VA Name: V.A., DEPARTMENT OF
Docket Number: 03034325 City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: PHILADELPHIA, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42038	10/06/2005	2/3/2006	EVENT NOTIFICATION

NMED Item Number: 060040

PACKAGING FOR TRANSPORT

Narrative:

Last Updated: 03/22/2006

The licensee reported receiving a leaking Cs-131 source that contained an activity of 0.14 GBq (3.8 mCi). They received four packages containing sources (IsoRay, Incorporated, model CS-1) that had been loaded into applicators, as well as loose seeds for reference and potential application. One of the four packages contained 10 sealed sources and 42 additional sources that were pre-loaded into treatment applicators by Anazao Health. The outer packaging was free from radioactive contamination, but once the cardboard outer container and the secondary lead container were opened, a damaged seed was visually detected on the outer lead container. Associated radioactive contamination was subsequently found on the secondary container and the primary lead container, as well as on a second seed that had been trapped and bent within the primary lead container. Although all the seeds were accounted for, none of the 10 seeds were contained within the innermost glass vial, as its lid was not engaged. The Illinois Emergency Management Agency discovered that the licensee had experienced widespread radioactive contamination within the source preparation area as a result of the damaged seeds and the failure to don proper protective gloves. The affected surfaces and items had been subsequently decontaminated and set aside as waste. Contamination levels ranged from 1 to 5 kcpm, as measured by the licensee's Geiger counter and rate meter. Items that had been touched by the medical physicist who had not been wearing protective gloves were found to be contaminated. One of the assisting staff members experienced contamination on their hand, which was later decontaminated. An Illinois Agency representative was dispatched to the licensee's facility to determine the effectiveness of the decontamination efforts, the extent of any remaining contamination, and to interview the RSO. The inspector's initial investigation revealed that contamination was limited to the source handling room, which is a restricted area, and that all of the seeds were accounted for and secured. The only remaining contamination was two spots on a counter of approximately 1 to 2 kcpm and on the containers involved. The inspector interviewed the responsible physicist and the assisting technician. Follow-up investigation revealed that the shipment had been improperly prepared, which lead to the sources not remaining within the primary package. They also determined that the procedures for properly handling radioactive material had not been followed to prevent direct contamination or personnel. The damaged materials were returned to the manufacturer for additional investigation. A Florida Department of Health inspector visited the Anazao Health facility and found no violations of the regulations or license requirements. Anazao Health is implementing a secondary check on all seed vials to ensure all seeds are counted and in the vial prior to sealing the lead container.

Event Date: 01/05/2006 **Discovery Date:** 01/05/2006 **Report Date:** 01/11/2006

Licensee/Reporting Party Information:

License Number: IL-02015-01 **Name:** CHICAGO PROSTATE CANCER CENTER
Docket Number: NA **City:** WESTMONT, IL

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42255	01/17/2006	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL060003	02/22/2006	AGREEMENT STATE EVENT REPORT
FL06-007	03/22/2006	AGREEMENT STATE EVENT REPORT
IL060003A	03/22/2006	AGREEMENT STATE EVENT REPORT

NMED Item Number: 060082

DEVICE FAILURE

Narrative:

Last Updated: 02/20/2006

During an inspection conducted by the NRC Region I, a problem with a Varian high dose rate (HDR) remote afterloader unit (model VariSource, serial #VS286) was discovered. The HDR afterloader utilized a Varian Ir-192 source (model VS2000). On 11/18/2005, during a patient treatment, the unit reported a fault during source retraction (as a source path constriction). However, the source retracted fully and the error was cleared. The patient received the prescribed treatment and there was no unintended radiation exposure. During the following treatment on 11/21/2005, the error recurred and Varian was contacted to service the unit. The source again retracted fully and the patient received the prescribed treatment. Varian arrived at the licensee's facility on 11/26/2005. The engineer repaired the fault, but after the repair a new problem arose. During post-repair testing by Varian, the inactive wire failed to move from the shielded safe position. Varian subsequently sent a new loaner HDR unit to the licensee's facility and the faulty HDR unit was returned to the Varian factory in England for repair. Varian indicated that the cause of the inactive wire not moving was a signal wire that had been improperly stripped at the time of assembly. Over time, that connection oxidized causing a loss of contact for the signal, which was for the drive mechanism. Although the licensee reported this event as requested, it respectfully disagrees with the NRC interpretation of being reportable under 10 CFR 30.50(b)(2).

Event Date:	Discovery Date:	Report Date:
11/18/2005	11/18/2005	12/01/2005

Licensee/Reporting Party Information:

License Number:	37-02136-01	Name:	WEST PENNSYLVANIA HOSPITAL
Docket Number:	03003016	City:	PITTSBURGH, PA

Site of Event:

Site Name: PITTSBURGH, PA

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42304	02/06/2006	EVENT NOTIFICATION
LTR060215	02/20/2006	NRC LETTER

**Potential 10 CFR Part 35
Rulemaking**

April 2006

ACMUI Meeting

Donna-Beth Howe, Ph.D.

Potential 10 CFR Part 35 Rulemaking

32.72(b)(5) was not revised on March 30, 2005, when the training and experience criteria for the authorized nuclear pharmacist in 10 CFR 35.55 was revised to decouple the board certification from the attestation statement

Recommend revision to revising 10 CFR 32.72(b)(5) to read:

(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties and the written attestation(s), signed by a preceptor,..."

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.2 defines both medium-dose rate and high-dose rate remote after loaders. One is defined as delivering a dose rate of less than 12 gray (1200 rads) per hour and the other as delivering a dose rate in excess of 12 gray (1200 rads) per hour.

Recommend revising 35.2 to read: "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 or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.290 requires each AU for 35.200 medical uses to have supervised work experience in generator elution and radioactive drug preparation. Most AU use only unit dosages and most medical facilities, including broad scopes, obtain only unit dosages from a commercial nuclear pharmacy. It may be difficult to get supervised work experience eluting generators to fulfill the training and experience for this criterion.

Recommend providing two training and experience pathways for 35.200 physicians. One for physicians that can only administer unit dosages and the other for physicians that are permitted to prepare radioactive drugs.

9

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.390 requires the individual coming through the board certification route to meet the requirements in 35.390(b)(1)(ii)(G) but 35.390(b)(1)(ii)(G) does not require the individual to have clinical experience in all 4 types of dosage categories requiring a written directive. Only the supervising AU's that come through the alternate pathway are required to have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. This means a supervising AU coming through the board certification pathway may not have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

Recommend revising 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and 35.394(c)(2) to read: "...A supervising authorized user, who meets the requirements in § 35.390 must ..."

10

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.390 requires the individual coming through the board certification route to meet the requirements in 35.390(b)(1)(ii)(G) but 35.390(b)(1)(ii)(G) does not require the individual to have clinical experience in all 4 types of dosage categories requiring a written directive. Only the preceptor AU's that come through the alternate pathway are required to have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. This means a preceptor AU coming through the board certification pathway may not have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

Recommend revising 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and 35.394(c)(2) to read: "...A preceptor authorized user, who meets the requirements in § 35.390 must ..."

11

POTENTIAL 10 CFR PART 35 RULEMAKING

New ACMUI items

10 CFR 32

1. Problem: The text in 32.72(b)(5) was not revised on March 30, 2005, when the training and experience criteria for the authorized nuclear pharmacist in 10 CFR 35.55 was revised to decouple the board certification from the attestation statement.

Recommend revising 10 CFR 32.72(b)(5) to read:

(5) Shall provide to the Commission a copy of each individual's certification by the Board of Pharmaceutical Specialties and the written attestation(s), signed by a preceptor, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

10 CFR 35

2. Problem: 10 CFR 35.2 defines both medium-dose rate and high-dose rate remote after loaders. One is defined as delivering a dose rate of less than 12 gray (1200 rads) per hour and the other as delivering a dose rate in excess of 12 gray (1200 rads) per hour. The effect of these definitions is that a remote afterloader with an activity of 12 gray (1200 rads) per hour is not included in either definition.

Recommend revising the definition of the medium-dose rate remote afterloaded to read "*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 or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Clarifying 35.1000 Uses Submission and requirements

3. Problem: 10 CFR 35.12(d) requires an application for a license or amendment to use a 35.1000 medical use to meet the requirements in paragraphs 35.12(b) and (c). 10 CFR 35.12(b) requires an application for a license for medical use of byproduct material as described in 35.1000 to file 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). 10 CFR 35.12(c) requires an applicant for a license amendment or renewal to submit an original and one copy of either NRC Form 313 or a letter requesting the amendment or renewal but is silent on the need to submit the facility diagram or the training and experience of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s). It is unclear whether the information specified in 35.12(b) is included in

35.12(c).

Recommend that 35.12(d) be revised to clarify either a license application or amendment required submission of the information required in 10 CFR 35.12(b) regardless of the format used to submit it. (Not reviewed with the ACMUI.)

Radiation Safety Officer

4. **Problem:** The definition of radiation safety officer follows the same format as the definitions for authorized users, authorized nuclear pharmacist, and authorized medical physicist but an individual cannot be an RSO until the NRC or Agreement state identifies the individual on the license. The definition in 10 CFR 35.2 should be revised to clarify the RSO is an individual approved to be an RSO by the NRC or agreement State who meets criteria listed in the definition.

Correct 10 CFR 35.2 definition of an RSO to read:

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §35.57 or §§ 35.50 and 35.59; and

(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.

5. **Problem:** 10 CFR 35.50(c)(2) permits an authorized user, authorized medical physicist, or authorized nuclear pharmacist **identified on the licensee's license** and that has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities to be an RSO. This restricts the licensee from naming a qualified authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on another licensee's license as an RSO. It also prohibits an individual who meets the requirements to be an authorized user, authorized medical physicist, or authorized nuclear pharmacist that has not been listed on a license to be an RSO.

Recommend revising 10 CFR 35.50(c) as follows“(2) **Will be identified** as an authorized user, authorized medical physicist, or authorized nuclear pharmacist 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; and

Source aggregation

6. **Problem:** 10 CFR 35.65 authorizes a medical use licensee to possess certain calibration, transmission and reference sources if each sealed source or individual amounts of other forms of byproduct material do not exceed a specific activity. A manufacturer of attenuation sources used for SPEC or PET scanners believes this authorization includes its array of 28 sources since each does not exceed the individual limits specifies. The requirement needs to be clarified to exclude bundling or aggregating the sources for one device.

Revise 10 CFR 35.65 (a) through (d) from:

(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 μ Ci) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

To read:

(a) Sealed sources, not exceeding either 1.11 GBq (30 mCi) each or a total activity of 1.11 GBq (30 mCi) when used as an aggregate, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations.

(b) Sealed sources, not exceeding either 1.11 GBq (30 mCi) each or a total activity of 1.11 GBq (30 mCi) when used as an aggregate, 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 either individual amounts not to exceed 0.56 GBq (15 mCi) or a total activity of 0.56 GBq (15 mCi) when used as an aggregate.

(d) Any byproduct material with a half-life longer than 120 days in either individual amounts not to exceed the smaller of 7.4 MBq (200 μ Ci) or 1000 times the quantities in Appendix B of Part 30 of this chapter or a total activity not to exceed the smaller of 7.4 MBq (200 μ Ci) or 1000 times the quantities in Appendix B of Part 30 of this chapter when used as an aggregate.

Decay in storage

7. Problem: 10 CFR 35.92 permits decay in storage by medical use licensees for radionuclides with half-lives less than 120 days. This requirement excludes radionuclides with half-lives equal to 120 days. Selenium 75 has a half life of 120 days. The current text also puts Part 35 out of alignment with the financial assurance guidance in NUREG 1757 Vol. 1.

Recommend revising 10 CFR 35.92 to read "A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage without regard to its radioactivity if it -"

(Not reviewed with the ACMUI.)

Supervised work experience

8. Problem 10 CFR 35.190(a), and 35.290(a) require the training and experience to cover

the topics in the alternate pathway but do not require the work experience to be obtained from an authorized user for that medical use.

Correction: Revise 10 CFR 35.190(a) to read "...hours of training and experience as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section." and Revise 35.290(a) to read "...hours of training and experience as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section.

Generator elution

9. Problem: 10 CFR 35.290 requires each authorized user for 35.200 medical uses to have supervised work experience, under a 35.200 authorized user, in eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs. Most medical facilities today, even broad scope medical use facilities, use unit dosages obtained from a commercial nuclear pharmacy and most physicians only use unit dosages. It is difficult to get supervised work experience eluting generators to fulfill the training and experience for this criterion.

Recommend providing two training and experience pathways for 35.200 physicians. One for physicians that can only administer unit dosages and the other for physicians that are permitted to prepare radioactive drugs.

Clinical experience of supervising AU's

10. Problem: 10 CFR 35.390 requires the individual coming through the board certification route to meet the requirements in 35.390(b)(1)(ii)(G) but 35.390(b)(1)(ii)(G) does not require the individual to have clinical experience in all 4 types of dosage categories requiring a written directive. Therefore, an individual may be an authorized user under 35.390(a) without having clinical experience in one or more of the types of dosage categories in 35.390(b)(1)(ii)(G) . Only the **supervising authorized users** that come through the alternate pathway are required to have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. This means a supervising authorized user coming through the board certification pathway may not have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

Correct the statement in 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and 35.394(c)(2) from:

"...A **supervising authorized user**, who meets the requirements in § 35.390(b) must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(G)) as the individual requesting authorized user status." Or "...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). Or "A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2)."

To read: "...A **supervising authorized user**, who meets the requirements in § 35.390 must ..."

11. Problem: 10 CFR 35.390 requires the individual coming through the board certification route to meet the requirements in 35.390(b)(1)(ii)(G) but 35.390(b)(1)(ii)(G) does not require the individual to have clinical experience in all 4 types of dosage categories requiring a written directive. Therefore, an individual may be an authorized user under 35.390(a) without having clinical experience in one or more of the types of dosage categories in 35.390(b)(1)(ii)(G) . Only the **preceptor authorized users** that come through the alternate pathway are required to have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. This means a preceptor authorized user coming through the board certification pathway may not have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

Correct the statement in 10 CFR 35.390(b)(1)(ii), 35.392(c)(2), and 35.394(c)(2) from:

"..The **preceptor authorized user**, who meets the requirements in § **35.390(b)** must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status." Or "...A preceptor authorized user, who meets the requirement in § **35.390(b)**, must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). " Or "A preceptor authorized user, who meets the requirements in § **35.390(b)**, must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2)."

To read: "...The **preceptor authorized user**, who meets the requirements in § **35.390** must ..."

12. Problem: 10 CFR 35.396 provides the training requirements for radiation oncologists seeking authorization for the parenteral administration of unsealed byproduct material requiring a written directive. A number of individuals and regulators have incorrectly interpreted current paragraph (d) to be a stand alone requirement.

Recommend revising the text of 35.396 to read:

"(b) Is an authorized user under §§ 35.490 or 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraphs (c)(2), (c)(3) and (c)(4) of this section; or

(c) (1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690; and.

(c)(2) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. 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

(3) Has work experience, under the supervision of an authorized user who meets the

requirements in §§ 35.390 or 35.396 or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in §§ 35.390 must have experience in administering dosages as specified in §§35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—

- (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of 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 unsealed 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 include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(4) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b),(c)(2), and (c)(3) or paragraphs (c)(1), (c)(2), and (c)(3) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).

Medical physicist for manual brachytherapy

13. Problem: 10 CFR 35.433 requires an authorized medical physicist to perform the only task described in this section , i.e., calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The Sr-90 eye applicators are used in locations that do not have access to authorized medical physicist and further description of the tasks required of a physicist during the eye applicator use would make it easier to permit other physicist to perform the tasks.

Recommend revising 10 CFR 35.433 to expand the description of the tasks and responsibilities of the medical physicist prior to, during and after use of the Sr-90 eye applicator.

14. Problem: 10 CFR 35.433 requires an authorized medical physicist to calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. Sr-90 eye applicators are used in locations that do not have access to

authorized medical physicist.

Recommend revising 10 CFR 35.433 to permit a medical physicist with training and experience in specific task related to the use of manual brachytherapy sources to perform the tasks in 35.433.

Reportable medical events

15. Problem: 10 CFR 35.3045, "Report and notification of a medical event," requires a licensee to 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 certain amounts, or (2) certain dose limits from a list of administration errors or a leaking sealed source, or (3) certain dose limits that differ from 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). The effect is that if a written directive was required but not prepared the administration may not be reported to NRC as a medical event.

Recommend revising 35.3045 (a)(2) to add a new condition for administrations of a dose requiring a written directive when a written directive does not exist. An oral directive meeting the requirements in 35.40(a)(1) would be considered an existing written directive.

Proposed Text:

(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) ...; or

(vi) An administration requiring a written directive when a written directive (or an oral directive meeting the requirements of 35.40(a)(1)) does not exist at the time of administration.

(Not reviewed with the ACMUI.)

16. Problem: Licensees find the criteria in 10 CFR 35.3045(a)(3) confusing because of the criteria includes the phrase "to an organ or tissue" twice.

Recommend revising 10 CFR 35.3045(3) by deleting the second "to an organ or tissue" to read:

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) 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).

17. Problem: Licensees find the criteria for determining if a dose to the wrong treatment site

constitutes a medical event confusing. The criteria is for the dose to the wrong treatment site to be 50 rem higher than the dose intended for that site if the treatment had been given correctly as well as 50 percent higher than the dose that would have been delivered to the site with the correct administration. Some have interpreted the criteria in 10 CFR 35.3045(a)(3) to be that the dose to the wrong treatment site needs to be 50 percent more than the dose specified in the written directive for the correct treatment site before it is a reportable medical event.

Correct 35.3045(a)(3) "A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) 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)."

To read: "A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) and exceeds 50 percent or more of the dose expected to that site from the administration if it had been given in accordance with the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)."

Administrative - ACMUI Review not needed

Patient Release

18. **Problem: Footnote 1 for 35.75(a) notes that draft 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). NUREG-1556, Vol. 9, is no longer in draft. Further, the current version Revision 1 is expect to be revised shortly.**

Recommend revising the foot note to reflect the current revision of NUREG-1556, Vol 9

(Open Session)
NO HANDOUT

(Open Session)
NO HANDOUT

**MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES**

February 13, 2006

MEETING SUMMARY

PURPOSE: To discuss a licensee's request that one of its physicians be granted authorized user (AU) status for the use of yttrium-90 microspheres. NRC staff sought the recommendations of the Advisory Committee on the Medical Uses of Isotopes on this issue.

OUTCOME: To determine if the licensee's request for exemption to the guidance should be granted.

Cindy Flannery, Acting Designated Federal Official, NRC, opened the meeting, then turned the discussion over to Dr. Leon S. Malmud, Chair, Advisory Committee on the Medical Uses of Isotopes (ACMUI). Dr. Malmud then requested that Donna-Beth Howe, PhD, NRC, provide some comments on the handling of Theraspheres.

Dr. Howe stated that Theraspheres (i.e., microspheres) are sealed sources treated as manual brachytherapy, therefore, they were originally regulated in 10 CFR 35.400, "Use of sources for manual brachytherapy." However, it was found that exemptions for the use of these microspheres was going to be needed so the staff began regulating the use of microspheres in 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material."

Another reason microspheres are categorized in 10 CFR 35.1000 uses is because of their unique characteristics. Because they are so small and abundant, they can not be manually counted. Thus, licensees are allowed to account for microspheres using their activity. The method of administration is also unique and there is a potential for shunting. Although both Theraspheres and Sirspheres are types of microspheres, they function differently from each other.

Following Dr. Howe's summarization of the use of microspheres, the ACMUI confirmed it received the package of materials that included the licensee's request for approval of one of their physicians as an authorized user for the use of microspheres.

The ACMUI made the following motion:

That the physician be granted recognition as an authorized user for the use of yttrium 90 microspheres and Theraspheres.

Discussion ensued. One ACMUI member's opinion was that the use of microspheres more closely resembles therapeutic nuclear medicine applications, including the dosimetry aspects,

OFFICIAL USE ONLY - SENSITIVE INTERNAL INFORMATION

Discussion ensued. One ACMUI member's opinion was that the use of microspheres more closely resembles therapeutic nuclear medicine applications, including the dosimetry aspects, rather than brachytherapy applications. Therefore, any well-trained nuclear medicine physician should also be allowed to administer microspheres.

A point made by another ACMUI member is that if the committee votes to approve this individual for recognition as an authorized user (AU) for microspheres administrations, given this person's current training and experience, the NRC staff would need to reconcile this decision with current guidance. This member stated that although this individual received an ample amount of additional training and appeared to be qualified for this exemption, the larger question to consider is whether this decision will lead to further discussion on moving microsphere therapy use out of 10 CFR 35.490 in the regulations, into a different category.

Dr. Howe stated that, in the past, the staff discussed the possibility of recognizing physicians approved for 35.300 use as qualified to use microspheres. However, if such recognition is to be granted, the physician approved for 35.300 use would also need to possess a lot of experience in many types of therapeutic applications in 10 CFR 35.300, rather than a physician who had achieved AU status under the 10 CFR 35.390 pathway. Dr. Howe stated that the individual's application did not supply enough information to confirm or deny that this individual has experience handling therapeutic quantities of nuclear materials.

As the ACMUI continued discussion, it was suggested that the committee focus on whether it was appropriate to grant exemption to this individual and that the issue of re-categorizing microsphere therapy should be saved for an open discussion at a future public meeting. The ACMUI voted on the above motion, and the motion carried. The individual's training and experience was noted for the record. The training and experience received was above and beyond that required for radionuclide therapy in that it included participation in a two-day clinical symposium followed by specific vendor training at each of the manufacturers and suppliers and supervised case experience for nine cases.

Although the ACMUI agreed that an exemption should be granted to this particular individual, concerns continued to be verbalized that were of a general nature. The Food and Drug Administration representative to the ACMUI, Dr. Orhan Suleiman, stated his professional opinion that microspheres have characteristics - from a radiation safety perspective - that more closely resemble the characteristics of unsealed radiopharmaceuticals. Dr. Suleiman suggested that the guidance for microspheres be viewed again, from a strictly radiation protection perspective, and discussed at a future public meeting.

The ACMUI made a second motion:

The ACMUI recommends that future cases involving 10 CFR 35.300 authorized users seeking authorization to administer yttrium microspheres be submitted to the ACMUI on a case-by-case basis, until the ACMUI has an opportunity to make recommendations generalizing the licensing guidance currently found on the NRC website. Moreover, the

OFFICIAL USE ONLY - SENSITIVE INTERNAL INFORMATION

OFFICIAL USE ONLY - SENSITIVE INTERNAL INFORMATION

ACMUI recommends that a discussion be added on the agenda for the next face-to-face ACMUI public meeting on the generic issue of whether the guidance as currently written needs revising to re-categorize Y-90 microspheres.

One ACMUI member expressed his concern that the staff would be sending every request for exemption to the ACMUI for review and recommendation. Ronald Zelac, Ph.D., NRC, stated that many of the physicians who seek this exemption are licensed under broad scope licensees. Thus, the licensee, through its Radiation Safety Committee, is empowered to review exemption requests such as these and render a decision. This particular case was brought to the ACMUI because this case happened to involve a specific license. Even so, the ACMUI agreed that the effect of any change to licensing guidance should be discussed further in a public meeting.

Before the above motion was made, it was necessary for Dr. Suleiman to exit the teleconference meeting. This resulted in the ACMUI losing the quorum necessary to carry the above motion. Nevertheless, the NRC staff stated that it understood the intent of the motion, and since the staff is already in the practice of forwarding to the ACMUI requests for exemptions to the regulations or guidance, the staff, in effect, already practices the activities described in the above motion. A discussion of the substance of this motion will be added to the agenda for the next public ACMUI meeting.

OFFICIAL USE ONLY - SENSITIVE INTERNAL INFORMATION

ACMUI recommends that a discussion be added on the agenda for the next face-to-face ACMUI public meeting on the generic issue of whether the guidance as currently written needs revising to re-categorize Y-90 microspheres.

One ACMUI member expressed his concern that the staff would be sending every request for exemption to the ACMUI for review and recommendation. Ronald Zelac, Ph.D., NRC, stated that many of the physicians who seek this exemption are licensed under broad scope licensees. Thus, the licensee, through its Radiation Safety Committee, is empowered to review exemption requests such as these and render a decision. This particular case was brought to the ACMUI because this case happened to involve a specific license. Even so, the ACMUI agreed that the effect of any change to licensing guidance should be discussed further in a public meeting.

Before the above motion was made, it was necessary for Dr. Suleiman to exit the teleconference meeting. This resulted in the ACMUI losing the quorum necessary to carry the above motion. Nevertheless, the NRC staff stated that it understood the intent of the motion, and since the staff is already in the practice of forwarding to the ACMUI requests for exemptions to the regulations or guidance, the staff, in effect, already practices the activities described in the above motion. A discussion of the substance of this motion will be added to the agenda for the next public ACMUI meeting.

Distribution:
IMNS r/f

ML060620616

OFFICE	MSIB	MSIB	MSIB	IMNS
NAME	AMcIntosh	SWastler	TEssig	CMiller
DATE	3/3/06	3/8/06	3/ /06	3/ /06

OFFICIAL RECORD COPY

January 31, 2006

MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Thomas H. Essig, Chief */RA/*
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE
OCTOBER 25-26, 2005 MEETING OF THE ADVISORY COMMITTEE
ON THE MEDICAL USES OF ISOTOPES

Below are recommendations from the October 25-26, 2005, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's response and/or position.

ACMUI RESPONSES TO THE ACMUI SELF-EVALUATION

ACMUI recommendation: That, as a means to remind the ACMUI to submit responses to the self-evaluation, the NRC staff should e-mail the entire ACMUI the names of those members who have not responded to the self-evaluation, no later than one week prior to the deadline for response. The self-evaluation should be attached to the e-mail.

NRC staff response: The NRC staff agrees with this recommendation. The NRC staff, in providing administrative support for the ACMUI self-evaluation process, currently sends routine e-mail reminders to ACMUI members in order to obtain their completed self-assessments in a timely manner. In addition to these measures, in accordance with this recommendation, the NRC staff will e-mail the entire ACMUI no later than one week prior to the deadline for response, with the names of members have not responded. The staff will attach the self-evaluation to the e-mail.

CONTACT: Angela McIntosh, NMSS/IMNS
(301) 415-5030

ACMUI SELF-EVALUATION QUESTION

ACMUI recommendation: That the NRC staff add a question to the ACMUI self-evaluation that allows the ACMUI to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists.

NRC staff response: The NRC staff supports this recommendation. The NRC staff is currently revising the ACMUI self-evaluation questions, and will include a question that provides the ACMUI the opportunity to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists. The staff will forward the set of revised questions to ACMUI for review and comment. After receiving ACMUI comment, the staff will then forward the set of revised questions to the Commission for final approval.

BOARD CERTIFICATION RECOGNITION

ACMUI recommendation: That NRC staff provide a more detailed explanation of the reason for any case in which a board certified individual is not recognized by the NRC, because the board's certifying process does not meet NRC's requirements.

NRC staff response: The NRC staff agrees with this recommendation. However, to date, there have been no reported denials of certified individuals. The NRC recognition of boards' certification processes is ongoing.

ACMUI SUPPORT OF MILTON HERSHEY MEDICAL CENTER

ACMUI motion: The ACMUI goes on the record to register its support and commendation to Hershey Medical Center for its handling of this case [that involved the alleged misuse of byproduct material]. The motion was unanimously approved by the ACMUI.

NRC staff response: The NRC staff takes no position on this motion. The motion was made as a matter of the ACMUI's position on an action carried out by the Hershey Medical Center.

PUBLICLY AVAILABLE INFORMATION REGARDING MEDICAL EVENTS

ACMUI recommendation: That the NRC staff does not make available to the general public, information regarding a medical event until such time that the event is confirmed.

NRC staff response: The NRC staff agrees with this recommendation. The recommendation has been incorporated into a paper, for Commission consideration and approval, entitled "Adequacy of Medical Event Definitions in 10 CFR 35.3045 and Communicating Associated Risks to the Public."

ACMUI SELF-EVALUATION QUESTION

ACMUI recommendation: That the NRC staff add a question to the ACMUI self-evaluation that allows the ACMUI to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists.

NRC staff response: The NRC staff agrees with this recommendation. The staff is currently drafting revised ACMUI self-evaluation questions for Commission approval. The staff will include, in the revised questions, a question whereby the ACMUI can evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists. The staff will forward the set of revised questions to the ACMUI for comment. After receiving ACMUI comment, the staff will then forward the set of revised questions to the Commission for final approval.

BOARD CERTIFICATION RECOGNITION

ACMUI recommendation: That NRC staff provide a more detailed explanation of the reason for any case in which a board certified individual is not recognized by the NRC, because the board's certifying process does not meet NRC's requirements.

NRC staff response: The NRC staff agrees with this recommendation. However, to date, there have been no reported denials of certified individuals. The NRC recognition of boards' certification processes is ongoing.

ACMUI SUPPORT OF MILTON HERSHEY MEDICAL CENTER

ACMUI motion: The ACMUI goes on the record to register its support and commendation to Hershey Medical Center for its handling of this case [that involved the alleged misuse of byproduct material]. The motion was unanimously approved by the ACMUI.

NRC staff response: The NRC staff takes no position on this motion. The motion was made as a matter of the ACMUI's position on an action carried out by the Hershey Medical Center.

PUBLICLY AVAILABLE INFORMATION REGARDING MEDICAL EVENTS

ACMUI recommendation: That the NRC staff does not make available to the general public, information regarding a medical event until such time that the event is confirmed.

NRC staff response: The NRC staff agrees with this recommendation. The recommendation has been incorporated into a paper, for Commission consideration and approval, entitled "Adequacy of Medical Event Definitions in 10 CFR 35.3045 and Communicating Associated Risks to the Public."

ACMUI RECOMMENDATION AND ACTION ITEM TABLE - FY06

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)				Staff member Assigned	Name and Description of Recommendation or Action Item	Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A						
Oct 2005	2006-01R	X				A. McIntosh	<p>ACMUI RESPONSES TO THE ACMUI SELF-EVALUATION</p> <p>That, as a means to remind the ACMUI to submit responses to the self-evaluation, the NRC staff should e-mail the entire ACMUI the names of those members who have not responded to the self-evaluation, no later than one week prior to the deadline for response. The self-evaluation should be attached to the e-mail.</p>	Y	The NRC staff agrees with this recommendation. The NRC staff, in providing administrative support for the ACMUI self-evaluation process, currently sends routine e-mail reminders to ACMUI members in order to obtain their completed self-assessments in a timely manner. In addition to these measures, in accordance with this recommendation, the NRC staff will e-mail the entire ACMUI no later than one week prior to the deadline for response, with the names of members have not responded. The staff will attach the self-evaluation to the e-mail.	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)				Staff member Assigned	Name and Description of Recommendation or Action Item	Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A						
Oct 2005	2006-02R	X				A. McInosh	<p>ACMUI SELF-EVALUATION QUESTION</p> <p>That the NRC staff add a question to the ACMUI self-evaluation that allows the ACMUI to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists.</p>	Y	The NRC staff supports this recommendation. The NRC staff is currently revising the ACMUI self-evaluation questions, and will include a question that provides the ACMUI the opportunity to evaluate the degree that it believes the Commission recognizes the experience and daily responsibilities of medical specialists. The staff will forward the set of revised questions to ACMUI for review and comment. After receiving ACMUI comment, the staff will then forward the set of revised questions to the Commission for final approval.	CLOSED
Oct 2005	2006-03R	X				C. Flannery	<p>BOARD CERTIFICATION RECOGNITION</p> <p>That NRC staff provide a more detailed explanation of the reason for any case in which a board certified individual is not recognized by the NRC, because the board's certifying process does not meet NRC's requirements.</p>	Y	The NRC staff agrees with this recommendation. However, to date, there have been no reported denials of certified individuals. The NRC recognition of boards' certification processes is ongoing.	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)				Staff member Assigned	Name and Description of Recommendation or Action Item	Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A						
Oct 2005	2006-04R	X				N/A	<p>ACMUI SUPPORT OF MILTON HERSHEY MEDICAL CENTER</p> <p>The ACMUI goes on the record to register its support and commendation to Milton S. Hershey for its handling of this case (that involved the alleged misuse of byproduct material by an authorized user physician).</p>	N/A	The NRC staff takes no position on this motion. The motion was made as a matter of the ACMUI's position on an action carried out by the Hershey Medical Center.	CLOSED
Oct 2005	2006-05R	X				R. Zelac	<p>PUBLICLY AVAILABLE INFORMATION REGARDING MEDICAL EVENTS</p> <p>That the NRC staff does not make available to the general public information regarding a medical event until such time that the event is confirmed.</p>	Y, with addition	<p>The NRC staff agrees with this recommendation. The recommendation has been incorporated into a paper, for Commission consideration and approval, entitled "Adequacy of Medical Event Definitions in 10 CFR 35.3045 and Communicating Associated Risks to the Public."</p> <p>Staff incorporated this recommendation in the Commission paper, with the caveat that medical events be made publicly available after five days if not yet confirmed.</p>	<p>SECY is due to Commission on 12/21/05</p> <p>CLOSED.</p>

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)					Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Staff member Assigned	Name and Description of Recommendation or Action Item			
Oct 2005	2006- 01A		X		A. McINTOSH	<p>BAPTIST MEMORIAL HOSPITAL EVENT: AO DETERMINATION</p> <p>Staff requested that Jeffrey F. Williamson, PhD, therapy physicist, would review the Baptist Memorial Hospital medical event (captured in the Nuclear Materials Events Database as event # 040828) and make a determination as to whether this event meets the abnormal occurrence criteria.</p>	N/A	<p>Oct 2005 update: Dr. Williamson provided a report dated October 22, 2005, entitled "Baptist Memorial Hospital Event." Dr. Williamson found that the event was as an AO, but requested additional information to verify his finding.</p> <p>Nov 2005 update: the staff has contacted the licensee through NRC's Office of State and Tribal Programs, and requested the additional information.</p> <p>April 2006 update: Dr. Williamson found that the additional data supports the findings of his October 22, 2005 report. Dr. Williamson submitted to staff an addendum, dated February 13, 2006, confirming the findings of his October 2005 report.</p>	CLOSED

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)				Staff member Assigned	Name and Description of Recommendation or Action Item	Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A						
Oct 2005	2006-02A			X	R. Zelao	<p>REPORT ON INDIVIDUALS DENIED RECOGNITION</p> <p>That the NRC staff provide a report to the ACMUI on the actual number of board certified individuals who have been denied recognition as AUs. The report should include a rationale for excluding these individuals.</p>	N/A	No denials of certified individuals as AUs reported to date. Should any occur, staff will provide an explanation for the reason for denial. The NRC recognition of board certification processes is ongoing	Recognition of board certification processes still in progress. CLOSED	
Oct 2005	2006-03A			X	A. McIntosh	<p>DISTRIBUTION OF SECTION 651 OF THE ENERGY POLICY ACT</p> <p>NRC staff will distribute Section 651 of the Energy Policy Act to the ACMUI</p>	N/A	Staff distributed Section 651 of the Energy Policy Act to the ACMUI at the October 2005 ACMUI public meeting.	CLOSED	
Oct 2005	2006-04A		X		N/A	<p>ACMUI REPRESENTATIVE TO THE ROUNDTABLE DISCUSSION OF THE ENERGY POLICY ACT</p> <p>The ACMUI will supply a representative to participate in the November 9, 2005, stakeholder discussion of the Energy Policy Act, to be held at NRC headquarters.</p>	N/A	The ACMUI Chairman named Ralph Ereto, Medical Physicist, and Sally W. Schwarz, Nuclear Pharmacist, as the ACMUI representatives to the November 9, 2005 stakeholder discussion of the Energy Policy Act.	CLOSED	

**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 Materials Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, IMNS

3. **Time period (duration of this Committee):**

From March 18, 2006, to March 18, 2008

4. **Official to whom this Committee reports:**

Charles L. Miller, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

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

U.S. Nuclear Regulatory Commission

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

7. **Estimated annual direct cost of this Committee:**

1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 FTE for ACMUI members compensation and travel).

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

Five meetings per year, three of which are teleconferences.

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

March 18, 2008

Enclosure

10

Filing date:

March 18, 2006

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

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
BYLAWS

CONTENTS

1.	Scheduling and Conduct of Meetings.....	1
2.	Minutes.....	2
3.	Appointment of Members.....	3
4.	Conduct of Members.....	4
5.	Amendments.....	5

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, and that the resulting reports represent, to the extent 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 regulations as appropriate.

1.1 Scheduling of Meetings:

- 1.1.1 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

Bylaws - Advisory Committee on the Medical Uses of Isotopes

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.

Bylaws - Advisory Committee on the Medical Uses of Isotopes

- 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 three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).
- 3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

- 4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.
- 4.2 Upon completing their tenure on the committee, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.
- 4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations.

Bylaws - Advisory Committee on the Medical Uses of Isotopes

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.

Management System (ADAMS). The request for exemption dated January 31, 2006, and March 6, 2006, was docketed under 10 CFR part 72, Docket No. 72-28. These documents may be inspected at NRC's Public Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209 or (301) 415-4737, or by e-mail to pdr@nrc.gov.

Dated at Rockville, Maryland, this 31st day of March, 2006.

For the Nuclear Regulatory Commission.
Joseph M. Sebrosky,
Senior Project Manager, Spent Fuel Project
Office, Office of Nuclear Material Safety and
Safeguards.

[FR Doc. 06-3416 Filed 4-10-06; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 52-009]

System Energy Resources, Inc. Notice of Availability of the Final Environmental Impact Statement for an Early Site Permit (ESP) at the Grand Gulf ESP Site

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC or the Commission) has published NUREG-1817, "Environmental Impact Statement for an Early Site Permit (ESP) at the Grand Gulf ESP Site—Final Report." The site is located near the Town of Port Gibson in Claiborne County, Mississippi. The application for the ESP was submitted by letter dated October 16, 2003, pursuant to Title 10 of the Code of Federal Regulations Part 52 (10 CFR Part 52). A notice of receipt and availability of the application, which included the environmental report (ER), was published in the Federal Register on November 14, 2003 (68 FR 64665). A notice of acceptance for docketing of the application for the ESP was published in the Federal Register on December 1, 2003 (68 FR 67219). A notice of intent to prepare an environmental impact statement (EIS) and to conduct the scoping process was published in the Federal Register on December 31, 2003 (68 FR 75656). A

notice of availability of the draft EIS was published in the Federal Register on April 28, 2005 (70 FR 22155).

The purpose of this notice is to inform the public that NUREG-1817, "Environmental Impact Statement for an Early Site Permit (ESP) at the Grand Gulf ESP Site—Final Report," is available for public inspection in the NRC Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, 20852, or from the Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS), and will also be placed directly on the NRC Web site at <http://www.nrc.gov>. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov. In addition, the Harriette Person Memorial Library, located at 606 Main Street, Port Gibson, Mississippi, has agreed to make the final EIS available for public inspection.

FOR FURTHER INFORMATION CONTACT:
James H. Wilson, Environmental Branch
A, Division of License Renewal, U.S.
Nuclear Regulatory Commission,
Washington, DC, 20555-0001. Mr.
Wilson may be contacted by telephone
at 301-415-1108 or by e-mail at
jhw1@nrc.gov.

Dated at Rockville, Maryland, this 3rd day of April 2006.

For the Nuclear Regulatory Commission
Frank P. Gillespie,
Director, Division of License Renewal, Office
of Nuclear Reactor Regulation.
[FR Doc. E6-5256 Filed 4-10-06; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: Nuclear Regulatory
Commission.

ACTION: Updated 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 25 and 26, 2006. A sample of agenda items to be discussed during the public sessions includes: (1) Updates on Proposed Regulations to Include Discrete Radium Sources and

Accelerator-Produced Radioactive Materials in 10 CFR Part 35; (2) RIS on Visitor Dose Limits; (3) Part 35, Training and Experience; (4) Supply of High Enriched Uranium for Molybdenum-99 Generation; (5) Training and Experience for Use of Microspheres for Therapy; (6) ACMUI Review of Medical Events Involving I-131. To review the agenda see: <http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda/> or contact, via e-mail: mss@nrc.gov.

Purpose: Discuss issues related to 10 CFR 35, Medical Use of Byproduct Material.

Date and Time for Closed Session Meeting: April 25, 2006, from 8 a.m. to 10:15 a.m. This session will be closed so that NRC staff can brief the ACMUI on information relating solely to internal personnel rules and can discuss protected information of an investigatory nature. Time may be added to the closed session or an additional closed session may be added as needed.

Dates and Times for Public Meetings:
April 25, 2006, from 10:30 a.m. to 5 p.m.; and April 26, 2006, from 8 a.m. to 11:30 a.m.

ADDRESSES: Address for Public Meetings: The meeting will be held at National Institute of Health (NIH). The address and room number is below: National Institute of Health, Natcher Conference Center, 45 Center Drive, Bethesda, MD 20892.

April 25—Balcony B.
April 26—Room E1/E2.

Security on the NIH Campus

All non-NIH employees are required to provide picture IDs upon entering the campus whether walking on to campus or driving on to campus, and all belongings are subject to searches. Increased security procedures are in place at all entrances to the NIH campus, including drive-in and walk-in access gates. Please allow adequate time when making your plans to attend the conference functions at the Natcher Conference Center. Preregistration will expedite the security process. Visitor parking is extremely limited and driving to the NIH campus for this event is not recommended.

MetroRail Service and Map

The NIH Campus is very accessible by the Washington D.C. area MetroRail (Metro) system. The Natcher Conference Center (Building 45) is located a short walk from the Medical Center Metro stop located on the Red Line. Note the signs and directions to the gated campus security entrance located behind the metro stop. For more details about the Washington DC area MetroRail services

and stops, please visit <http://www.wmata.com/> or go directly to <http://www.wmata.com/metrorail/systemmap.cfm> for an overview map of the metro stops. For more information on shuttle bus services to the NIH campus, please visit http://dtt.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp.

Driving to the NIH Campus

If you will be driving to the NIH campus, please note that all non-NIH registered vehicles must enter at the Rockville Pike-South Drive or Georgetown Road-Center Drive entrance for inspection. Follow the direction signs to Building 45. Please allow extra time for compliance with these security measures. Visitors must park in designated visitor parking lots. Visitor Parking is extremely difficult to find at NIH. Visitor parking at the Natcher Conference Center is available at \$12 per day; however, parking is limited and visitors to the NIH campus are encouraged to take public transportation. For a detailed map of the NIH campus please visit http://dtt.ors.od.nih.gov/visitor_access_map.htm.

FOR FURTHER INFORMATION CONTACT: Mohammad S. Saba, telephone (301) 415-7608; e-mail mss@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Conduct of the Meeting

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

1. Persons who wish to provide a written statement should submit a reproducible copy to Mohammad S. Saba, U.S. Nuclear Regulatory Commission, Mail Stop T8F03, Washington DC 20555. Alternatively, an e-mail can be submitted to mss@nrc.gov. Submittals must be postmarked or e-mailed by April 23, 2006, and must pertain to the topics on the agenda for the meeting.

2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection on NRC's Web site (<http://www.nrc.gov>) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about July 20, 2006.

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

Dated at Rockville, Maryland, this 4th day of April, 2006.

For the Nuclear Regulatory Commission.
Andrew L. Bates,
Advisory Committee Management Officer.
[FR Doc. E6-5254 Filed 4-10-06; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATE: Weeks of 10, 17, 24, May 1, 8, 15, 2006.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of April 10, 2006—Tentative

There are no meetings scheduled for the Week of April 10, 2006.

Week of April 17, 2006—Tentative

There are no meetings scheduled for the Week of April 17, 2006.

Week of April 24, 2006—Tentative

Monday, April 24, 2006

2 p.m. Meeting with Federal Energy Regulatory Commission (FERC) FERC Headquarters, 888 First St., NE., Washington, DC 20426 Room 2C (Public Meeting). (Contact: Mike Mayfield, (301) 415-3298.)

This meeting will be webcast live at the Web address, <http://www.ferc.gov>.

Wednesday, April 26, 2006

1 p.m. Discussion of Management Issues (Closed—ex. 2).

Thursday, April 27, 2006

1:30 p.m. Meeting with Department of Energy (DOE) on New Reactor Issues (Public Meeting).

This meeting will be webcast live at the Web address, <http://www.nrc.gov>.

Week of May 1, 2006—Tentative

Tuesday, May 2, 2006

9:30 a.m. Briefing on Status of Emergency Planning Activities—Morning Session (Public Meeting) (Contact: Eric Leeds, (301) 415-2334.)

1 p.m. Briefing on Status of Emergency Planning Activities—Afternoon Session (Public Meeting).

These meetings will be webcast live at the Web address, <http://www.nrc.gov>.

Wednesday, May 3, 2006

9 a.m. Briefing on Status of Risk-Informed, Performance-Based Regulation (Public Meeting). (Contact: Eileen McKenna, (301) 415-2189.)

This meeting will be webcast live at the Web address, <http://www.nrc.gov>.

Week of May 8, 2006—Tentative

There are no meetings scheduled for the Week of May 8, 2006.

Week of May 15, 2006—Tentative

Monday, May 15, 2006

1 p.m. Briefing on Status of Implementation of Energy Policy Act of 2005 (Public Meeting).

This meeting will be webcast live at the Web address, <http://www.nrc.gov>.

Tuesday, May 16, 2006

9:30 a.m. Briefing on Results of the Agency Action Review Meeting—Reactors/Materials (Public Meeting).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

* * * * *

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415-1292. Contact person for more information: Michelle Schroll, (301) 415-1662.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/what-we-do/policy-making/schedule.html>.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Deborah Chan, TDD: (301) 415, or by e-mail at DLC@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301-415-1969).

ACMUI MEMBERS

NAME	SPECIALTY
Edgar D. Bailey	State Government Representative Email: ebaileychp@msn.com Phone: 916-601-9543
David A. Diamond, M.D. Florida Oncology Network Walt Disney Memorial Cancer Institute Florida Hospital - Orlando 2501 N. Orange Ave., Suite 181 Orlando, FL 32804	Radiation Oncology Physician Email: dagdmail@yahoo.com Phone: 407-303-2030/407-646-7777 FAX: 407-303-2042 Cell: 407-694-8327
Douglas F. Eggli, M.D. Dept. of Radiology, H066 Penn State University Hospital The Milton S. Hershey Medical Center Room # HG300Z P.O. Box 850 500 University Drive Hershey, PA 17033	Nuclear Medicine Physician Email: deggli@psu.edu Phone: 717-531-8940 FAX: 717-531-5596 Debra Pavone: Phone: 717-531-5341 E-mail: dpavone@psu.edu
Vikki Kinsey/Orhan Suleiman, PhD U.S. Food and Drug Administration White Oak Building 22 Room 2206 1093 Newhamshire Avenue Silver Spring, MD 20993	The choice of FDA appointees is made by FDA. Ms. Kinsey chooses the FDA representative for each meeting. Email: kinseyv@cder.fda.gov suleimano@cder.fda.gov Phone: 301-443-5368/301-796-1471 Fax: 301-594-5493 (Kinsey) Fax: 301-796-9909 (Suleiman)
Ralph P. Lieto Radiation Safety Office St. Joseph Mercy Hospital 5301 E. Huron River Dr. Ann Arbor, MI 48106-0995	Medical Physicist, Nuclear Medicine Email: lietor@trinity-health.org Phone: 734-712-8746 FAX: 734-712-5344
Leon S. Malmud, M.D., Chairman Dean Emeritus, Temple University School of Medicine Temple University Health System 3401 N. Broad St Philadelphia, PA 19140	Health Care Administrator Physician Email: martinp@tuhs.temple.edu or Malmudis@tuhs.temple.edu Phone : 215-707-7078 (Pat Martin) Phone: 215-885-0756 FAX: 215-707-3261
Subir Nag, M.D. Division of Radiation Oncology Department of Radiology Arthur G. James Cancer Hospital	Radiation Oncology Physician Email: nag.1@osu.edu Phone: 614-293-3246 614-293-3276

NAME	SPECIALTY
and Research Institute Ohio State University 300 W. Tenth Avenue Columbus, OH 43210	FAX: 614-293-4044
Robert Schenter, PhD Pacific Northwest National Lab MS P7-25, PO Box 999 Richland, WA 99352	Patient Advocate Email reschenter@comcast.net Phone: 509-376-3935/ 503-244-3042
Sally Wagner Schwarz, RPh Division of Nuclear Medicine Mallinckrodt Institute of Radiology Washington University School of Medicine 510 south Kingshighway Blvd. St. Louis, MO 63310	Nuclear Pharmacist Email: schwarz@mir.wustl.edu Phone: 314-362-8426 FAX: 314-362-9940
William A. Van Decker, MD Temple University 3401 N. Broad St, 9PP Philadelphia, PA 19140	Nuclear Cardiology Physician (designated prospective appointee) Email: vandecwa@tuhs.temple.edu Phone: 215-707-3347 215-707-9587 (Nancy)
Richard J. Vetter, Ph.D. Mayo Clinic Medical Sciences B-28 or 200 1 st St. SW Rochester, MN 55905	Radiation Safety Officer Email: vetter.richard@mayo.edu Phone: 507-284-4408 FAX: 507-284-0150
Jeffrey F. Williamson, Ph.D. Professor and Director, Medical Physics Department of Radiation Oncology Medical College of Virginia Hospitals Virginia Commonwealth University 401 College Street Richmond, VA 23298-0058	Therapy Physicist Phone: 804-628-1047 Fax: 804 827-1670 E-mail jfwilliamson@vcu.edu Sahira Muhammed_SMuhammad@mcvh-vcu.edu

**MEDICAL ISOTOPE
PRODUCTION IN THE USA/
AN NRC CONCERN?**

POWER POINT PRESENTATION

Robert E. Schenter

**Advisory Committee on the Medical Use
of Isotopes (ACMUI) Meeting**

April 25, 2006

Bethesda Maryland

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

ACMUI Meeting

April 26, 2006

U.S. Nuclear Regulatory Commission

Please PRINT legibly, as this is a public document.

PRINTED NAME	ORGANIZATION
1 Lynne Fairbent	AAPM
2 GERALD WHITE	AAPM
3 Lisa Shuger Hublitz	ASTRO
4 Jim Hagerman	MDS Nordion
5 Lisa Dimmick	Nucletron
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	

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

ACMUI Meeting
April 26, 2006

U.S. Nuclear Regulatory Commission

Please PRINT legibly, as this is a public document.

PRINTED NAME	ORGANIZATION
1 Todd Wiesenberg	Biodiversity
2 Gloria Romanello	AER
3 ANN WARBIER	MDS NORDION
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	

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

ACMUI Meeting
April 25, 2006

U.S. Nuclear Regulatory Commission

Please PRINT legibly, as this is a public document.

PRINTED NAME	ORGANIZATION
1 Lynne Fairbent	AAPM
2 HUGH CANNON	SNM
3 Roy W. Brown	CORAR
4 GERALD WHITE	AAPM
5 Michael Peters	SNM
6 Gloria Romanello	ACR
7 JAMES WELSH	ASTRO
8 Lisa Shuger Hublitz	ASTR
9 ANN WARBICK	MD'S NORDION
10 LYDIA CHANG	NRC -
11 RICHARD BLANTON	NRC
12 Tricia McLenny	SIR
13 Lisa Dimmell	Nucletron
14 RICHARD FEJKA	FDA
15 MARK MCCARTY	MEDICAL DEVICE DRUGS
16 RIMD SAHAR	Site SIR
17 Vanessa Gates	SIR
18 Neil Haggerty	NRC
19	
20	