U.S. Nuclear Regulatory Commission’s

ACMUI Advisory Committee on the Medical Uses of Isotopes

ADAMS Copy

October 25-26, 2005
NRC Headquarters
Rockville, Maryland
MEMBERS OF THE PUBLIC SIGN IN SHEET  
(DO NOT REMOVE THIS FORM)  
ACMUI Meeting  
October 25, 2005  
U.S. Nuclear Regulatory Commission  
Please PRINT legibly, as this is a public document.

<table>
<thead>
<tr>
<th>PRINTED NAME</th>
<th>ORGANIZATION</th>
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<tbody>
<tr>
<td>1 Jean St. Germain</td>
<td>AM. OF MED. PHYSICS</td>
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<tr>
<td>2 Manuel A. Brown</td>
<td>American College of Radiology</td>
</tr>
<tr>
<td>3 Jason Dunavant</td>
<td>Georgetown University Hospital</td>
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<td>4 Lynne F. Pollard</td>
<td>AAPM</td>
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<td>5 K. Drummond-Dye</td>
<td>ASTRO</td>
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<td>6 Wayne Powell</td>
<td>Soc. for Cardiovascular Angiol. Intern.</td>
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<tr>
<td>7 Gloria R. Ramei</td>
<td>American College of Radiology</td>
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<td>8 Greg Hatcher</td>
<td>NRC</td>
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<tr>
<td>9 Michael Peters</td>
<td>SNM</td>
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<td>10 Terence Beven, MD</td>
<td>SNM</td>
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<td>11 Douglas E. Segr</td>
<td>Penn State Hershey Medical</td>
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<td>12 Robert Forrest</td>
<td>University of Penn</td>
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<td>13 Roy Brown</td>
<td>GORAL</td>
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<td>14 Keith Cannon</td>
<td>SNM</td>
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<td>15 Donna Bethune</td>
<td>USNRC</td>
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MEMBERS OF THE PUBLIC SIGN IN SHEET  
(Do Not Remove This Form)  

ACMUI Meeting  
October 26, 2005  
U.S. Nuclear Regulatory Commission  
Please PRINT legibly, as this is a public document.

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<tr>
<td>Ray W. Brown</td>
<td>CORAR</td>
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<tr>
<td>Hugh Cannon</td>
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<td>Michael Peters</td>
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<td>Rosshunda Drummond-Dye</td>
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<td>Joe DeCicco</td>
<td>NMSS/IMNS</td>
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<td>Randy Erickson</td>
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<td>Susan Childress</td>
<td>OGC</td>
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<td>Lynne Treadwell</td>
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<td>James Kostka</td>
<td>Eastern Idaho</td>
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<td>Michael A. Nestke</td>
<td>FDA/CORH</td>
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<td>Rob Forrest</td>
<td>Univ. of Penn</td>
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<td>Grant Markeske</td>
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<td>Lloyd Bolting</td>
<td>STP</td>
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<td>Tim Harris</td>
<td>NMSS</td>
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<tr>
<td>Courtney Johnson</td>
<td>NRC</td>
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<tr>
<td>Lisa Dimmack</td>
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</tbody>
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21 Lisa Dimmack
SPEAKERS and PARTICIPATING NRC STAFF
ACMUI MEETING
OCTOBER 25-26, 2005

Terrence Beven, MD, Society of Nuclear Medicine
Richard Blanton, NMSS/IMNS
Roy Brown, Council on Radionuclides and Radiopharmaceuticals
Douglas F. Eggli, MD, ACMUI
Thomas H. Essig, NMSS/IMNS/MSIB, Designated Federal Official
Cindy M. Flannery, NMSS/IMNS/MSIB
Sandra L. Gabriel, DNMS, Region I
Robert L. Gallagher, State of Massachusetts
Patricia K. Holahan, PhD, NMSS/IMNS
Donna-Beth Howe, PhD, NMSS/IMNS/MSIB
Leon S. Malmud, MD, ACMUI Chairman
Angela R. McIntosh, NMSS/IMNS/MSIB
Charles L. Miller, PhD, NMSS/IMNS
Mohammad Saba, NMSS/IMNS/MSIB
Sami S. Sherbini, PhD, NMSS/IMNS/MSIB
John Szabo, OGC
Ronald E. Zelac, PhD, NMSS/IMNS/MSIB
AGENDA
ACMUI MEETING
OCTOBER 25-26, 2005

TUESDAY, OCTOBER 25, 2005, CONFERENCE ROOM, T-2B3, TWO WHITE FLINT NORTH, ROCKVILLE, 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 open the closed session with a status update of ACMUI/NRC staff interactions, and will also provide an outline of the topics to be discussed during the closed session.

3) 8:15 - 8:45  Ethics Briefing (Closed Session) (Presenter: John Szabo, NRC)
   Mr. Szabo, Office of the General Counsel, will provide the ACMUI its required annual ethics briefing.

4) 8:45 - 9:45  Administrative Issues (Closed Session) (Presenter: Thomas Essig, NRC)
   Mr. Essig will brief the ACMUI on issues related to committee management, logistics, and the roles and responsibilities of the ACMUI and the NRC staff.

5) 9:45 - 10:00  ***BREAK***

6) 10:00 - 11:00  Evaluation for Exemption to Authorized Medical Physicist for Sr-90 Eye Application (Closed Session) (Presenter: Donna-Beth Howe, PhD, NRC)
   Dr. Howe will present an individual's credentials for possible exemption to the regulations for recognition as an authorized medical physicist for Sr-90 eye application.

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.

6) 11:00 - 11:05  Opening Remarks (Open Session) (Presenter: Thomas Essig, NRC)
   Mr. Essig will formally open the meeting.
7) 11:05 - 11:10 Opening Remarks (Open Session) (Presenter: Charles Miller, PhD, NRC) 
Dr. Miller will provide opening remarks.

8) 11:10 - 12:15 Status of Board Applications (Open Session) (Presenter: Cindy Flannery; Ronald Zelac, PhD; Donna-Beth Howe, PhD, NRC) 
NRC staff will present the status of applications submitted for recognition under the various category of users in 10 CFR Part 35.

12:15 - 1:15 ***LUNCH***

9) 1:15 - 2:00 Unauthorized Injections of Radiopharmaceuticals (Open Session) 
(Presenter: Douglas F. Eggli, MD, ACMUI) 
Dr. Eggli will present a case history of unauthorized self injections of radiopharmaceuticals by nuclear medicine technologists for purposes of acquiring unauthorized imaging studies on themselves.

10) 2:00 - 3:00 Revision of NRC Form 313A (Open Session) (Presenter: Sandra Gabriel, NRC) 
Ms. Gabriel will present revisions to NRC Form 313A, Training and Experience and Preceptor Attestation.

3:00 - 3:15 ***BREAK***

11) 3:15 - 4:00 Status of Guidance on Reducing Doses to Members of the Public 
(Open Session) (Presenter: Sami Sherbini, PhD, NRC) 
Dr. Sherbini will discuss the reason for not implementing some of the suggestions provided by commenters.

12) 4:00 - 4:15 RIS on Visitor Dose Limits (Open Session) (Presenter: Sami Sherbini, PhD, NRC) 
Dr. Sherbini will present his approach plan for developing a RIS on rapidly granting exemptions from regulatory dose limits for certain caregivers.

13) 4:15 - 5:00 Electronic Signatures in Written Directives (Open Session) (Presenter: Donna-Beth Howe, PhD, NRC) 
Dr. Howe will seek ACMUI insight on the acceptability of electronic signatures in written directives.

5:00 ADJOURN
14) 8:00 – 10:00 Discussion of Congressional Energy Bill: NRC Regulation of Accelerator Produced Isotopes and Nuclear Medicine Perspective: NRC Regulation of Accelerator Produced Isotopes (Open Session) (Presenters: Richard Blanton, NRC; Roy Brown, Senior Director of Federal Affairs, Council on Radionuclides and Radiopharmaceuticals (CORAR)) and Terrence Beven, MD, Chairman, ACNP-SNM Joint Government Relations Committee

Mr. Blanton will discuss the section 170H of the energy bill, "Radiation Source Protection", negotiated into the Conference Report by Representative Edward J. Markey. This bill essentially contains language granting the Nuclear Regulatory Commission jurisdiction over accelerator-produced radioactive material. Staff will share its perspective on how this might affect the practice of nuclear medicine.

Mr. Brown will be presenting the CORAR's position on how the Energy Act of 2005 affects the manufacturers of radiopharmaceuticals.

Dr. Beven, speaking on behalf of the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), will present on the nuclear medicine community's desire to work cooperatively with the NRC to ensure the public's safety from unnecessary exposure to radiation while simultaneously protecting medical and scientific accessibility to short-lived accelerator-produced isotopes.

10:00 – 10:15 ***BREAK***

15) 10:15 – 11:15 Recognition of Foreign Trained Physicians and Physicists as AUs or AMPs (Open Session) (Presenter: Cindy Flannery, NRC)

Ms. Flannery will seek ACMUI recommendations on standardizing the process to grant foreign-trained physicians and physicists recognition as Authorized Users (AU) or Authorized Medical Physicists (AMP)

16) 11:15 – 12:15 Status of Medical Events (Standing Item) (Open Session) (Presenter: Donna-Beth Howe, PhD, NRC)

Dr. Howe will seek the ACMUI's advice, recommendations, and insights regarding the cause of medical events, and possible methods to reduce them.

12:15 – 1:15 LUNCH
17) 1:15 – 3:00 Review of the Medical Events Definition Commission Paper (Open Session) (Presenter: Ronald Zelac, PhD, NRC) Dr. Zelac will lead a discussion on the medical events definition Commission Paper.

3:00 – 3:15 ***BREAK***

18) 3:15 – 4:15 Guidance on I-125 Seeds as Markers for Breast Cancer Tumors (Open Session) (Presenter: Robert L. Gallaghar, State of Massachusetts) Mr. Gallaghar will lead a discussion on a draft document giving guidance on the off-label use of I-125 seeds as markers for breast cancer tumors.

19) 4:15 – 5:00 Administrative Closing/Action Item Review (Open Session) (Presenter: Angela McIntosh, NRC) The NRC staff and the ACMUI will discuss miscellaneous items of interest arising from the April 20-21, 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 Spring 2006 meeting.

5:00 ADJOURN
OPENING REMARKS
(CLOSED SESSION)

NO HANDOUT
ETHICS BRIEFING
(CLOSED SESSION)

NO HANDOUT
ADMINISTRATIVE ISSUES
(CLOSED)

NO HANDOUT
EVALUATION FOR EXEMPTION TO AMP REQUIREMENTS (CLOSED)

NO HANDOUT
OPENING REMARKS
NO HANDOUT
Recognition of Specialty Boards

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

Approvable: Board certification process meets the criteria for NRC recognition

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

Recognition of Specialty Boards

- Federal Register Notice, March 30, 2005, change in requirements for recognition of specialty boards whose certifications may be used to demonstrate the adequacy of T&E for RSOs, AMPs, ANPs and AUs (Effective April 29, 2005)
- Subpart J expires October 24, 2005
- Letters from NRC sent to 12 specialty boards on April 4, 2005
- Applications received from nine specialty boards in July and August, 2005
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Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35(1,2) (Effective October 24, 2002 and April 29, 2005)

§35.50 Training for Radiation Safety Officer
None

§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 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, 2005 to present for certificates issued to physicians residing in the United States. American Board of Nuclear Medicine certification process from October 18, 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 18, 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

(1) These recognitions apply to 10 CFR Part 35 (effective October 24, 2002 and April 29, 2005).
(2) Specialty boards recognized by NRC under Subpart J of 10 CFR Part 35 (before October 24, 2002) will continue to be recognized by NRC under Subpart J of 10 CFR Part 35 (effective October 24, 2002) until October 24, 2005.
Unauthorized Self Administration of a Diagnostic Radiopharmaceutical by a Nuclear Medicine Technologist

A Case History
Presented by
Douglas F. Eggli, M.D.
Professor of Radiology, Medicine, and Pediatrics
The Pennsylvania State University
College of Medicine
In April of 2004 a staff Nuclear Medicine technologist at the Milton S. Hershey Medical Center had a student technologist perform both an unauthorized injection of radiopharmaceutical (20 mCi of Tc-99m HMPAO) and a subsequent brain perfusion SPECT study on herself.

Several weeks earlier the technologist involved had been specifically warned by the Chief of Nuclear Medicine that the scan she wanted to perform on herself was medically unindicated, a violation of NRC regulation, and would result in disciplinary action.
Case History

- The self-administration was discovered within hours when the student technologist reported the administration to the chief technologist.
- The staff technologist involved was immediately suspended by the Chief of Nuclear Medicine after consultation with the RSO.
- The suspension was confirmed in writing by the RSO and made permanent by the Radiation Safety Committee within 24 hours.
The Penn State Hershey Medical Center reported the event to NRC Region I.
In May of 2004 Region I initiated an investigation.
Results of the Investigation

- The technologist involved never expressed any remorse for her action.
- In defense of her action, she alleged that unauthorized self-administration of diagnostic radiopharmaceuticals was a common practice.
  - She never addressed the specific prior warning against her planned self-administration.
- Based on that allegation, NRC investigators discovered two prior incidents of unauthorized self-administrations of radiopharmaceuticals by technologists; one in 2002 and one in 1997.
- The prior two events were not detected by the administration of the Nuclear Medicine Division at the Penn State Milton S. Hershey Medical Center.
The Problem

- The incidence of such unauthorized self-administrations is unknown, but in discussion with Region I staff, this was not an isolated occurrence.
- Only those incidents discovered and reported by the licensee are detected.
  - Neither internal Penn State procedures nor multiple regular inspections by NRC detected the 1997 and 2002 incidents.
  - It is actually easy to make such incidents “invisible.”
- The two prior incidents at Penn State Hershey Medical Center would not have been detected if the last incident had not been discovered by HMC and reported to the NRC.
  - “You don’t know what you don’t know.”
The Dilemma

- Diagnostic nuclear medicine studies are "low risk" procedures
- No adverse outcomes can be expected from inappropriate or unauthorized diagnostic administrations of licensed radioactive materials
- Unauthorized diagnostic administrations of radioactive materials are none-the-less a violation of NRC regulation
We believed that we had a rigorous radiation safety program with policies and procedures adequate to prevent such an incident.

We were obviously wrong.

A technologist intent on violating NRC regulation, for whatever reason, can probably do so with a small risk of discovery.
Prevention

- Creation of a culture of respect for NRC’s regulations
  - It must be clear that willful violation of NRC regulation will result in swift and certain disciplinary action
  - Complicity by other staff technologists must be avoided
    » All three cases at Penn State Hershey Medical Center involved more than one technologist
    - It is more difficult to self-administer a radiopharmaceutical than to get someone else to perform the injection

- The secondary participating technologist may be the key to prevention
  - In all three cases, the secondary participating technologist believed that the injection had been properly authorized
Prevention

- We now require a written directive for diagnostic administrations on radiology staff.
- The technologist performing the injection is required not only to see the written directive, but to also review it with the responsible authorized user prior to administration of a diagnostic radiopharmaceutical on a staff member.
- We have initiated new employee training and annual staff training emphasizing the regulation and the consequences for willful violation.
ACMUI committee members are invited to further discuss this incident and offer recommendations to avoid similar incidents in the future.
Revision of NRC Form 313A

ACMUI Meeting
October 25-26, 2005

Sandy Gabriel
Senior Health Physicist
Region I/DNMS/Medical Branch

Background: Form 313A

- Available (not required) for medical licensees to submit training, experience, and preceptor statements/attestations for proposed authorized individuals (AU/RSO/AMP/ANP)
- Revised in 2002 with 10 CFR Part 35 revision and NUREG-1556, Vol. 9 initial publication
- Revised again in early 2005 with revision of Part 35 training and experience requirements and NUREG-1556, Vol. 9, revision 1

Licensee/reviewer feedback:

Form 313A

- Pre-2002 version
  - Part 35 T&E requirements relatively simple
  - 313A relatively simple to use
  - Addressed AU and RSO only
Licensee/reviewer feedback:
Form 313A
- 2002 version
  - Part 35 T&E requirements more complex (Subparts B and D-H)
  - 313A form more complex
  - Added AMP and ANP, so 1 form addressed 4 types of authorized individuals
  - Licensees had difficulty determining which sections to complete for each type of authorized individual and correct way to complete applicable sections

Licensee/reviewer feedback:
Form 313A
- 2002 version (cont'd)
  - Form was used infrequently, partly because most applications were made under the older Subpart J requirements

Licensee/reviewer feedback:
Form 313A
- 2005 version
  - Instructions on form provide more direction about which sections to complete but form remains confusing to licensees and regional license reviewers
  - Need for a user-friendly form becomes more urgent on October 25, 2005, with expiration of Subpart J and limited number of approved specialty boards
Revision of Form 313A

- Regional participants in Part 35 Working Group proposed revision of 313A into separate forms for each type of authorized individual
- Region I assigned to coordinate project
- Team includes representatives from Regions I, III, IV and NMSS/IMNS
- Working by e-mail and telephone to expedite process

Revision of Form 313A

- Current proposal is for 6 versions of form:
  - RSO: AU for 35.100/200/500
  - AMP: AU for 35.300
  - ANP: AU for 35.400/600
- Project also includes update of guidance in Appendix D of NUREG-1556, Vol. 9

Revision of Form 313A: ACMUI input

- Copies of latest draft distributed to ACMUI members for review
- Discussion
RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND
PRECEPTOR ATTESTATION [10 CFR 35.50]

Name of Proposed Radiation Safety Officer: ________________________________

Requested Authorization to be Radiation Safety Officer for a program that includes the following
types of medical use (check all that apply):

☐ 35.100  ☐ 35.200  ☐ 35.300  ☐ 35.400
☐ 35.500  ☐ 35.600 (remote afterloader)  ☐ 35.600 (teletherapy)
☐ 35.600 (gamma stereotactic radiosurgery)  ☐ 35.1000

PART I - TRAINING AND EXPERIENCE

Choose one of the four methods below:

☐ 1. Board Certification
   a. Provide a copy of the board certification. If board certification is older than 7 years,
      provide dates, duration, and description of continuing education and experience
      related to the radiation safety of uses checked above.
   b. Provide completed Part II Preceptor Attestation.
   c. Radiation safety training for the following types of medical use:
      ☐ 35.100  ☐ 35.200  ☐ 35.300  ☐ 35.400
      ☐ 35.500  ☐ 35.600 (remote afterloader)  ☐ 35.600 (teletherapy)
      ☐ 35.600 (gamma stereotactic radiosurgery)  ☐ 35.1000

Describe radiation safety training in each type of use for which authorization is
sought, use Tables c to record the training provider and the dates of training:

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<th>Table c. Radiation Safety Training Provider and the Dates</th>
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<tbody>
<tr>
<td>Training provided by</td>
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<tr>
<td>Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses</td>
</tr>
<tr>
<td>Radiation safety, regulatory issues, and emergency procedures for 35.300 uses</td>
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## Radiation safety, regulatory issues, and emergency procedures for 35.400 uses

| Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses |
| Radiation safety, regulatory issues, and emergency procedures for 35.1000 use |

If training is provided by supervising individual: (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Name of individual: __________________________

License/Permit Number listing supervising individual as an:

- Radiation Safety Officer
- Authorized user
- Authorized Nuclear Pharmacist
- Authorized Medical Physicist

Authorized as AU, or RSO, ANP, or AMP for the following medical uses:

- 35.100
- 35.200
- 35.300
- 35.400
- 35.500
- 35.600 (remote afterloader)
- 35.600 (teletherapy)
- 35.600 (gamma stereotactic radiosurgery)

OR

- 2. Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer on a License with the Additional Medical Uses Checked above.
  a. Document radiation safety training for medical uses in Tables c(1), c(2), and/or c(3) above as appropriate
  b. Provide completed Part II Preceptor Attestation

Page 2 of 6
### 3. Structured Educational Program

#### a. Classroom and Laboratory Training

<table>
<thead>
<tr>
<th>Description of Training</th>
<th>Location of Training</th>
<th>Clock Hours</th>
<th>Dates of Training*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation physics and instrumentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mathematics pertaining to the use and measurement of radioactivity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation biology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation dosimetry</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Training:**

*Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

#### b. Supervised Radiation Safety Experience

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Training/ License or Permit Number of Training Facility</th>
<th>Dates of Training*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipping, receiving, and performing related radiation surveys</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Securing and controlling byproduct material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using administrative controls to avoid mistakes in administration of byproduct material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using emergency procedures to control byproduct material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disposing of byproduct material</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Draft revision of 313A (RSO)

Licensed Material Used (e.g., 35.100, 35.200, etc.)*

Supervising Individual [If more than one supervising individual is necessary to document supervised radiation safety experience, provide multiple copies of this page.]

Name of individual: ____________________________________________

License/Permit Number listing supervising individual as Radiation Safety Officer: __________________________

This license authorizes the following medical uses:

☐ 35.100 ☐ 35.200 ☐ 35.300 ☐ 35.400
☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.1000 (___________)
☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery)

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

+ Choose all applicable sections of 10 CFR Part 35 to describe radiisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

- Provide completed Part II Preceptor Attestation.

OR

☐ 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

a. Provide license number.

b. Use Table c to describe training in radiation safety, regulatory issues, and emergency procedures for the types of use on the license.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.
Draft revision of 313A (RSO)

Check one of the following:

☐ 1. **Board Certification**

I attest that ______________________ (insert proposed Radiation Safety Officer’s name) has satisfactorily completed the requirements in 10 CFR 35.50(a)(1)(i) and (a)(1)(ii); 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☐ 2. **Structured Educational Program**

I attest that ______________________ (insert proposed Radiation Safety Officer’s name) has satisfactorily completed a structured educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

AND

Check all that apply:

☐ I attest that ______________________ (insert proposed Radiation Safety Officer’s name) has training in the radiation safety, regulatory issues, and emergency procedures for the following types of use:

- ☐ 35.100
- ☐ 35.200
- ☐ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required
- ☐ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131
- ☐ 35.300 parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- ☐ 35.300 parenteral administration of any other radionuclide for which a written directive is required
- ☐ 35.400
- ☐ 35.500
- ☐ 35.600 remote afterloader units
- ☐ 35.600 teletherapy units
- ☐ 35.600 gamma stereotactic radiosurgery units
- ☐ 35.1000 emerging technologies, including:

AND

☐ I attest that ______________________ (insert proposed Radiation Safety Officer’s name) has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.
Draft revision of 313A (RSO)

I am Radiation Safety Officer for __________________________ insert medical facility name).

License/Permit Number: __________________________

Print Name of Preceptor: __________________________ Phone Number of Preceptor: __________

Signature of Preceptor: __________________________ Date: __________________________
AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.51]

Name of Proposed Authorized Medical Physicist: ________________________________

Requested Authorization(s) (check all that apply):

- [ ] 35.400 Ophthalmic use of strontium-90
- [ ] 35.600 Remote afterloader unit(s)
- [ ] 35.600 Teletherapy unit(s)
- [ ] 35.600 Gamma stereotactic radiosurgery unit(s)
- [ ] 35.1000 (Specify device/use)

PART I - TRAINING AND EXPERIENCE

Choose one of the three methods below:

- [ ] 1. Board Certification
  
  a. Provide a copy of the board certification. If board certification is older than 7 years, provide dates, duration, and description of continuing education and experience related to the uses checked above.

  b. Provide completed Part II Preceptor Attestation.

  c. Describe training in each type of use for which authorization is sought, use Table c. to record the training provider and the dates training:

<table>
<thead>
<tr>
<th>Table c. Training Provider and Date(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>35.600 Devices</td>
</tr>
<tr>
<td>35.1000 Device</td>
</tr>
<tr>
<td>Training in:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Remote afterloader</td>
</tr>
<tr>
<td>Teletherapy</td>
</tr>
<tr>
<td>Gamma stereotactic radiosurgery</td>
</tr>
<tr>
<td>Specify device</td>
</tr>
<tr>
<td>Hands-on device operation</td>
</tr>
<tr>
<td>Safety procedures for the device use</td>
</tr>
<tr>
<td>Clinical use of the device</td>
</tr>
</tbody>
</table>
If training is provided by supervising individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Name of individual: ______________________

License/Permit Number listing supervising individual as an Authorized Medical Physicist: ______________________

Authorized for use of:

☐ Remote afterloader unit(s)
☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)
☐ 35.1000 ______________________ (Specify device/use)

If Applicable:

<table>
<thead>
<tr>
<th>Authorization sought</th>
<th>Device</th>
<th>Training provided by</th>
<th>Dates of training</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.400 Ophthalmic use of strontium-90</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OR

☐ 2. **Authorized Medical Physicist Seeking Additional Authorization for material checked above**
   a. Document training and experience in new device using use Table c above
   b. Provide completed Part II Preceptor Attestation

☐ 3. **Education, Training, and Experience**
   a. Education: Document master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

   Degree: ______________________  Major field: ______________________

   Name of college or university: ______________________

   b. Supervised Full-Time Medical Physics Training and Work Experience
<table>
<thead>
<tr>
<th>Description of Training/Experience</th>
<th>Location of Training/License or Permit Number of Training Facility/Medical Devices Used+</th>
<th>Dates of Training*</th>
<th>Dates of Work Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Physics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing sealed source leak tests and inventories</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing decay corrections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing full calibration and periodic spot checks of external beam treatment unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing full calibration and periodic spot checks of remote afterloading unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducting radiation surveys around external beam treatment unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducting radiation surveys around stereotactic radiosurgery unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducting radiation surveys around remote afterloading unit(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Supervising Individual [If more than one supervising individual is necessary to document training and work experience, provide multiple copies of this page.]

Name of individual: ____________________________

License/Permit Number listing supervising individual as Authorized Medical Physicist: ____________________________

Authorized for use of:
- [ ] Remote afterloader unit(s)
- [ ] Teletherapy unit(s)
- [ ] Gamma stereotactic radiosurgery unit(s)
- [ ] 35.1000 (Specify device/use)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.
Draft revision of 313A (AMP)  

* 1 year of full-time medical physics training and 1 year of full-time work experience cannot be concurrent. Additionally, training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing training and experience since the required training and experience was completed.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

c. Describe training in each type of use for which authorization is sought, use Table c. to record the training provider and the date of training:

<table>
<thead>
<tr>
<th>Table c. Training Provider and the Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>35.600 Devices</strong></td>
</tr>
<tr>
<td>Training in:</td>
</tr>
<tr>
<td>Hands-on device operation</td>
</tr>
<tr>
<td>Safety procedures for the device use</td>
</tr>
<tr>
<td>Clinical use of the device</td>
</tr>
<tr>
<td>Treatment planning system operation</td>
</tr>
</tbody>
</table>

If training is provided by supervising medical physicist (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

Name of individual: _______________________

License/Permit Number listing supervising individual as an Authorized Medical Physicist: _______________________

for the following types of use:

- [ ] Remote afterloader unit(s)
- [ ] Gamma stereotactic radiosurgery unit(s)
- [ ] Teletherapy unit(s)
- [ ] 35.1000 ________ (Specify device/use)

As Appropriate:

<table>
<thead>
<tr>
<th>Authorization sought</th>
<th>Device</th>
<th>Training provided by</th>
<th>Dates of training</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.400 Ophthalmic use of strontium-90</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
d. Provide completed Part II Preceptor Attestation.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

Check one of the following:

☐ 1. **Board Certification**
   
   I attest that ______________________ (insert proposed Authorized Medical Physicist's name) has satisfactorily completed the requirements in 35.51(a)(1) and (a)(2).

   OR

☐ 2. **Education, Training, and Experience**
   
   I attest that ______________________ (insert proposed Authorized Medical Physicist's name) has satisfactorily completed the 1 year of full-time training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

   AND

Complete all of the following:

☐ I attest that ______________________ (insert proposed Authorized Medical Physicist's name) has training for the types of use for which authorization is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

   AND

☐ I attest that ______________________ (insert proposed Authorized Medical Physicist's name) has achieved a level of competency sufficient to function independently as an Authorized Medical Physicist for the following:

   - 35.400 strontium-90 eye applicator
   - 35.600 remote afterloader units
   - 35.600 teletherapy units
   - 35.600 gamma stereotactic radiosurgery units
   - 35.1000 _______________ (Specify device/use)
AND

☐ I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

☐ 35.400 strontium-90 eye applicator
☐ 35.600 remote afterloader units
☐ 35.600 teletherapy units
☐ 35.600 gamma stereotactic radiosurgery units
☐ 35.1000 ________________ (Specify device/use)

Print Name of Preceptor: ____________________ Phone Number of Preceptor: ____________

Signature of Preceptor: ____________________ Date: ________________________________

License/Permit Number/Facility Name: _____________________________________________
**PART I – TRAINING AND EXPERIENCE**  
*(Select one of the two methods below)*

Training and Experience must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

- [ ] 1. **Board Certification**
  - a. Provide a copy of the board certification. If board certification is older than 7 years, provide dates, duration, and description of continuing education and experience related to the uses checked above.
  - b. Provide completed Part II Preceptor Attestation.

- [ ] 2. **Structured Educational Program**
  - a. Classroom and Laboratory Training

<table>
<thead>
<tr>
<th>Description of Training</th>
<th>Location of Training</th>
<th>Clock Hours</th>
<th>Dates of Training*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation physics and Instrumentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mathematics pertaining to the use and measurement of radioactivity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemistry of byproduct material for medical use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation biology</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Training:**
2. Structured Educational Program

b. Supervised Practical Experience in a Nuclear Pharmacy

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipping, receiving, and performing related radiation surveys</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculating, assaying, and safely preparing dosages for patients or human research subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using administrative controls to avoid medical events in administration of byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Hours of Experience:

Supervising Individual

c. Provide completed Part II Preceptor Attestation.
PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the Individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

Check one of the following:

1. **Board Certification**
   - [ ] I attest that ___________________________ has satisfactorily completed the requirements in
     - 10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

2. **Structured Educational Program**
   - [ ] I attest that ___________________________ has satisfactorily completed a 700-hour structured educational program consisting of both 200 hours of classroom and laboratory training and practical experience in nuclear pharmacy as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

I am an Authorized Nuclear Pharmacist for ___________________________.

_______________
Name of Nuclear Pharmacy or Medical Facility

_______________
License/Permit Number

<table>
<thead>
<tr>
<th>Name of Preceptor</th>
<th>Signature</th>
<th>Telephone Number</th>
<th>Date</th>
</tr>
</thead>
</table>
PART I -- TRAINING AND EXPERIENCE

(Select one of the three methods below)

* Training and Experience must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

1. **Board Certification**
   a. Provide a copy of the board certification. If board certification is older than 7 years, provide dates, duration, and description of continuing education and experience related to the uses checked above.
   b. Except for 35.500 uses, provide completed Part II Preceptor Attestation.

2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
   a. Authorized user on Materials License ____________________ for 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
   b. Supervised Work Experience
      (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs</td>
<td>________________________________________________________</td>
<td>__________________</td>
<td>__________________</td>
</tr>
</tbody>
</table>

**Total Hours of Experience:**

<table>
<thead>
<tr>
<th>Supervising Individual</th>
<th>License/Permit Number listing supervising individual as an authorized user</th>
</tr>
</thead>
</table>

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply)

- [ ] 35.290
- [ ] 35.390 + generator experience
3. Training and Experience

* Training and Experience must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

a. Classroom and Laboratory Training

<table>
<thead>
<tr>
<th>Description of Training</th>
<th>Location of Training</th>
<th>Clock Hours</th>
<th>Dates of Training*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation physics and instrumentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mathematics pertaining to the use and measurement of radioactivity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemistry of byproduct material for medical use <em>(not required for 35.590)</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation biology</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Training:**

b. Supervised Work Experience *(completion of this table is not required for 35.590)*
*(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculating, measuring, and safely preparing patient or human research subject dosages</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 3. Training and Experience (continued)

#### b. Supervised Work Experience

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using administrative controls to prevent a medical event involving the use of unsealed byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using procedures to contain spilled byproduct material safely and using proper decontamination procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administering dosages of radioactive drugs to patients or human research subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs (required for 35.290 only)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Experience:**

<table>
<thead>
<tr>
<th>Supervising Individual</th>
<th>License/Permit Number listing supervising individual as an authorized user</th>
</tr>
</thead>
</table>

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one)

- [ ] 35.190
- [ ] 35.290
- [ ] 35.390
- [x] 35.390 + generator experience

**c.** Except for 35.500 uses, provide completed Part II Preceptor Attestation.

**d.** For 35.590 only, provide documentation of training on use of the device.

<table>
<thead>
<tr>
<th>Device</th>
<th>Type of Training</th>
<th>Location and Dates</th>
</tr>
</thead>
</table>
PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that ________________________________ has satisfactorily completed the requirements in 10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that ________________________________ has satisfactorily completed the 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that ________________________________ has satisfactorily completed the requirements in 10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☐ I attest that ________________________________ has satisfactorily completed the 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Complete the following:

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190  ☐ 35.290  ☐ 35.390  ☐ 35.390 + generator experience

<table>
<thead>
<tr>
<th>Name of Preceptor</th>
<th>Signature</th>
<th>Telephone Number</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

License/Permit Number/Facility Name

Page 4 of 4
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

Name of Proposed Authorized User: ________________________________

State or Territory Where Licensed: ________________________________

Requested Authorization(s) (check all that apply):

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

OR

- 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

- 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

- 35.300 Parenteral administration of any beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

- 35.300 Parenteral administration of any other radionuclide for which a written directive is required

PART I - TRAINING AND EXPERIENCE

Choose one of the three methods below:

- **1. Board Certification**

  a. Provide a copy of the board certification. If board certification is older than 7 years, provide dates, duration, and description of continuing education and experience related to the uses checked above.

  b. Provide completed Part II Preceptor Attestation.

  c. For 35.390, provide documentation on supervised clinical case experience. Table c in Item 3 may be used to document this experience.

  d. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in Item 3 may be used to document this experience.
☐ 2. Current 35.300, 35.400 or 35.600 Authorized User Seeking Additional Authorization

a. Authorized User on Materials License ________________ under the requirements below or equivalent Agreement State requirements (check all that apply):

☐ 35.390 ☐ 35.392 ☐ 35.394
☐ 35.490 ☐ 35.690

b. If previously authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. Table c in Item 3 may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If previously authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in Item 3 may be used to document this experience. Also provide completed Part II Preceptor Attestation.

☐ 3. Training and Experience

| a: Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396 |
|---------------------------------|-----------------|-----------------|-----------------|
| Description of Training        | Location of Training | Clock Hours | Dates of Training* |
| Radiation physics and instrumentation |                     |                |                  |
| Radiation protection            |                     |                |                  |
| Mathematics pertaining to the use and measurement of radioactivity |                     |                |                  |
| Chemistry of byproduct material for medical use |                     |                |                  |
| Radiation biology               |                     |                |                  |

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.
<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calculating, measuring, and safely preparing patient or human research subject dosages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using administrative controls to prevent a medical event involving the use of unsealed byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using procedures to contain spilled byproduct material safely and using proper decontamination procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Hours of Supervised Work Experience:

Supervising Individual [If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.]

Name of individual: __________________________

License/Permit Number listing supervising individual as an Authorized User: ________________

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>35.390</td>
<td>With experience administering dosages of:</td>
</tr>
<tr>
<td>35.392</td>
<td>- Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)</td>
</tr>
<tr>
<td>35.394</td>
<td>- Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)</td>
</tr>
<tr>
<td>35.396</td>
<td>- Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required</td>
</tr>
<tr>
<td></td>
<td>- Parenteral administration of any other radionuclide requiring a written directive</td>
</tr>
</tbody>
</table>

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.
### c. Supervised Clinical Case Experience

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Number of Cases Involving Personal Participation</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parenteral administration of any beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parenteral administration of any other radionuclide for which a written directive is required</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Supervising Individual [If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.]

Name of individual: ____________________________

License/Permit Number listing supervising individual as an Authorized User: ____________________________

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:

- 35.390
- 35.392
- 35.394
- 35.396

With experience administering dosages of:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as
DRAFT REVISION OF 313A (AUT)

the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

Check one of the following for each requested authorization:

For 35.390:

Board Certification

☐ I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the training and experience requirements in 35.390(a)(1) and the supervised clinical case experience requirements in 35.390(b)(1)(ii)(G) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.300.

OR

Training and Experience

☐ I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1), and the supervised clinical case experience requirements in 35.390(b)(1)(ii)(G), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.300.

For 35.392:

☐ I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.300 for oral administration of sodium iodide 1-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).
For 35.394:

☐ I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.394(c)(1), and the supervised work and clinical case experience required in 35.394(c)(2), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.300 for oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that __________________________ (insert proposed Authorized User's name) is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396(d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☐ I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the board certification requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396(d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required
Complete the following:

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.390
☐ 35.392
☐ 35.394
☐ 35.396

☐ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☐ Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
☐ Parenteral administration of any other radionuclide requiring a written directive

Print Name of Preceptor: ___________________ Phone Number of Preceptor: ______________

Signature of Preceptor: ___________________ Date: ________________________________

License/Permit Number/Facility Name: ____________________________________________
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]

Name of Proposed Authorized User: ________________________________

State or Territory Where Licensed: ________________________________

Requested Authorization(s) (check all that apply):

- □ 35.400 Manual brachytherapy sources
- □ 35.400 Ophthalmic use of strontium-90
- □ 35.600 Remote afterloader unit(s)
- □ 35.600 Teletherapy unit(s)
- □ 35.600 Gamma stereotactic radiosurgery unit(s)

PART I - TRAINING AND EXPERIENCE

Choose one of the three methods below:

1. Board Certification
   a. Provide a copy of the board certification. If board certification is older than 7 years, provide dates, duration, and description of continuing education and experience related to the uses checked above.
   b. Provide completed Part II Preceptor Attestation
   c. For 35.600, describe training in each type of use for which authorization is sought, use Table c. to record the training provider and the date of training:

<table>
<thead>
<tr>
<th>Table c. Training Provider and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.600 Devices</td>
</tr>
<tr>
<td>Training in:</td>
</tr>
<tr>
<td>Device operation including</td>
</tr>
<tr>
<td>Safety procedures for the device/use</td>
</tr>
</tbody>
</table>

Page 1 of 8
### 2. Authorized User Requesting Additional Authorization for Material Checked above
- a. Document training and experience in new device using Table c above
- b. Provide completed Part II Preceptor Attestation

### 3. Training and Experience

<table>
<thead>
<tr>
<th>Classroom and Laboratory Training</th>
<th>35.490</th>
<th>35.491</th>
<th>35.690</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of Training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation physics and instrumentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation protection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mathematics pertaining to the use and measurement of radioactivity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation biology</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Training:**

*Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.*

<table>
<thead>
<tr>
<th>Supervised Work and Clinical Experience for 10 CFR 35.490</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of Experience</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys</td>
</tr>
<tr>
<td>Checking survey meters for proper operation</td>
</tr>
</tbody>
</table>
b. Supervised Work and Clinical Experience for 10 CFR 35.490

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing, implanting, and safely removing brachytherapy sources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintaining running inventories of material on hand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using administrative controls to prevent a medical event involving the use of byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using emergency procedures to control byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Supervised Work Experience:**

<table>
<thead>
<tr>
<th>Clinical experience in radiation oncology as part of an approved formal training program</th>
<th>Approved by:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Residency Review Committee for Radiation Oncology of the ACGME</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Royal College of Physicians and Surgeons of Canada</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Committee on Postdoctoral Training of the American Osteopathic Association</td>
<td></td>
</tr>
</tbody>
</table>

**Supervising Individual** (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Name of individual: ____________________________

License/Permit Number listing supervising individual as an Authorized User: ____________________________

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Supervised clinical experience may be concurrent with supervised work experience.
### c. Supervised Clinical Experience for 10 CFR 35.491

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Number of Individuals Treated</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supervising Individual**

Name of individual: ____________________________

License/Permit Number listing supervising individual as an Authorized User: ____________________________

*Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed.

### d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader
- Gamma stereotactic radiosurgery unit(s)
- Teletherapy

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewing full calibration measurements and periodic spot-checks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparing treatment plans and calculating treatment doses and times</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using administrative controls to prevent a medical event involving the use of byproduct material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checking and using survey meters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selecting the proper dose and how it is to be administered</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader
- Teletherapy
- Gamma stereotactic radiosurgery unit(s)

<table>
<thead>
<tr>
<th>Description of Experience</th>
<th>Location of Experience/License or Permit Number of Facility</th>
<th>Clock Hours</th>
<th>Dates of Experience*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical experience in radiation therapy as part of an approved formal training program</td>
<td>Approved by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Residency Review Committee for Radiation Oncology of the ACGME</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Royal College of Physicians and Surgeons of Canada</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Committee on Postdoctoral Training of the American Osteopathic Association</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Hours of Supervised Work Experience:**

**Supervising Individual**

Name of individual: __________________________

License/Permit Number listing supervising individual as an Authorized User: __________________________

* Training must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Supervised clinical experience may be concurrent with supervised work experience.
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e. For 35.690, describe type of training in each type of use for which authorization is sought and use Table e. to record the training provider and date of the training:

<table>
<thead>
<tr>
<th>Training Provider and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.600 Devices</td>
</tr>
<tr>
<td>35.1000 Device</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training in:</th>
<th>Remote afterloader</th>
<th>Teletherapy</th>
<th>Gamma stereotactic radiosurgery</th>
<th>Specify device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device operation including</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety procedures for the device/use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical use of the device</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If training provided by supervising individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Name of individual: __________________

License/Permit Number listing supervising individual as an Authorized User: __________________

f. Provide completed Part II Preceptor Attestation.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

Check one of the following for each requested authorization:

For 35.490

Board Certification
I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the requirements in 35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 51 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

For 35.690:

Board Certification:

I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the requirements in 35.690(a)(1), has training for the types of devices for which authorization is sought as required by 10 CFR 35.690(c), and has achieved a level of competency sufficient to function independently as an authorized user for:

- 35.600 Remote afterloader unit(s)
- 35.600 Teletherapy unit(s)
- 35.600 Gamma stereotactic radiosurgery unit(s)

OR

Training and Experience:

I attest that __________________________ (insert proposed Authorized User's name) has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2), has training for the types of devices for which authorization is sought as required by 10 CFR 35.690(c), and has achieved a level of competency sufficient to function independently as an authorized
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user for:

- 35.600 Remote afterloader unit(s)
- 35.600 Teletherapy unit(s)
- 35.600 Gamma stereotactic radiosurgery unit(s)

Complete the following:

- I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

- 35.400 Manual brachytherapy sources
- 35.400 Ophthalmic use of strontium-90
- 35.600 Remote afterloader unit(s)
- 35.600 Teletherapy unit(s)
- 35.600 Gamma stereotactic radiosurgery unit(s)

Print Name of Preceptor: ___________________________ Phone Number of Preceptor: ____________

Signature of Preceptor: ___________________________ Date: ___________________________

License/Permit Number/Facility Name: ___________________________
RIS on the Control of Dose to Visitors

Discussion on the Resolution of Some Comments

The draft RIS dismisses the adoption of this program (using self-reading dosimeters) as "relatively inexpensive" and "easy to maintain." Currently, very few of our medical licensees use self-reading dosimeters in their programs.

Please be consistent in the use of radiation terminology, using SI units. The use of older units continues to portray the US as decades behind the rest of the world...I have problems with interjecting TEDEs into such analyses.
I feel that ...(collection of data on excretion) ...should be deleted as collection and measurement of excreta is not routinely performed.

I would reconsider discussing retrospective dose reconstruction in this document.

Change

In 2002, several members of the public were inadvertently permitted to receive doses in excess of regulatory limits ...

To

In 2002, several members of the public inadvertently received doses in excess of the regulatory limit
- Delete item 6, which addresses contamination and internal dose.

- Change

Several factors were identified that indicated a lack of sufficient control of visitor activities.

To

Several factors were identified that indicated a lack of compliance of visitor activities with the guidelines.

- In the statement

In cases where it is anticipated that the dose to a visitor will approach a substantial fraction of the applicable limit...

remove the word "substantial"
- In the section on suggested actions to control visitor dose, remove the discussion on non-uniformity of the radiation field around the patient and its variation with time.

- Change the title of the section from "Dose Assessment" to "Dose Estimates".

- Delete the section on biological dosimetry in the retrospective dosimetry section.
- In the retrospective assessment section...delete references to instrument calibration and response data.
RIS on Caregiver Dose Limits

Intended steps to completion

- Solicit, from the regional staff, suggested procedures, information to be submitted, methods of contacting NRC, etc.
- Use the regional input to develop a draft RIS.
- Provide the draft to the regions and Headquarters staff for review and comment.

- Submit the draft for general comment, including ACMUI, the States, licensees, and any other interested parties.
- Resolve comments and make appropriate changes.
- Issue the RIS (by about the last part of 2006).
Electronic Signatures in Written Directives

October 2005

ACMUI MEETING

Donna-Beth Howe, Ph.D.

Electronic Signatures in Written Directives

35.5 Maintenance of records
- Stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.
- Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures.
- The licensee shall maintain adequate safeguards against tampering with and loss of records.

Electronic Signatures in Written Directives

35.40 Written directives.
- A written directive must be:
  - dated and signed by an authorized user
  - before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.
Electronic Signatures in Written Directives

35.40 Written directives.

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

Electronic Signatures in Written Directives

35.40 Written directives.

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

Electronic Signatures in Written Directives

35.2040 Records of written directives

- A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.
Electronic Signatures in Written Directives

Electronic Signatures in Written Directives

Electronic Signatures in Written Directives
<table>
<thead>
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<th>Electronic Signatures in Written Directives</th>
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</table>
Energy Policy Act of 2005

- Signed into law August 8, 2005
- NARM Legislation – One Aspect of EPAct
  - NARM Rulemaking
  - IMNS Task Force

NARM Legislation

- Section 651(e) of EPAct amended the definition of byproduct material in Section 11e of the Atomic Energy Act to include:
  - Accelerator-produced radioactive material
  - Discrete sources of radium-226
  - Discrete sources of other naturally occurring radioactive material that the NRC determines, in consultation with EPA, DOE & DHS, pose a threat similar to radium-226
NARM Legislation

- Waivers
  - EPAct allows the Commission to grant waivers allowing current programs to continue regulating new materials for up to 4 years after enactment
  - NRC issued waiver August 25, 2005
  - Waiver published in FR August 31, 2005 (70 FR 51581)

NARM RULEMAKING

NARM Rulemaking

- Amended byproduct material definition is applicable to:
  - Materials produced, extracted or converted after extraction before, on, or after August 8, 2005
  - Materials used in commercial, medical, or research activities
NARM Rulemaking

* Amended definition is NOT applicable to:
  - Low-Level Radioactive Waste - the new materials are not considered low-level radioactive waste
  - Accelerators (only the material produced by the accelerators)
  - NORM which does not pose a threat similar to radium-226

NARM Rulemaking

* Additional Provisions of NARM Legislation
  - Agreement States
    - Section 274 b. of the AEA was amended to include the expanded byproduct material definition
    - Transition Plan required for implementation of Program
  - Radiopharmaceuticals
    - EPAct requires NRC to consider the impact of the availability of radiopharmaceuticals to physicians and patients

NARM Rulemaking

* Additional Provisions of NARM Legislation (cont.)
  - Stakeholder Input
    - States
      - To the maximum extent practicable, NRC will
      - Consult and cooperate with States
      - Use model State standards
    - Other stakeholders
      - Consultation
NARM Rulemaking

- Rulemaking Process
  - Working Group
    - Representatives from NRC Headquarters, Regions, and States
  - Schedule (subject to Commission approval)
    - Proposed Rule - April 2006
    - Final Rule - NLT February 7, 2007 (required by EPAct)

IMNS TASK FORCE

IMNS Task Force

- Significant new NRC/State cooperative activities
  - Energy Policy Act of 2005
- Task Force established September '05
  - Multi-organizational
  - Develop regulatory framework
  - Integrated implementation of activities
  - Up to 1 year term
Task Force - Significant Activities

- Develop Regulatory Framework for NARM
  - Technical Basis for rulemaking (Nov. '05)
  - Definition of "discrete source" (Nov. '05)
  - EPAct Sec. 651(e)(4) Transition Plan (Sept. '06)
  - Policy on new State Agreements (Sept. '06)
  - Guidance Development (concurrent with rule)
  - NRC regulatory program changes

QUESTIONS?
The Industry's Perspective on NRC's Jurisdiction Over ARM

ACMUI Meeting
October 26, 2005

Roy W. Brown
Senior Director, Federal Affairs
Council on Radi nuclides & 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

The Energy Act of 2005

- Signed into law on August 8, 2005
- CORAR has been very supportive of adding ARM to the Atomic Energy Act
- CORAR presented these views at last year's OAS meeting
- CORAR has concerns with ARM being handled differently than material formerly designated as byproduct material
- CORAR has been seeking uniformity in regulations between BPM & ARM
Previous Problems with States

- CORAR member companies have had trouble getting new ARM R/Ps licensed in states
  - Delays in some states
  - Non-uniformity of Agreement state regs
  - NRC states not having the expertise to approve
- CORAR member companies have had operational concerns in some states

Examples of Operational Problems with Individual States

- Requirement that RSO has to have B.S. in Health Physics or Radiological Health
- Continuous changes in requirements for facility decommissioning
- State-specific product approval and labeling requirements
- State-specific protocols for reciprocity
- Differing approaches to level of detail and approval in sealed source/device registry
- State defining byproduct material to include the PET radionuclides F-18, N-13 & C-11

Examples of Operational Problems with Individual States

- Manufacturers must stay current with the different state's regulations
- New technologies may be handled differently by different states
- Varying regulations may create a competitive advantage
- It is more difficult for manufacturers to assist customers in complying with state regs when many states are so different
Non-Uniform Regulations

- It is impractical to prepare different versions of products and different labeling to comply with different regulations.
- Regulations should focus on generally acceptable safety and protection standards.
- Establishing one set of comprehensive regulations conserves limited agency and licensee resources for improving safety.
- States with uniform regulations are better able to be compatible with new requirements from other agencies.

CORAR Concerns with Implementation of NARM

- NRC staff is considering a fast track program for new states to regulate ARM.
- Creation of new agreement states may lead to more non-uniformity.
- New fast track agreement states may create NRC-state ARM regs vs. Agreement state ARM regs disparity.
- CORAR needs uniformity in states rather than consistency.

Society of Nuclear Medicine's Position

- Nuclear Medicine physicians are concerned about how the new regulations may be implemented.
- New regs could limit patient access to beneficial diagnostic/therapeutic procedures.
- Delays to access may raise patient safety issues.
- SNM welcomes the opportunity to work with those drafting the new regulations.
- SNM is confident that reasonable regs that will address security issues without limiting patient access can be achieved.
Comparative Regulation Matrix

- CORAR's biggest concern continues to be inconsistency between state regulations.
- CORAR is encouraging OAS and CRCPD, to develop a matrix in which specific regulations from different states could be compared & matched against NRC regs.
- Important differences in the regs could be identified using this matrix.
- CORAR would be pleased to work with OAS, CRCPD and NRC on development of this matrix.

Summary

- CORAR would like to work with NRC, OAS and CRCPD on the implementation of new ARM regulations.
- CORAR will push for uniformity over consistency.
- CORAR would like to see new regulations implemented without hurting physicians and the use of PET radiopharmaceuticals.
- CORAR suggests developing a Comparative Regulation Matrix.
- Workshop on Nov 9th is good, but more input from stakeholders is necessary.
Society of Nuclear Medicine

Nuclear Medicine Perspective

NRC Regulation of Accelerator Produced Isotopes

Presented by, Terence Beven, MD
Chair, ACNP-SNM Joint Government Relations Committee

SNM General Position

The Society of Nuclear Medicine (SNM)—an international scientific and professional organization with over 16,000 members dedicated to promoting the science, technology and practical application of nuclear medicine—supports regulations which would ensure public safety from unnecessary exposure to radiation while simultaneously protecting medical/scientific accessibility to short-lived accelerator produced materials for nuclear medicine procedures and research.

To achieve this common goal, the SNM will work cooperatively with NRC staff, the states, and fellow medical associations through the public rulemaking process.
Energy Policy Act: NARM Language

Section 170H of the Energy Policy Act of 2005 granted the NRC full regulatory authority over naturally occurring and accelerator-produced radioactive materials (NARM). This section also contained language directing the NRC to consider the impact of these regulations on radiopharmaceutical availability (subparagraph D):

**(D) Availability of Radiopharmaceuticals**

In promulgating regulations under subparagraph (A), the Commission shall consider the impact on the availability of radiopharmaceuticals to—

(i) physicians; and

(ii) patients the medical treatment of which relies on radiopharmaceuticals.


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Energy Policy Act: NARM (recommendations)

To fulfill the requirements outlined in subparagraph D, the SNM recommends the NRC offer exemptions for isotopes with short half-lives and for isotopes with low levels of radioactivity. These accelerator-produced products pose no conceivable threat to the public.

Additionally, the SNM recommends a full threat assessment of each medically-used isotope included within the NARM regulations.
**Recommendations (continued...)**

Isotopes (with half-life) that are short-lived and/or pose no conceivable terrorist threat to the public include, but are not limited to:

<table>
<thead>
<tr>
<th>Isotope</th>
<th>Half-life</th>
</tr>
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<tbody>
<tr>
<td>Carbon-11</td>
<td>20 min</td>
</tr>
<tr>
<td>Nitrogen-13</td>
<td>10 min</td>
</tr>
<tr>
<td>Oxygen-15</td>
<td>2 min</td>
</tr>
<tr>
<td>Fluorine-18</td>
<td>1.84 h</td>
</tr>
<tr>
<td>Zinc-62</td>
<td>9.2h parent for copper-62 generator</td>
</tr>
<tr>
<td>Xenon-122</td>
<td>20h parent for 3.76m iodine-122 generator</td>
</tr>
<tr>
<td>Bromine-76</td>
<td>16h</td>
</tr>
<tr>
<td>Copper-64</td>
<td>12.7h</td>
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<tr>
<td>Copper-61</td>
<td>3.3h</td>
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<tr>
<td>Copper-67</td>
<td>2.6d</td>
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<tr>
<td>Copper 60</td>
<td>23.4m</td>
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<tr>
<td>Indium-111</td>
<td>3d</td>
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<tr>
<td>Thallium-201</td>
<td>3d</td>
</tr>
<tr>
<td>Iodine-124</td>
<td>4d</td>
</tr>
<tr>
<td>Xenon-127</td>
<td>36d</td>
</tr>
<tr>
<td>Lead-203</td>
<td>~2d</td>
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</tbody>
</table>

Additionally, other radionuclides, such as Ga-66, Zr-89, Co-55, may be used for medical applications in future years. Therefore, any list of exempted isotopes cannot be considered exclusive, but must evolve alongside scientific innovation.
Conclusion

The SNM asks members of the ACMUI to endorse exemptions for medically-used isotopes with short half-lives and isotopes with low levels of radioactivity in adherence with subparagraph D of Sec. 170H of the Energy Policy Act of 2005.

If exemptions are not offered for these products, the regulations could have an unintended, but highly detrimental impact on U.S. patients who need unfettered access to lifesaving diagnostic and therapeutic nuclear medicine procedures.

Questions?

Please contact the Society of Nuclear Medicine national office should you have questions or concerns:

Public Affairs Office
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316
(703) 708-9000 ext. 1322
RECOGNITION OF FOREIGN TRAINED PHYSICISTS & PHYSICIANS AS AMPs AND AUs

October 26, 2005

Cindy Flannery, CHP
Office of Nuclear Material Safety and Safeguards,
Division of Industrial and Medical Nuclear Safety

10 CFR 35.51 requirements:
- Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university
- 1 year full-time training in medical physics
- 1 year full-time work experience under the supervision of an AMP for the type(s) of use for which the individual is seeking authorization
- Written attestation signed by a preceptor AMP

Three questions considered by NRC staff:
- May NRC or Broadscope licensees accept foreign degrees?
- May NRC or Broadscope licensees accept a degree not specifically mentioned in the regulations if the degree can be shown to be equivalent to the degrees listed in the regulations?
- May NRC or Broadscope licensees rely on a preceptor statement from a foreign physician?
### RECOGNITION OF FOREIGN TRAINED PHYSICISTS & PHYSICIANS AS AMPs AND AUs

**May NRC or Broadscope licensees accept foreign degrees?**

Staff did not identify any prohibition against the acceptance of foreign degrees.

---

**May the NRC or Broadscope licensees accept a degree not specifically mentioned in the regulations if the degree can be shown to be equivalent to the degrees listed in the regulations?**

Staff did not identify any prohibition against the acceptance of a degree equivalent to, but not specifically listed in 10 CFR 35.51.

---

**May NRC or Broadscope licensees rely on a preceptor statement from a foreign physician?**

Staff did not identify any prohibition against reliance on a preceptor statement from a foreign-born or foreign trained physician, however, the definition of AU states, in part, that the individual must be licensed in US (to include Puerto Rico). Although foreign training of the preceptor AU may be acceptable, holding only a foreign license would not be acceptable.
RECOGNITION OF FOREIGN TRAINED PHYSICISTS & PHYSICIANS AS AMPs AND AUs

Current practice of reviewing training and experience of foreign trained physicists and physicians
Reviewed by ACMUI members on a case-by-case basis

Proposed practice of reviewing training and experience of foreign trained physicists and physicians

*Authority for review by Regions on a case-by-case basis

NOTE: Broadscope licensees already have this authority through review by Radiation Safety Committee

Proposed practice of reviewing training and experience of foreign trained physicists and physicians

*When unusual circumstances warrant further review (e.g., question on the validity of degree), a Technical Assistance Request will be submitted to Headquarters from Regions for review by ACMUI.

*Only attestations by a preceptor licensed in the U.S. will be accepted because the preceptor must be an AU or AMP listed on a U.S. license. Preceptor attestation from a non-U.S. licensed preceptor will not be accepted.
RECOGNITION OF FOREIGN TRAINED PHYSICISTS & PHYSICIANS AS AMPs AND AUs

DISCUSSION
Status of Medical Events

October 2005
ACMUI Meeting

Donna-Beth Howe, Ph.D.

Status of Medical Events

<table>
<thead>
<tr>
<th>40 Medical Events reported - FY 2005</th>
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<tbody>
<tr>
<td>35.200</td>
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<td>35.300</td>
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<td>35.400</td>
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<td>35.600</td>
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<tr>
<td>LDR</td>
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<tr>
<td>HDR</td>
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<tr>
<td>Gamma-Knife</td>
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<tr>
<td>Teletherapy</td>
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<tr>
<td>35.1000 Y-90 Microspheres</td>
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Status of Identifying/Reporting Medical Events

<table>
<thead>
<tr>
<th>40 Medical Events reported - FY 2005</th>
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<tbody>
<tr>
<td>Date Reported</td>
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</table>
### Diagnostic Medical Events

<table>
<thead>
<tr>
<th>Code</th>
<th>Count</th>
<th>Description</th>
</tr>
</thead>
</table>
| 35.200 | 4 | Three with Technetium-99m:
- 1 administered whole bulk dose
- 2 pediatric cases
- 1 iodine-131 ordered for wrong procedure |

### Therapy Medical Events

<table>
<thead>
<tr>
<th>Code</th>
<th>Count</th>
<th>Description</th>
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</thead>
</table>
| 35.300 | 8 | 6 Sodium Iodide I-131
- 1 Samarium-153: Calibration error
- 1 Yttrium -90 Zevalin: Ordering confusion |

### Brachytherapy Medical Events

<table>
<thead>
<tr>
<th>Code</th>
<th>Count</th>
<th>Description</th>
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</thead>
</table>
| 35.400 | 8(12) | 5 patients sources moved to wrong site - Gyn.
- 1 leaking source - prostate
- 2 ultrasound wrong site - prostate
- 1 wrong seed activity sent - prostate
- 1 error in seed holder cartridges used some Pd-103 - prostate
- 1 wrong size applicator - Gyn
- 1 ribbon moved - bile duct |
**HDR Medical Events**

HDR (11)
- One licensee
  - Data entry errors by medical physicist
- Wrong reference distance entered
- Wrong position orientation
- Catheter not fully inserted
- Used diameter not radius
- Entered wrong source travel distance

**Gamma Knife Medical Events**

Gamma-Knife (5)
- Wrong site - patient movement
- Contributing factor: equipment jam - clip fell
- Transpose y & z coordinates
- Poor communications within team

**Y-90 Microsphere Medical Events**

Y-90 (1000)
- Back pressure from liver catheter - tube popped off 25% of Y-90 microspheres leaked out
- Attempted to determine delivery amount visually - significant fraction remained in stopcock
The licensee reported that a patient was accidentally administered a 14.8 GBq (400 mCi) bulk dose of Tc-99m sodium pertechnetate instead of 0.15 GBq (4 mCi) of Tc-99m cardiolite. In order to protect the patient, the licensee administered IV fluids and oral fluids to help flush the Tc-99m and a thyroid blocker. Using the calculated organ specific and whole body radiation doses, the licensee predicted radiation doses to the patient of 100 cGy (rad) to the gastrointestinal tract, 100 cGy (rad) to the salivary gland, 80 cGy (rad) to the thyroid, 4.8 cGy (rad) to the testes, 6 cGy (rad) to the liver, 8.8 cGy (rad) to the red marrow, and 5.2 cGy (rad) to the whole body. The licensee stated that the radiopharmacy delivered the bulk dose of Tc-99m in the same type of syringe that their unit doses are delivered in. The technologist assayed the delivered bulk dose, but at the time of administration picked up the wrong syringe. The licensee had recently changed from generators to delivered unit doses. The licensee notified the patient, the referring physician, the RSO, the authorized user on-site, the nuclear pharmacy, and the consultant. Corrective actions taken by the licensee included requesting bulk Tc-99m to be provided in a vial rather than a syringe, writing a new procedure, and providing additional training to personnel.
NMED Item Number: 040855

Narrative: The licensee reported that a two year old pediatric patient was prescribed 88.8 MBq (2.4 mCi) of Tc-99m HDP for a total body bone scan, but was mistakenly administered 703.4 MBq (19.01 mCi), an adult dosage. The nuclear technologist selected the wrong dosage. Corrective actions taken by the licensee included reinstructing involved personnel.

Event Date: Discovery Date: Report Date:

Licensee/Reporting Party Information:
License Number: CA-0165-19 Name: LONG BEACH MEMORIAL MEDICAL CENTER
Docket Number: NA City: LONG BEACH, CA

Site of Event:
Site Name: LONG BEACH, CA

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
CA-XCA629 12/07/2004 AGREEMENT STATE EVENT REPORT
The licensee reported that a 5-month-old infant was administered 414.4 MBq (11.2 mCi) of Tc-99m myoview, instead of the prescribed dosage of 18.5 MBq (0.5 mCi) of Tc-99m sulfur colloid for a gastric emptying study. The technologist did not look at the label when measuring the dose to be administered. The licensee estimated a whole body dose to the infant of 8.3 cSv (rem), instead of the expected dose of 0.009 cSv (rem). The dose to the lower intestine could be as high as 58.2 cSv (rem). The physician informed the infant's parents. Corrective actions included counseling the technologist, revising procedures, and retraining staff. The NRC's medical consultant determined that there were no acute or subacute effects noted in the patient, but did not rule out the possibility of long-term consequences.

Event Date: 03/09/2005
Discovery Date: 03/09/2005
Report Date: 03/11/2005

Licensee/Reporting Party Information:
License Number: 24-00794-03
Name: SAINT JOHNS MERCY MEDICAL CENTER
Docket Number: 03002283
City: SAINT LOUIS, MO

Site of Event:
Site Name: SAINT LOUIS, MO

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41483 03/14/2005
LTR050504 05/09/2005 EVENT NOTIFICATION
LTR050523 05/25/2005 NRC LETTER
ML051450214 06/09/2005 INSPECTION REPORT
ML051450214 06/09/2005 NRC LETTER
LTR050608 06/13/2005 NRC LETTER
Iodine-131

NMED Item Number: 050124

Narrative:

The licensee reported that a patient scheduled to receive 0.63 MBq (17 uCi) of I-131 for a thyroid uptake study received 133.2 MBq (3.6 mCi) of I-131 for a total body scan. A nuclear medicine technologist received the appointment roster form, posted it on the exam scheduling bulletin board, and incorrectly placed the order for a total body scan without looking at the diagnosis. The total body scan ordered on the roster was reviewed by a nuclear medicine physician and checked off for that day's activity. On the day of the exam, a second nuclear medicine technologist retrieved the paper work and administered 133.2 MBq (3.6 mCi) of I-131 for a total body scan. The patient was sent home and came back two days later for a thyroid scan. A third nuclear medicine technologist noted that the thyroid scan did not look as expected, reviewed all of the paperwork, and discovered that the wrong procedure had been administered. The patient was notified of the event. The administration resulted in a thyroid dose of 13,111 cGy (rad) and a TEDE of 2.6 cGy (rad). Corrective actions taken by the licensee included modifying procedures to include removing Central Booking from radioisotope ordering (referring physician will fax order directly to Nuclear Medicine), switching from I-131 to I-123 for thyroid uptake studies, revising the nuclear medicine request form for thyroid procedures, and other procedure changes.

Event Date: Discovery Date: Report Date:
01/07/2005 01/09/2005 02/24/2005

Licensee/Reporting Party Information:
License Number: MA-60-0095 Name: BAYSTATE HEALTH SYSTEMS
Docket Number: NA City: SPRINGFIELD, MA

Site of Event:
Site Name: SPRINGFIELD, MA

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41438 03/01/2005 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050520 05/25/2005 AGREEMENT STATE LETTER
Iodine-131

NMED Item Number: 050145

Narrative: Last Updated: 03/15/2005
The licensee reported that a patient was administered 1 GBq (27 mCi) of Tc-99m MDP for a bone scan instead of the prescribed 185 MBq (5 mCi) of I-131 for a total body scan. The event was caused by an error in transcription of the order by a student technologist. The patient was notified of the error and the correct radiopharmaceutical was later administered. The senior technologist was reprimanded by the Radiology Department Head for not properly supervising the procedure. The physician was notified of the event. The State of Louisiana Department of Environmental Quality will conduct an investigation.

Event Date: 01/26/2005
Discovery Date: 01/26/2005
Report Date: 03/10/2005

Licensee/Reporting Party Information:
License Number: LA-0004-L01
Docket Number: NA
Name: TULANE UNIVERSITY
City: NEW ORLEANS, LA
Site Name: NEW ORLEANS, LA

Reference Documents:
Reference Document Number: EN41478
Entry Date: 03/15/2005
Retraction Date: Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
The licensee reported that a patient scheduled to receive 74 MBq (2 mCi) 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 (2 mCi) of I-131 as a diagnostic procedure to verify effectiveness of previous treatments. The error occurred due to lack of attention to detail. Corrective actions taken by the licensee included providing additional training to involved personnel.
NMED Item Number: 050172

Narrative:  
The licensee reported that a patient received approximately 146.2 MBq (3.95 mCi) of I-131 instead of the prescribed 185 MBq (5 mCi). The event was caused by a clogged filter in the IV tubing used to administer the radioisotope. The manufacturer’s protocol states that if the filter clogs, the remainder of the radioisotope is to be administered without the presence of the filter. When the filter clogged, the nuclear medicine technologist first attempted to flush the clog with saline and then bypassed the filter to complete the administration. After the administration, it was determined by dose calibrator that 43.7 MBq (1.18 mCi) of I-131 was trapped in the tubing behind the filter. As a corrective action, the RSO has recommended immediately bypassing the filter during administration instead of attempting to unclog it. The RSO plans to contact the vendor to get a protocol clarification.

Event Date: 03/17/2005  
Discovery Date: 03/17/2005  
Report Date: 03/17/2005

Licensee/Reporting Party Information:  
License Number: WA-WN-M008-1  
Name: SWEDISH MEDICAL CENTER  
Docket Number: NA  
City: SEATTLE, WA

Site of Event:  
Site Name: SEATTLE, WA

Reference Documents:  
Reference Document Number:  
Entry Date: 03/23/2005  
Retraction Date: 03/23/2005  
Type of Report:

WA-05-010  
AGREEMENT STATE EVENT REPORT

EN41501  
EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NMED Item Number: 050174

Narrative:

The licensee reported that during a quarterly review of written directives, it was noted that a patient was administered a dosage of 462.9 MBq (12.51 mCi) of I-131 for hyperthyroidism instead of the prescribed dosage of 777 MBq (21 mCi). Radiopharmaceutical unit dose dispensing records as well as internal scheduling paperwork confirm that a 444 MBq (12 mCi) dose was in fact ordered and subsequently administered to the correct patient. The licensee determined that the root cause of the event was a lack of strict attention to detail. The licensee has evaluated their policy and procedures to prevent recurrence. The attending physician reviewed the patient’s records and felt that there would be no adverse affect. He will notify the patient of the event.

Event Date: Discovery Date: Report Date:
03/21/2005 03/21/2005 03/22/2005

Licensee/Reporting Party Information:
License Number: 21-04127-02 Name: HARPER UNIVERSITY HOSPITAL
Docket Number: 03002045 City: DETROIT, MI

Site of Event:
Site Name: DETROIT, MI

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41515 03/23/2005 EVENT NOTIFICATION
LTR050425 04/26/2005 NRC LETTER
LTR050523 05/25/2005 NRC LETTER
The licensee reported that a patient scheduled to receive 0.44 GBq (12 mCi) of I-131 actually received 0.55 GBq (14.8 mCi) of I-131, due to an error by the nuclear medicine technician. There were two doses for different patients being measured in the laboratory at the same time. Typically the prescribing physician writes nuclear medicine directives with a range, such as 0.44 to 0.52 GBq (12 to 14 mCi). In this specific instance, the physician wrote the directive for exactly 0.44 GBq (12 mCi). The licensee's RSO stated that the prescribing physician would be notifying the patient. The RSO intends to reinforce following proper laboratory procedures and exercising caution when working with multiple doses to all physicians and laboratory personnel. The INL has requested additional information for this event.

Event Date: 05/11/2005
Discovery Date: 05/11/2005
Report Date: 05/12/2005

Licensee/Reporting Party Information:
License Number: 29-11642-01
Name: SHORE MEMORIAL HOSPITAL
Docket Number: 
City: SOMERS POINT, NJ

Site of Event:
Site Name: SOMERS POINT, NJ

Reference Documents:
Reference Document Number: EN41693
Entry Date: 05/16/2005
Retraction Date: 
Type of Report: EVENT NOTIFICATION
 NMED Item Number: 050394

Narrative:

The licensee reported that a hyperthyroid patient received one of the intended two sodium iodide I-131 capsules sent by the radiopharmacy. The patient received 0.38 GBq (10.2 mCi) in one capsule instead of the prescribed 0.76 GBq (20.6 mCi) in two capsules. This was approximately 49% of the prescribed dosage. Both capsules were received in one plastic vial. The entire vial was assayed, but the technologist failed to notice that there were two capsules in the vial, because a desiccant inside the vial blocked the view of the second capsule and prevented it from leaving the vial. The licensee stated that normally hyperthyroid therapy doses are received in one capsule. Therefore, the technologist was not expecting a second capsule. The radiopharmacy discovered the second capsule in the returned package on 6/10/2005. They called the licensee, the prescribing physician requested that the patient receive the second capsule, and the patient returned on 6/10/2005 and received the second capsule. The second capsule assayed at 0.36 GBq (9.74 mCi) at the time of administration. The patient received a total dosage of 0.74 GBq (19.94 mCi). To prevent a recurrence, the licensee will assay all applicable capsule vials after the patient has received their dosage, but before the patient leaves the facility. This event was retracted by the licensee based on a re-reading of Part 35 and a conversation with the NRC Region III. However, the NRC Medical Team evaluated the event and determined that it did indeed meet Part 35 reporting requirements.

Event Date: 06/09/2005  
Discovery Date: 06/10/2005  
Report Date: 06/10/2005

Licensee/Reporting Party Information:

License Number: 21-01430-01  
Name: EDWARD W. SPARROW HOSPITAL  
Docket Number: 03002009  
City: LANSING, MI

Site of Event:

Site Name: LANSING, MI

Reference Documents:

Reference Document Number: EN41763  
Enter Date: 06/13/2005  
Retraction Date: 06/15/2005  
Type of Report: EVENT NOTIFICATION

Reference Document Number: LTR050615  
Enter Date: 06/15/2005  
Retraction Date:  
Type of Report: NRC LETTER
Samarium-153

NMED Item Number: 050492

Narrative:  
Last Updated: 07/28/2005

The licensee reported that a patient was administered 2.44 GBq (66 mCi) of Sm-153 instead of the intended 3.96 GBq (107 mCi) dose for bone pain therapy. The patient received a calculated exposure of 26.4 cSv (rem) to the whole body, 16,498 cGy (rad) to the bony surfaces, and 3,753 cGy (rad) to the bone marrow (assuming a quality factor of 10). The event was discovered when the medical technologist questioned the dose and raised a question with the supervisor. The technologist checked the calibration setting of the instrument used to measure the dose and discovered that it was incorrect. The prescribing physician will notify the patient’s doctor, who will contact the patient. Corrective actions taken by the licensee included retraining personnel and adding a check on their administration sheet that requires the technologist to check the instrument calibration setting.

Event Date:  Discovery Date:  Report Date:  
07/22/2005  07/26/2005  07/26/2005

Licensee/Reporting Party Information:  
License Number:  45-01589-01  Name:  VALLEY HEALTH SYSTEM
Docket Number:  03003308  City:  WINCHESTER, VA

Site of Event:  
Site Name:  WINCHESTER, VA

Reference Documents:  
Reference Document Number:  EN41872  Entry Date:  Retraction Date:  Type of Report:  
EN41872  07/27/2005  EVENT NOTIFICATION
Yttrium-90

NMED Item Number: 050235

Narrative: Last Updated: 06/21/2005

The licensee reported that a patient was administered a 1.78 GBq (48 mCi) dose of Y-90 Zevalin; based upon patient weight and platelet count, the intended dose should have been 1.04 GBq (28 mCi). The Zevalin product insert indicates that as a result of the 1.78 GBq (48 mCi) dosage, the patient received an exposure of 107 to 320 cGy (rad) to the red marrow, with a median exposure of 231 cGy (rad). The dose was dispensed as a unit dose by a nuclear pharmacy and administered as received. A written directive, required by Wisconsin regulations, was not prepared for the therapy. The error was not discovered until 4/7/2005 during a licensee review of records. The ordering physician was notified. The State of Wisconsin initiated an investigation at the licensee's facility on 4/11/2005. The licensee suspended use of Y-90 Zevalin and conducted a root cause investigation of the event. A medical consultant was contracted by the State of Wisconsin to provide the State with a medical analysis of the consequences of the event. The patient and referring physician were notified of the event. It was determined that the licensee failed to prepare a written directive prior to administering the Y-90, failed to prevent usage of a dose that differed from the intended dosage by more than 20%, failed to establish appropriate administrative procedures, failed to ensure that radiation safety activities were performed, and failed to instruct individuals working under the supervision of an authorized user of the licensee's written directive procedures. Corrective actions taken by the licensee included writing new policies and procedures and implementing new training programs.

Event Date: 04/05/2005  Discovery Date: 04/07/2005  Report Date: 04/08/2005

License/Reporting Party Information:

License Number: WI-025-1323-01  Name: UNIVERSITY OF WISCONSIN
Docket Number: NA  City: MADISON, WI

Site of Event:

Site Name: MADISON, WI

Reference Documents:

Reference Document Entry Date: Retraction Date: Type of Report:

EN41576  04/13/2005  EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML051040561  04/19/2005  PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN305008  04/19/2005  PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI050006  06/21/2005  AGREEMENT STATE EVENT REPORT

Page 12 of 37
35.400  Iodine-125 Seeds

NMED Item Number: 050640

Narrative:  
The licensee reported that they had found I-125 contamination during the post-operative clean-up of an I-125 prostate seed implant. The licensee indicated that they were not sure if there was a leaking seed implanted into the patient. None of the seeds remaining after the procedure were leaking. A thyroid scan performed on the patient on 9/22/2005 showed that there had been an uptake. Potassium iodide was administered to the patient. The seeds (model ProstaSeed 1125-SL) were distributed by Mantor Brachytherapy and the applicator (model 200TP) was manufactured by MICK. The licensee is performing a dose assessment. This event is being tracked by Alabama Radiation Control as Item Number AL050048.

Event Date:  Discovery Date:  Report Date:
09/22/2005  09/22/2005  09/26/2005

Licensee/Reporting Party Information:
License Number:  NR  Name:  BAPTIST MEDICAL CENTER - PRINCETON
Docket Number:  NA  City:  BIRMINGHAM, AL

Site of Event:
Site Name:  BIRMINGHAM, AL

Reference Documents:
Reference Document Number:  Entry Date:  Retraction Date:  Type of Report:
EN42016  09/29/2005  EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
Narrative: The licensee reported that a patient received a lower dose than prescribed to a portion of the prostate gland during an I-125 prostate gland treatment. The dose differed by greater than 20% of the prescribed dose. The prescribed treatment was for 14,500 cGy (rad) to the prostate gland. The patient received 88 I-125 seeds with an average activity of 11.1 MBq (0.3 mCi) per seed and a total activity of 1.0 GBq (26.8 mCi). Only 16.5% of the intended area of the prostate volume received 14,500 cGy (rad). The anterior 1/3 of the rectum received the prescribed dose in a few spots, but the posterior 2/3 of the rectum did not exceed 10,000 cGy (rad). The cause of the event was an error reading the coordinates on the ultrasound image, which resulted in the needle being inserted in the wrong location. The patient was notified of the error and the treatment was re-performed correctly. The RSO discussed the error with the authorized user and agreed on corrective actions to prevent a recurrence. Corrective actions included procedure modifications to require fluoroscopic imaging for verifying coordinates and confirming needle placement.

Event Date: Discovery Date: Report Date: 11/10/2004 11/10/2004 11/18/2004

Licensee/Reporting Party Information:
License Number: MS-232-02 Name: BAPTIST MEMORIAL HOSPITAL - NORTH MISSISSIPPI
Docket Number: NA City: OXFORD, MS

Site of Event:
Site Name: OXFORD, MS

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41210 11/24/2004 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MS-04-006 12/09/2004 AGREEMENT STATE EVENT REPORT
LTR041209 12/09/2004 AGREEMENT STATE LETTER
LTR050223 02/23/2005 AGREEMENT STATE LETTER
NMED Item Number: 050098

Narrative: The licensee reported that a patient was implanted with 63 I-125 seeds that contained an activity of 13.69 MBq/seed (0.37 mCi/seed) instead of the prescribed 9.99 MBq/seed (0.27 mCi/seed). The licensee ordered I-125 seeds with activities of 9.99 MBq/seed (0.27 mCi/seed) from Anazahealth Corporation (dba Custom Care Pharmacy), but received seeds with activities of 13.69 MBq/seed (0.37 mCi/seed). The order had been placed and confirmed with Anazahealth, but the incorrect seeds were sent for the first of three implants for the patient. The documentation supplied with the order correctly identified that the seeds contained 13.69 MBq/seed (0.37 mCi/seed). As a result of the difference in activity, the patient's dose was approximately 37% more than intended during the first implant procedure. Both the patient and the referring physician were notified of the error. The licensee has implemented actions that would prevent loading seeds of an activity different than prescribed without notification to the manufacturer and licensed medical institution.

Event Date: 02/16/2005  Discovery Date: 02/17/2005  Report Date: 02/17/2005

Licensee/Reporting Party Information:
License Number: 13-17073-01  Name: PORTER VALPARAISO HOSPITAL CAMPUS
Docket Number: 03012150  City: VALPARAISO, IN

Site of Event:
Site Name: VALPARAISO, IN

Reference Documents:
Reference Document Number: EN41416  Entry Date: 02/21/2005  Retraction Date: Type of Report:
LTR050404  04/07/2005  EVENT NOTIFICATION
FL05-034  05/10/2005  NRC LETTER
AGREEMENT STATE EVENT REPORT
NMED Item Number: 050121

Narrative:

The licensee reported that a patient received a permanent brachytherapy seed implant procedure to the prostate, but a number of seeds were mistakenly placed in fatty tissue outside the intended area of treatment. The procedure involved 84 I-125 seeds that contained an activity of 14.8 MBq (0.4 mCi) each. The patient’s prostate received less than 80% of the prescribed dose and the unintended site received more than 50 cGy (rad) and greater than 50% of the prescribed dose. The authorized user notified the patient and will notify the referring physician. The cause of the event was determined to be misidentification of the base of the prostate due to the patient’s size and weight. Corrective actions taken by the licensee included modifying procedures used to locate the prostate to incorporate fluoroscopy, in addition to ultrasonic imaging.

Event Date: 02/24/2005  Discovery Date: 02/25/2005  Report Date: 02/25/2005

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: DURHAM, NC

Reference Documents:

Reference Document Number: EN41443  Entry Date: 02/28/2005  Retraction Date: 04/14/2005  Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR050413  Entry Date: 04/14/2005  Type of Report: NRC LETTER
Reference Document Number: LTR050523  Entry Date: 05/23/2005  Type of Report: NRC LETTER
NMED Item Number: 050176

Last Updated: 04/14/2005

The licensee reported that a patient scheduled for a prostate implant received 83 I-125 seeds, each containing an activity of 11.47 MBq (0.31 mCi), and 15 Pd-103 seeds, each containing an activity of 44.4 MBq (1.2 mCi). The patient was prescribed 98 I-125 seeds. The patient received 98% of the planned dose. The holders for the I-125 seeds and the Pd-103 seeds are similar in shape and size. The Ohio Bureau of Radiation Protection investigated the event on 3/21/2005. Results revealed that two patients were scheduled to receive permanent seed implants for prostate cancer. The sealed source containers for both patients were taken to the operating room. At some point during the procedure, one cartridge containing 15 Pd-103 seeds was implanted into the patient who was to receive I-125 seeds. The patient and referring physician were notified of the event on 3/11/2005. The licensee has instituted a new procedure where only one sealed source container will be taken into the operating room. The staff has received training on the new procedure. The Ohio Bureau of Radiation Protection will periodically inspect the licensee to ensure that the corrective action is implemented and is adequate.

Event Date: 03/11/2005  Discovery Date: 03/11/2005  Report Date: 03/16/2005

Licensee/Reporting Party Information:
License Number: OH-02120850007  Name: MARIETTA MEMORIAL HOSPITAL
Docket Number: NA  City: MARIETTA, OH

Site of Event:
Site Name: MARIETTA, OH

Reference Documents:
Reference Document Number: EN41507  Entry Date: 03/24/2005  Retraction Date: 04/14/2005  Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
Reference Document Number: OH050012  Entry Date: 03/28/2005  Type of Report: AGREEMENT STATE EVENT REPORT
Reference Document Number: OH050012A  Entry Date: 04/14/2005  Type of Report: AGREEMENT STATE EVENT REPORT
NMED Item Number: 050301

Narrative: The licensee reported that a patient received 27% less dose than prescribed during a 29 hour 22 minute gynecological brachytherapy procedure. The patient received 1,825 cGy (rad) instead of the intended 2,500 cGy (rad). The dose was administered using a 2.5 cm solid vaginal cylinder with two Cs-137 sources, each with an activity of 19.56 Radium-milligram equivalent, or 1.81 GBq (48.9 mCi). The planned procedure specified that a 1.93 cm vaginal cylinder be used. This event was discovered on 5/4/2005 during a summary review. The patient was contacted and the licensee planned to administer the remaining dose on 5/5/2005. To prevent recurrence, the licensee will provide additional training to staff.

Event Date: 05/02/2005  
Discovery Date: 05/04/2005  
Report Date: 05/05/2005

Licensee/Reporting Party Information:
License Number: 13-16457-01  
Name: UNION HOSPITAL
Docket Number: 03011072  
City: TERRE HAUTE, IN

Site of Event:
Site Name: TERRE HAUTE, IN

Reference Documents:
Reference Document Number: EN41666  
Entry Date: 05/06/2005  
Retraction Date: 06/13/2005  
Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR050608  
Entry Date: 06/13/2005  
Retraction Date:  
Type of Report: NRC LETTER
Iridium-192 Ribbon

NMED Item Number: 050451

Narrative:

The licensee reported that a dose was delivered to an unintended site during a bile duct carcinoma brachytherapy procedure using 22 Ir-192 sources totaling 1.99 GBq (53.9 mCi) in a seed ribbon. The ribbon was routed through the nasal gastric system to the treatment site. A radiograph was taken of the source placement in the bile duct before releasing the patient to a hospital room. The radiograph verified that the sources were in the prescribed location. On 7/7/2005, a verification image was taken and revealed that the sources had moved approximately 5 cm toward the gastrointestinal tract. The location of the sources was outside of the intended site. An attempt to reposition the source ribbon was unsuccessful. The authorized user amended the written directive and removed the sources.

Event Date: Discovery Date: Report Date:
07/06/2005 07/07/2005 07/08/2005

Licensee/Reporting Party Information:
License Number: WI-073-1342-01 Name: ASPIRUS - WAUSAU HOSPITAL
Docket Number: NA City: WAUSAU, WI

Site of Event:
Site Name: WAUSAU, WI

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41827 07/13/2005 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050711 07/13/2005 NRC LETTER
The licensee reported that a patient being treated for cervical cancer received an incorrect dose distribution. Treatment site A received 821 cGy (rad) instead of the intended 1,643 cGy (rad), while treatment site B received 372 cGy (rad) instead of the intended 465 cGy (rad). This treatment also resulted in higher than intended doses to other locations. The intended doses to the bladder and the rectum were 1,147 cGy (rad) each, but they received 1,448 cGy (rad) and 2,012 cGy (rad), respectively. The 31-hour treatment was delivered using a low dose rate brachytherapy device with a tandem-ovoid applicator. The tandem portion of the applicator required an insert to properly position three sources within the tandem. The licensee cut the insert 6 cm too short, such that when the tandem was positioned in the patient, the three Cs-137 tandem sources (one with an activity of 1,295 MBq [35 mCi], and two with activities of 906.5 MBq [24.5 mCi]) were not extended the proper distance. The ovoid sources were positioned properly. The referring physician and patient were informed of this event. The licensee does not believe that this event will have any adverse effect on the patient. The patient subsequently received a follow-up treatment to deliver the full intended dose to the treatment sites. Corrective actions taken by the licensee included stopping all LDR treatments until all individuals are trained and modifying procedures to incorporate a dual verification system.

Event Date: Discovery Date: Report Date:
01/24/2005 01/27/2005 01/27/2005

Licensee/Reporting Party Information:
License Number: 22-00187-46 Name: MINNESOTA, UNIVERSITY OF
Docket Number: 03000842 City: MINNEAPOLIS, MN

Site of Event:
Site Name: MINNEAPOLIS, MN

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41361 01/28/2005 EVENT NOTIFICATION
ML050280423 01/31/2005 PRELIMINARY NOTIFICATION
PN305002 01/31/2005 PRELIMINARY NOTIFICATION
LTR050404 04/07/2005 NRC LETTER
LTR050422 04/22/2005 NRC LETTER
NMED Item Number: 040744

Narrative: The licensee reported that a 49-year-old female patient did not receive the prescribed dose of 350 cGy (rad) during the first of two treatments for endometrial cancer. A total dose of 700 cGy (rad) was prescribed to be delivered in two fractions using a Nucletron HDR remote afterloading unit (model Microselectron, serial #32250) with an AEA Technology 383 GBq (10.35 Ci) Ir-192 source (model 105.002, serial #D36A-5918) and a 1,500 mm transfer tube. The treatment was to involve a treatment time of 189 seconds with an active length of 5 cm and an indexer position of 1,500 mm. Due to an error on the part of the medical physicist, an indexer position of 995 mm was programmed into the treatment unit. This resulted in the source not entering the patient during the treatment. The distance between the source and the patient’s skin was approximately 35 to 50 cm. The calculated dose to the patient’s skin was between 1.4 and 4.3 cGy (rad). Both the patient and the prescribing physician were informed of the event. A new treatment plan was developed and the patient was rescheduled. Corrective actions taken by the licensee included improving the management oversight of their licensed activities involving therapeutic uses of licensed material and monthly quality assurance reviews by the medical physicist of the therapeutic uses of licensed material. The licensee also established an Interdisciplinary Therapeutic Physics Quality Assurance Committee, which will hold monthly meetings to discuss findings/suggestions, potential radiation safety concerns, initiate measures to provide corrective actions, and verify occurrence of corrective actions taken.

Event Date: 10/11/2004  Discovery Date: 10/11/2004  Report Date: 10/19/2004

Licensee/Reporting Party Information:
License Number: 13-00133-02  Name: SAINT VINCENT HOSPITAL & HEALTH CARE
Docket Number: 03001579  City: INDIANAPOLIS, IN

Site of Event:
Site Name: INDIANAPOLIS, IN

Reference Documents:
Reference Document Number: EN41133  Entry Date: 10/20/2004  Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR041222  Entry Date: 01/14/2005  Type of Report: LICENSEE REPORT
Reference Document Number: LTR050113  Entry Date: 01/14/2005  Type of Report: NRC LETTER
Reference Document Number: LTR050127  Entry Date: 01/27/2005  Type of Report: NRC LETTER
NMED Item Number: 050504

Narrative:

The licensee reported that an 87-year-old male patient received as much as 74% over treatment to a portion of his esophagus and as much as 92% under treatment to another portion of his esophagus. The event was discovered when a simulated plan was calculated on 7/29/2005 to reproduce the initial treatment plan and actual treatment delivered. The patient was being treated for esophageal cancer using a remote high dose rate afterloading unit. The event occurred during the first of two HDR treatments on 7/21/2003. The physician prescribed a dose of 500 cGy (rad) at 0.5 cm from the surface of the naso-gastric tube for an active length of 5.5 cm using a 205.4 GBq (5.551 Ci) Ir-192 source. The treatment plan called for 12 indexer step positions at 5 mm spacing. The medical physicist entered 12 indexer step positions with 2.5 mm spacing and the treatment was delivered. The second fraction was delivered on 8/14/2003. The patient returned to the licensee’s facility on 7/14/2005 for additional treatment. Also see Item Numbers 040229, 050591, 050592, and 050593.

Event Date: 07/21/2003  Discovery Date: 07/29/2005  Report Date: 07/29/2005

Licensee/Reporting Party Information:

License Number: 13-00133-02  Name: SAINT VINCENT HOSPITAL & HEALTH CARE
Docket Number: 03001579  City: INDIANAPOLIS, IN

Site of Event:

Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number: EN41881  Entry Date: 08/01/2005  Retraction Date: Type of Report: EVENT NOTIFICATION
NMED Item Number: 050591

Narrative: The licensee reported that a 70-year-old female patient received an overdose to an unintended site and an underdose to the intended site during three Nucletron high dose rate (HDR) brachytherapy administrations for endometrial cancer. The physician authorized user prescribed a dose of 500 cGy (rad) at 0.5 cm from the surface of a 3-cm diameter vaginal cylinder for an active length of 6 cm on three dates of treatment. The licensee used three Ir-192 sources, each containing an activity of 296.4, 277.9, and 260.1 GBq (8.01, 7.51, and 7.03 Ci). The treatment plan called for 25 indexer step positions at 5.0 mm spacing. The patient received 25 indexer step positions at 2.5 mm spacing. The treatments occurred on 12/19/2002, 12/26/2002, and 1/2/2003. A simulated plan was calculated on 8/23/2005 to reproduce the initial treatment plan and actual treatment delivered. The simulation revealed that the patient may have received as much as 360 cGy (rad) to an unintended site with each fraction, for a total of 1,080 cGy (rad). The simulation further indicated that the intended treatment site may have received 28% underdosage. The patient reported having some excoriation of the unintended site. The licensee will notify the referring physician and the patient of the event. This event was discovered while investigating the event in Item Number 040229. Also see Item Numbers 050504, 050592 and 050593.

Event Date: Discovery Date: Report Date:
12/19/2002 09/07/2005 09/07/2005

Licensee/Reporting Party Information:
License Number: 13-00133-02 Name: SAINT VINCENT HOSPITAL & HEALTH CARE
Docket Number: 03001579 City: INDIANAPOLIS, IN

Site of Event:
Site Name: INDIANAPOLIS, IN

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41973 09/09/2005 EVENT NOTIFICATION
LTR050909 09/09/2005 NRC LETTER
The licensee reported that a 56-year-old female patient received an overdose to an unintended site and an underdose to the intended site during the third of three Nucletron high dose rate (HDR) brachytherapy administrations for cervical cancer. The physician authorized user prescribed a dose of 500 cGy (rad) at 0.5 cm from the surface of a 2.5-cm diameter vaginal cylinder for an active length of 4 cm. The licensee used an Ir-192 source with an activity of 299.3 GBq (8.089 Ci). The treatment plan called for 17 indexer step positions at 2.5 mm spacing. The medical event occurred on 12/18/2002. For the third and final fraction the medical physicist entered 17 indexer step positions with 10 mm spacing rather than 2.5 mm spacing. A simulated plan was calculated on 8/23/2005 to reproduce the initial treatment plan and actual treatment delivered. The simulation revealed that the patient may have received as much as 200 cGy (rad) to an unintended site. The simulation further indicates that the intended treatment site may have received 60% underdosage. For the entire course of treatment, the calculated dose through simulation indicates that 1,200 cGy (rad) rather than 1,500 cGy (rad) was delivered to the intended site. This event was discovered while investigating the event in Item Number 040229. Also see Item Numbers 050504, 050591 and 050593.
NMED Item Number: 050593

Narrative: The licensee reported that an 85-year-old female patient received an overdose to an unintended site and an underdose to the intended site during the first of three Nucletron high dose rate (HDR) brachytherapy administrations for cervical cancer. The physician authorized user prescribed a dose of 500 cGy (rad) at 0.5 cm from the surface of a 2-cm diameter vaginal cylinder for an active length of 6 cm. The licensee used an Ir-192 source with an activity of 175.4 GBq (4.74 Ci). The treatment plan called for 13 indexer step positions at 5 mm spacing. Instead, the medical physicist entered a spacing of 2.5 mm for the first fraction. The medical event occurred on 8/7/2003. The second and third fractions occurred without incident. A simulated plan was calculated on 8/23/2005 to reproduce the initial treatment plan and actual treatment delivered. The simulation revealed that the patient may have received as much as 800 cGy (rad) or 60% overdose to the proximal portion of the intended site and as much as 280 cGy (rad) or 44% underdose to the distal portion of the intended site. The intended site was to receive a dose of 500 cGy (rad) for three fractions for a total of 1,500 cGy (rad). The calculated simulation revealed the proximal site received 1,800 cGy (rad) or 20% overdose and the distal site received 1,280 cGy (rad) or 15% underdose. This event was discovered while investigating the event in Item Number 040229. Also see Item Numbers 050504, 050591 and 050592.

Event Date: 08/07/2003  Discovery Date: 09/07/2005  Report Date: 09/07/2005

Licensee/Reporting Party Information:
License Number: 13-00133-02  Name: SAINT VINCENT HOSPITAL & HEALTH CARE
Docket Number: 03001579  City: INDIANAPOLIS, IN

Site of Event:
Site Name: INDIANAPOLIS, IN

Reference Documents:
Reference Document Number: EN41973  Entry Date: 09/09/2005  Retraction Date: 09/09/2005  Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR050909  Entry Date: 09/09/2005  Retraction Date: 09/09/2005  Type of Report: NRC LETTER
NMED Item Number: 050642

Narrative:

The licensee reported that a 62-year-old female patient received a dose of 500 cGy (rad) to the wrong location during an esophageal HDR brachytherapy treatment. The patient was treated with a Nucletron HDR brachytherapy remote afterloader and an Ir-192 source with an activity of 314.1 GBq (8.49 Ci). The physician prescribed a dose of 500 cGy (rad) at 0.5 cm from the surface of the naso-gastric tube for an active length of 8 cm. The treatment plan called for 17 indexer step positions at 5 mm spacing to begin at dwell position 23 and terminating at dwell position 39. The medical physicist entered 17 indexer step positions with 5 mm spacing at dwell positions 1 through 17 and the treatment was delivered. The dose delivered to the unintended site was 500 cGy (rad) while the intended treatment site was not treated. The event was discovered as a result of a retrospective review.

Event Date: 03/11/2004  
Discovery Date: 09/28/2005  
Report Date: 09/28/2005

Licensee/Reporting Party Information:

License Number: 13-00133-02  
Name: SAINT VINCENT HOSPITAL & HEALTH CARE  
Docket Number: 03001579  
City: INDIANAPOLIS, IN

Site of Event:

Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number: EN42023  
Enter Date: 09/29/2005  
Retraction Date:  
Type of Report: EVENT NOTIFICATION
The licensee reported a medical event involving a male patient receiving a palliative treatment for metastatic disease, using a Nucletron Corporation HDR brachytherapy unit (model 105.999, serial #31062) with an Ir-192 source (model 105.002, serial #D36A-7277) containing an activity of 252 GBq (6.81 Ci). The patient was prescribed to receive three palliative fractions to the left bronchus using a special catheter separately placed, imaged, and digitized for each fraction occurring approximately a week apart. The intended dose for each fraction was 700 cGy (rad). The first fraction was delivered as prescribed. During the second fraction, the catheter was in a slightly different location with the left bronchus than in the first fraction. A reference distance of 995 mm was specified at the first digitized treatment position. The reference distance should have been 965 mm at the first digitized treatment position. A 3 cm length of the left bronchus received 640 to 1,860 cGy (rad) more at 0.5 cm depth than would have been received from planned proximity to the source. That same 3 cm length received 254 to 662 cGy (rad) more at 1 cm depth than would have been received from the planned proximity. A 3 cm length of the 4 cm region intended for treatment received up to 600 cGy (rad) less than the intended dose. The patient and referring physician were notified on 8/11/2005. The physician decided not to alter the patient’s treatment plan for the third fraction or attempt to compensate for the lack of dose at the proximal end of the intended region. The cause of the event was determined to be insufficient time to insure adequate preparation and verification for a non-typical HDR treatment. Corrective actions taken by the licensee included adding a question addressing the reference distance to the second check of the procedure.

Event Date: Discovery Date: Report Date:
08/04/2005 08/04/2005 08/10/2005

Licensee/Reporting Party Information:
License Number: UT-18000-01 Name: UTAH, UNIVERSITY OF
Docket Number: NA City: SALT LAKE CITY, UT

Site of Event:
Site Name: SALT LAKE CITY, UT

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41925 08/22/2005 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
UT050006 09/07/2005 AGREEMENT STATE EVENT REPORT
NMED Item Number: 050560

Narrative:

The licensee reported that a patient received 1,451 cGy (rad) instead of the intended 550 cGy (rad) during the first of two fractions for vaginal cancer treatment. The patient was scheduled to receive 1,100 cGy (rad) in two fractions during remote high dose rate afterloader treatment using Ir-192. The first fraction was oriented interior 4.5 cm, resulting in a dose of 164% greater than intended. The second fraction was not administered and the patient is not returning for further treatment.

Event Date: Discovery Date: Report Date:
08/15/2005 08/15/2005 08/16/2005

Licensee/Reporting Party Information:

License Number: TX-L00384-004 Name: UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
Docket Number: NA City: DALLAS, TX

Site of Event:
Site Name: DALLAS, TX

Reference Documents:

Reference Document Number: TX-I-8253 Entry Date: Retraction Date: Type of Report:
08/23/2005 08/23/2005 AGREEMENT STATE EVENT REPORT
EN41932 08/23/2005 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
The licensee (dba Brown Cancer Center) reported that a patient received the wrong dose to the intended treatment site during an HDR procedure using a 3.0 cm vaginal cylinder. The patient was prescribed to receive 750 cGy (rad) to the site of interest. The catheter was placed in position under the supervision of the attending physician. When the setup was complete, and upon leaving the room, the resident physician noticed that the catheter was draped around the patient’s foot as it ran from the cylinder to the HDR machine. The resident physician undraped the catheter and then left the room. The treatment ran for the scheduled 5.5 minutes. After the treatment was complete, the medical physicist removed the catheter. He noticed that the catheter was not fully inserted into the cylinder as required and estimated that it had been withdrawn from the desired location by approximately 15 cm. The treatment was the second of three prescribed treatments. The event occurred due to the lack of a positive mechanical lock of the HDR catheter to metal guide insert tube. The system uses a movable nylon collar surrounding the catheter, which is slid into position once the catheter is placed into the metal guide insert tube. A nut is then screwed over the nylon collar forming a compression fitting. The event may have occurred when the resident physician undraped the catheter from around the patient’s foot. The manufacture also offers a different type of collar/nut compression fitting that uses a stainless steel collar that is glued onto the catheter at the appropriate distance. The licensee will use the alternate compression fitting system henceforth. Additionally, the catheter is now length/position marked and is checked by both the physician and the physicist prior to treatment and upon completion of treatment. The patient and referring physician were informed of the event. The patient was also informed that the second treatment would not be repeated. With the source offset by 15 cm, the delivered dose would have been 4 cGy (rad) to the intended site. Assuming that the source was approximately 2 cm exterior to the vagina, the dose to the labia would have been 100 cGy (rad). The INL has requested additional information for this event.

Event Date: 01/18/2005  Discovery Date: 01/18/2005  Report Date: 02/03/2005

Licensee/Reporting Party Information:
License Number: KY-202-029-22  Name: UNIVERSITY OF LOUISVILLE
Docket Number: NA  City: LOUISVILLE, KY

Site of Event:
Site Name: LOUISVILLE, KY

Reference Documents:
Reference Document Number: EN41399  Entry Date: 02/15/2005  Retraction Date: 02/15/2005  Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
The licensee reported that a patient received 2,756 cGy (rad – worse case scenario) instead of the prescribed 500 cGy (rad) at one dwell position inside the tracheotomy tube during treatment for larynx cancer. The event involved a Varian Medical Systems HDR brachytherapy unit (model GammaMed Plus, serial #E159) with a sealed source (model GammaMed 232, serial #24-07-445-004-082504-11622-71) that contained Ir-192 with an activity of 244.2 GBq (6.6 Ci). The treatment plan called for four fractions. An error was discovered prior to the third fraction. The prescribing physician stopped the treatment until dosimetry information was completed. The error involved a computer software program and the use of a circular tool to mark the treatment site; the diameter of the tool was used instead of the radius. As a result, the area treated was 2 cm away from the defined locus instead of 1 cm. The prescribed dose was 500 cGy (rad) to a length of 11 cm. The worse case scenario was that the patient received 2,756 cGy (rad) at 1 of 23 dwell positions along the 11 cm treatment length. The dose delivered would have been 451% greater than the prescribed dose at that position. The Utah Division of Radiation Control investigated the event on 11/3/2004. The impact of the additional dose is probable acute radiation effects and possible late or chronic toxicities. Unrelated to the event, the patient expired. The licensee suggested that the software manufacturer should label the dimension associated with the circle contouring tool with the word “radius.” The licensee will measure the distance on the brachyvision hard copy output with a ruler to confirm that the distance is entered correctly. The licensee also modified the HDR dose check program so that, in addition to confirming the doses to coordinates entered into the brachyvision program, user specified point coordinates may be manually entered into the check program and compared to what is calculated.

Event Date: Discovery Date: Report Date: 10/26/2004 10/26/2004 10/28/2004

Licensee/Reporting Party Information:
License Number: UT-18001-02 Name: LDS HOSPITAL
Docket Number: NA City: SALT LAKE CITY, UT

Site of Event:
Site Name: SALT LAKE CITY, UT

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
EN41162 11/03/2004 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
UT040004 12/01/2004 AGREEMENT STATE EVENT REPORT
The licensee reported a medical event involving a breast cancer patient treated with a Varian Medical Systems remote high dose rate afterloading unit (model VS2000) and Ir-192 source with an activity of 277.5 GBq (7.5 Ci). Ten fractional treatments were administered from 1/24 to 1/28/2005. The prescribed dose was 350 cGy/fraction (rad/fraction) at 1 cm from the surface of the balloon, with two fractions per day, for a total of 3500 cGy. The patient returned on 3/18/2005 complaining of pain in her breast. A moist desquamation was noted at the breast surface where the catheter had entered the breast. Re-evaluation of the treatment plan revealed that the wrong catheter length parameter (source travel distance) was used during the treatment. The Ir-192 source was implanted 8 cm short of its planned location, near the catheter breast entry point. Dosimetry reconstruction indicated that the maximum dose delivered to tissue (area of 2.5 by 2.1 by 0.5 cm) at the entrance point was 7,000 cGy (rad). Corrective actions taken by the licensee included instituting a QA checklist requiring two persons to verify treatment parameter determinations and correct treatment computer inputs (and to document their verifications), to include the catheter length parameter. Additionally, normal catheter length parameters for standard treatments will be documented and checked before treatments. Staff will be trained in these new procedures before using the HDR unit.

Event Date: Discovery Date: Report Date: 01/24/2005 03/18/2005 04/08/2005

Licensee/Reporting Party Information:
License Number: CA-2652-30 Name: SADDLEBACK MEMORIAL HOSPITAL
Docket Number: NA City: LAGUNA HILLS, CA

Site of Event:
Site Name: LAGUNA HILLS, CA

Reference Documents:
Reference Document Number: Entry Date: Retraction Date: Type of Report:
CA-XCA716 04/13/2005 AGREEMENT STATE EVENT REPORT
EN41580 04/13/2005 EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050414 04/19/2005 AGREEMENT STATE LETTER
LTR050720 07/21/2005 AGREEMENT STATE LETTER
NMED Item Number: 050104

Narrative: The licensee reported that a patient received a radiation dose that was greater than 50% of the expected dose to a site outside of the intended treatment volume during a gamma knife treatment. Elekta, Incorporated, manufactured the gamma knife unit (model 24001, type C, serial #4149), which contained 119.6 TBq (3231.5 Ci) of Co-60. The patient was prescribed to receive 1,800 cGy (rad) to the intended treatment volume. During the process of manually programming the positioning system, the Y and Z coordinates were transposed. The error was not noticed during the double check of the treatment coordinates. As a result, the unintended site received an estimated dose of 506 cGy (rad) instead of the intended 40 cGy (rad). The volume of the unintended treatment site was 0.7 cm³ and the treatment duration was 2.42 minutes. The prescribed dose of 1,800 cGy (rad) was delivered and the patient’s treatment was completed. The referring physician was notified of the event. State of Wisconsin Radiation Protection Section personnel were dispatched on 2/18/2005 to investigate the event. The cause of the event was determined to be the licensee’s failure to conduct an adequate verification of the patient positioning parameters prior to administration. Contributing factors included: the individual who placed the Y/Z trunnion bar onto the head frame reversed their usual sequence of setting the Y and Z settings; and the independent coordinate verification by multiple individuals failed to detect the incorrect coordinates. The licensee has implemented additional procedural steps requiring more attention to detail and confirmation of patient positioning parameters on the frame.

Event Date: 02/16/2005  Discovery Date: 02/16/2005  Report Date: 02/17/2005

Licensee/Reporting Party Information:
License Number: WI-141-1162-01  Name: MARSHFIELD CLINIC
Docket Number: NA  City: MARSHFIELD, WI

Site of Event:
Site Name: MARSHFIELD, WI

Reference Documents:
Reference Document Number: EN41420  Entry Date: 02/23/2005  Retraction Date:  Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI050003  04/14/2005  AGREEMENT STATE EVENT REPORT
NMED Item Number: 050529

Narrative:

The licensee reported that a patient received 50% less dose than prescribed to two of seven lesions during a gamma knife treatment. The Elekta gamma knife unit (model 24001) contained several Co-60 sources (Eleckta model 43047) with a combined activity of 259 TBq (7,000 Ci). The patient was prescribed 1,500 cGy (rad) per lesion, but only received 750 cGy (rad) to two lesions. The event was discovered on 8/3/2005 during an internal audit of treatments. An investigation did not identify a problem with the gamma knife or the dose programs involved in planning. The cause of the event was determined to be personnel lack of knowledge concerning the treatment planning software and communication difficulties between the physicist and neurologist. Correction actions taken by the licensee included additional education in treatment planning and reinforcement of the necessity of communications between personnel.

Event Date: 07/18/2005  
Discovery Date: 08/03/2005  
Report Date: 08/03/2005

Licensee/Reporting Party Information:

License Number: RI-7A-051-02  
Docket Number: NA  
Name: RHODE ISLAND HOSPITAL  
City: PROVIDENCE, RI

Site of Event:

Site Name: PROVIDENCE, RI

Reference Documents:

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The licensee reported that a patient only received two of the scheduled five gamma knife treatments to a single tumor in the head. Prior to the third treatment, it was determined that the shield jaws on the Leksell gamma knife (manufactured by Elekta Instrument AB, model Leksell 23005 type B) were stuck closed and the gamma knife was considered inoperable. The patient had inadvertently knocked the metal clip that holds a microphone to the patient couch off and it fell into the unit’s shielding. The microswitches inside the unit would not allow the jaws of the shielding to open. Consequently, the patient did not receive the final three prescribed treatments. The licensee has requested repairs on the gamma knife from an authorized service representative. The licensee plans to continue treatment of the patient pending repairs.
NMED Item Number: 050237

Narrative:
The licensee reported that a patient being treated for spinal cord compression using a teletherapy device received a dose that was less than prescribed. The teletherapy device (model T1000, serial #21) was manufactured by Theratronics and contained a Co-60 source (model C-146, serial #S-5336) with an activity of 292.3 TBq (7,900 Ci). The patient was treated on 4/9 and 4/10/2005. The written directive prescribed a dose of 500 cGy (rad) in two equal daily fractions for a total dose of 1,000 cGy (rad). The treatment time for the fractions on 4/9 and 4/10/2005 was miscalculated and doses of 330 cGy (rad) were administered for a total dose of 660 cGy (rad). An additional fraction of 200 cGy (rad) will be administered to the patient. Corrective actions taken by the licensee included staff retraining, development of new forms, and designation of after hours on-call physics/dosimetry staff support.

Event Date: 04/09/2005  Discovery Date: 04/12/2005  Report Date: 04/12/2005

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: DALLAS, TX

Reference Documents:
Reference Document Number: EN41592  Entry Date: 04/13/2005  Retraction Date: Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR050628  Entry Date: 06/28/2005  Type of Report: NRC LETTER
The licensee reported that a patient received 75% of the prescribed 2 GBq (54 mCi) of Y-90 Siraspheres (microspheres) for liver treatment. Backpressure from the liver catheter popped the tubing off the three-way stopcock and approximately 25% of the material was spilled before the tubing could be re-attached. A lower flow-rate was used and no further problems were encountered. The spill was contained within the case around the stopcock. The Florida Department of Health continues to investigate this event.

Event Date: 05/25/2005  Discovery Date: 05/25/2005  Report Date: 06/01/2005

Licensee/Reporting Party Information:
License Number: FL-0031-1  Name: UNIVERSITY OF FLORIDA SHANDS HOSPITAL
Docket Number: NA  City: GAINSVILLE, FL

Site of Event:
Site Name: GAINSVILLE, FL

Reference Documents:
Reference Document Number: EN41756  Entry Date: 06/13/2005  Retraction Date: 06/27/2005  Type of Report: EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
Reference Document Number: FL05-086  Entry Date: 06/27/2005  Type of Report: AGREEMENT STATE EVENT REPORT
NMED Item Number: 050503

Last Updated: 08/11/2005

Narrative:
The licensee reported that a patient received less dose than prescribed during a SIR-sphere treatment for liver cancer. SIR-sphere treatments utilize radioactive microspheres that contain Y-90. The first of two scheduled treatments prescribed 0.46 GBq (12.4 mCi) of Y-90. Due to difficulty in determining how much of the Y-90 remained in the vial and the injection catheter, the licensee determined that only 0.25 GBq (6.8 mCi) was administered in the first treatment. The licensee determined that the fraction of Y-90 administered differs from the prescribed dose by 46%. The patient will be given a second treatment that takes into consideration the actual amount administered on the first treatment. The NRC determined that the event involved separate treatments, not two fractions of a treatment.

Event Date: 07/26/2005  Discovery Date: 07/26/2005  Report Date: 07/29/2005

Licensee/Reporting Party Information:
License Number: 37-07939-01  Name: SAINT LUKES HOSPITAL
Docket Number: 03003100  City: BETHLEHEM, PA

Site of Event:
Site Name: BETHLEHEM, PA

Reference Documents:
Reference Document Number: EN41880  Entry Date: 08/01/2005  Retraction Date: 08/11/2005  Type of Report: EVENT NOTIFICATION
Reference Document Number: LTR050811  Type of Report: NRC LETTER
Review of the Medical Events Definition Commission Paper

Ronald E. Zehet, Ph.D.
NMSS/ININS

ACMUI Meeting, 10/26/05

Background

- 11/03 - ACMUI recommends D90 as criteria for prostate brachytherapy underdosing
- 3/04 - Commission directs staff to consider basis and adequacy of medical event definitions and communicating associated risks to the public
- 10/04 to 7/05 - ACMUI develops recommendations on the issues, for staff

ACMUI Considerations/Recommendations

Categories/Issues

- Basis for the +/-20% of prescribed dose reporting threshold for medical events
- Recommendations concerning the current definition of medical event
- Improving public understanding of the risks associated with medical events
ACMUI Recommendations/Staff Responses

Basis for the +/-20% of prescribed dose reporting threshold for medical events:

- Retain the +/-20% delivered dose variation from prescription as an appropriate threshold for medical event reporting for all modalities except permanent implant brachytherapy.

- Staff endorses and supports this ACMUI recommendation.

ACMUI Recommendations/Staff Responses

Basis for the +/-20% of prescribed dose reporting threshold for medical events:

- ACMUI enforces Medical events (MEs) should not be treated by NRC as surrogates or harbinger of public harm, or even necessity of increased probability of patient harm. MEs should be considered as a quality assurance (QA) performance index indicative of technical or QA problems in accurately realizing AUS clinical intentions.

- Staff endorses and supports this ACMUI position, which is consistent with NRC's previously stated position.

ACMUI Recommendations/Staff Responses

For permanent implant brachytherapy, for reformulating the medical event reporting rule and associated definitions:

- Staff endorses and supports all of the following ACMUI recommendations for this item.

- For all permanent implants, MEs should be defined in terms of the total source strength implanted in the treatment site, not in terms of absorbed dose.
ACMUI Recommendations/Staff Responses

For permanent implant brachytherapy, for reformulating the medical event reporting rule and associated definitions:

- Any implant in which the total source strength implanted in the treatment site deviates from the written directive (WD) by more than 20% (in either direction) should be classified as an ME. As in the current medical event rule, ACMUI intends that seed migration be specifically excluded as grounds for a treatment-site accuracy ME.

ACMUI Recommendations/Staff Responses

For permanent implant brachytherapy, for reformulating the medical event reporting rule and associated definitions:

- Implants in which more than 20% of the total source strength documented in the preimplantation WD is implanted in tissue or organs adjacent to the treatment site (within 3 cm [1.2 in.] of the treatment site boundary) should be classified as MEs. Seeds that were correctly implanted but subsequently migrated are excluded as grounds for an ME.

ACMUI Recommendations/Staff Responses

For permanent implant brachytherapy, for reformulating the medical event reporting rule and associated definitions:

- Implants should be classified as MEs if (i) sealed radioactive sources (seeds) are implanted in distant (beyond 3 cm [1.2 in.] from the treatment site boundary) tissue or organs, (ii) the excess dose to the distant tissue or or organ exceeds 0.5 Sv (50 rem), and (iii) the excess dose to the tissue or organ is at least 50% greater than the dose that would have been delivered had the seeds been implanted in the correct tissue volume. Seeds that were correctly implanted but subsequently migrated are excluded as grounds for an ME.
ACMUI Recommendations/Staff Responses

1. For permanent implant brachytherapy, for reformatting the medical event reporting rule and associated definitions:

   - The AU is to complete any revisions to the WD for permanent implants to account for any medically necessary plan adaptations (read, per §3.40, complete the WD) before the patient is released from licensee control following the implantation procedure and immediate post-operative period.

ACMUI Recommendations/Staff Responses

1. For permanent implant brachytherapy, for reformatting the medical event reporting rule and associated definitions:

   - An implant is a ME if the dose calculations used to determine the total source strength documented in the WD are in error by more than 20% in either direction.

   - Staff endorses and supports all of the above ACMUI recommendations for this item.

ACMUI Recommendations/Staff Responses

1. For improving public understanding of the risks associated with medical events:

   - The patient reporting requirement 35.314(f) should be amended to require informing the patient and/or family and relatives only if the licensee determines that the ME may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient’s future medical treatment decisions.

   - Staff does not support this ACMUI recommendation because the Commission has repeatedly stated and endorsed its position that a patient or human research subject involved in a medical event should be notified of the occurrence.
ACMUI Recommendations/Staff Responses
For improving public understanding of the risks associated with medical events:

- NRC is encouraged to develop a more graded and risk-informed process for responding to ME reports that ties the intensity and immediacy of its inspection response to individual patient risk and public health implications of the event. For example, for a relatively minor ME, where public health and safety is not in question, NRC could minimize reactive inspection of the licensee pending a satisfactory investigation and quality improvement response on the part of the licensee.

- Staff does not support this ACMUI recommendation because NRC's approach to medical event assessment is already graded and risk-informed.
Staff Recommendations

For improving public understanding of the risks associated with medical events

- Publicize that NRC's medical event definitions provide thresholds for identifying events that are indicative of technical or QA problems in accurately realizing the clinical intentions (prescriptions) of AUs.
- Publicize that thresholds in NRC's medical event definitions, if exceeded, are not necessarily surrogates or harbingers of patient harm, or even of increased probability of patient harm.

Review of the Medical Events Definition Commission Paper

Questions?
Guidance on I-125 & Pd-103 Therapeutic Seeds Used as Markers in Breast Cancer Tumors

Robert Gallagher
Chairman, National Materials Program Pilot 4
Supervisor, Materials Inspection and Enforcement Branch
Massachusetts Radiation Control Program

INTRODUCTION

- Brief description of NMP Pilot 4
  - One of 5 pilot projects under NMP
  - Goal: Have an Agreement State, or group of Agreement States, assume responsibility for development of licensing and inspection guidance
  - Led by OAS, composed of 4 State members and 1 NRC Regional member.

How Radioactive Seed Localization was Selected

- Reviewed regulatory needs identified by NMP Pilot 1 Working Group;
- Surveyed Agreement States, NRC HQ and Regional offices;
- Contacted major medical institutions in the United States
Why Radioactive Seed Localization was Selected

- Iodine-125 and Palladium-103 are AEA materials, regulated by both NRC and Agreement States;
- Use in this application does not fit under 10 CFR 35.200 or 35.400;
- Therefore use does fit into 10 CFR 35.1000, Other medical uses;
- No review by the NRC or an Agreement State has been performed.

Description of Radioactive Seed Localization (RSL)

- Calls for the use of currently available seeds previously approved for permanent implantation;
- I-125 seed, typically 200-300 μCi/seed, implanted into breast lesion using 18-gauge needle;
- Seeds are then located using hand-held gamma probe by surgeon and surgically removed;

Description of Radioactive Seed Localization (RSL) - continued

- Seed may be removed from specimen in surgery;
- Or specimen with seed may be sent to pathology for removal of seed and analysis of the tissue;
- Seeds are then disposed of per 10 CFR 35.92 or equivalent Agreement State regulations.
Elements of Licensing Guidance for RSL

Locations of Use

- Facility diagrams – should include rooms where seeds will be:
  - Stored when not in use;
  - Implanted into patient;
  - Explanted from the patient;
  - Removed from the tissue sample; and
  - Stored for decay.

Elements of Licensing Guidance for RSL continued

- Authorized Users - Identify all authorized users and document his or her training. Considered qualified if they meet either the criteria:
  - 10 CFR 3.4490
  - 10 CFR 35.290 and preceptorship training by a 35.490 AU
  to include:
    - work experience in ordering, receiving, unpacking;
    - performing surveys using proper instrumentation;
    - Implanting and removing brachytherapy sources;
    - emergency procedures, administrative controls, and
      inventories

Safety Precautions for RSL

- Licensees should provide procedures addressing:
  - Safety procedures and instructions, including survey procedures;
  - Identifying individuals who must be present;
  - Source accountability and leak testing;
  - Verification of source activity, either by assay prior to implantation or by manufacturer certification
Safety Precautions for RSL

- Applicant should supply procedures for responding to an abnormal situation, such as a source ruptured or cut during removal, which should include:
  - Monitoring area using appropriate instruments;
  - Restricting access and posting;
  - Description of equipment and process for recovery of any dropped or mishandled seeds;
  - Patient follow-up should they not return;
  - Description of length of time seeds remain in patient;
  - Notification of medical emergency of patient prior to removal.

Change in Physical Conditions of Use

- If the conditions of use exceed those stated in the SS&D certificate, limited scope licensee will have to amend its license to allow for use under new conditions;
- Some states will not allow variations unless the original SS&D registration is amended or custom evaluation is performed.
Status of RSL Guidance Development

- Received comments from NRC and OAS, which were reviewed by the Working Group and incorporated into the final document;
- Draft licensing and inspection documents submitted to NRC in Sept., 2004 as part of the Final Report of the NMP Pilot Projects;
- Final draft of RSL Licensing Guidance submitted to OAS Board for their review and approval in Sept. of 2005;
- OAS Board approval received and sent to AS Directors and NRC for comment. Comment period will end Nov. 15, 2005.
Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions

Purpose

Radioactive seed localization (RSL) uses currently available radioactive seeds previously approved for the treatment of cancerous tumors. For instance, iodine-125 and palladium-103 titanium seeds\(^1\) typically between 200 - 300 \(\mu\)Ci/seed, are implanted into a breast lesion using a standard 18-gauge needle. These seeds are normally implanted within mammography or ultrasound suites and removed within surgical suites between 2 and 5 days post implantation. Use of more seeds or different implant locations may arise in the future. RSL differs from current location procedures where a wire is implanted into the lesion site and excised along with the affected tissue. The radioactive seed(s) can be easily located with a hand-held gamma probe (using a technique with which surgeons are familiar because of its similarity to sentinel lymph node biopsy and radioguided parathyroidectomy) and surgically removed with minimal injury to non-affected tissue. The seed(s) may be removed from the tissue specimen in surgery, or the tissue specimen with the seed(s) can be sent to pathology for removal of the seed and analysis of the tissue. The seed or seed are then disposed of in accordance with 10 CFR 35.92 or the equivalent Agreement State regulations.

Licensing Guidance

Use of these iodine-125 and palladium-103 seeds are currently regulated under 10 CFR 35.400: “Use of sources for manual brachytherapy” and the equivalent Agreement State regulations. In this application, the iodine or palladium seeds are implanted for localization by an authorized user and are not intended to deliver a therapeutic dose to tissue. This application is not regulated by 10 CFR 35.500: Use of sealed sources for diagnosis, because these sources are currently not approved for diagnostic use in the sealed source and device registry. Therefore, use of these seeds for RSL procedures will be regulated under 10 CFR 35.1000: Other medical uses and the equivalent Agreement State regulations.

This guidance is intended to address cases where the locations of implant, excision, and recovery of the seed(s) are all governed by the same radioactive materials license. In the case of a facility intending to use an external pathology laboratory not currently listed on their materials license, the license reviewer

\(^{1}\) Multiple seeds may be used to define the margins of irregularly shaped lesions.
should request the external laboratory submit an application for a new license.

This guidance represents one means acceptable to the NRC and Agreement State staff of complying with regulations and is not intended to be the only means of satisfying requirements for a license. Therefore, to meet the requirements of 10 CFR 35.12 or the equivalent Agreement State regulations, unless specifically required by regulation, the applicant must provide the information requested below or submit alternative commitments that will be reviewed by the NRC or Agreement State to determine whether they meet regulatory requirements. In addition, the commitments contained therein will be reviewed during routine inspections.

Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35 or the equivalent Agreement State regulations (e.g., applicable section of Subparts A, B, C, L, and M). For instance, 10 CFR 35.67 contains requirements for leak testing sealed sources, 10 CFR 35.75 contains provisions for release of patients containing implants, and 10 CFR 35.3045 contains requirements for reporting events when the effective dose equivalent of 50 rem to an organ or tissue is exceeded.

General

Radionuclides, Form, Possession Limits, and Purpose of Use: Identify the radionuclides, chemical/physical form, maximum quantity per treatment and total, and purpose of use. For example, the following provides the format for an acceptable response:

**Radionuclides, Form, Possession Limits**

Iodine-125 or Palladium-103. Sealed sources (manufacturer and model number to be supplied by licensee; 0.30 millicuries per source; 1.5 millicuries maximum per treatment and 15 millicuries total);

**Purpose of Use**

For use as temporary implants to localize non-palpable lesions.

Facility Diagram: Submit a description of the location where the radioactive sources will be used, administered, and stored. The description should include the rooms where the seeds will be:
• Stored when not in use;
• Implanted into the patient;
(Facility Diagram requirements continues)
• Explanted from the patient;
• Removed from the tissue sample; and
• Stored for decay.

If the tissues sent to pathology will still contain the seed(s), or more than 1 microcurie of iodine-125 or 100 microcuries of palladium-103 contamination from a leaking source, the licensee needs to clarify whether the tissues will be processed in its own pathology laboratory or sent to an external pathology laboratory. Provide a diagram of these locations, in addition to an overall floor plan that shows the proximity of these locations of use to other occupied areas of the building or floor. (30.33(a)(2); 35.12(b)(1)).

Authorized Users: Identify each authorized user and document his or her training and experience to the use iodine-125 or palladium-103 seeds for the RSL procedure. The authorized user will be considered qualified for implantation, localization and removal of the seeds if the individual meets the criterion in:

10 CFR 35.490 (or before October 24, 2005, the requirements in 10 CFR 35.940); or

10 CFR 35.290 (or before October 24, 2005, the requirements in 10 CFR 35.920) and preceptorship training by a 10 CFR 35.490 authorized user. Preceptorship training should include the following:

• Work experience which includes at least 3 cases, wherein the authorized user ordered, received, and unpacked radioactive materials safely;
• Work experience that includes performing the related radiation surveys using the appropriate instrumentation;
• Work experience that includes preparing, implanting, and removing RSL sources safely;
• Work experience that includes using emergency procedures;
• Work experience that includes reviewing and understanding the administrative controls in place to prevent a medical event; and,
• Work experience in maintaining running inventories of radioactive material on hand.

General surgeons, working under the supervision of an authorized user described
above, who locate and remove the tissue containing the seed(s) should complete radiation safety training that includes:

- Performing the related radiation surveys using appropriate instrumentation;
- Preparing, implanting, and safely removing brachytherapy sources; and
- Emergency procedures, including how to respond to a leaking source.

This training shall be provided by the authorized user described above or the Radiation Safety Officer, as applicable.

Pathology personnel handling specimens containing radioactive material should be instructed in the radiation safety aspects of safely handling the seeds. Radiation safety training should include:

- Minimizing time handling the specimen;
- Using an appropriate survey instrument to perform surveys of hands and work area following handling of the specimen;
- Emergency procedures to be followed in the event contamination is identified;
- Accountability, security of the seeds post-implantation; and,
- Proper disposal of the seeds and/or specimens containing the seed(s).

**Records**

Because the iodine and palladium sealed sources are temporarily implanted, the applicant may simplify its submission by confirming that it will:

Meet the brachytherapy requirements appropriate for a temporary implant in 10 CFR Part 35, Subpart F, “Manual Brachytherapy,” Subpart L, “Record” and Subpart M, “Reports.” (35.310, 35.404, 35.410, 35.406, 35.2404, 35.2406 (a) and (b), and 35.3045).

**Safety Precautions and Instructions for Iodine-125 and Palladium-103 Seed Localization for Non-Palpable Lesions**

Describe the radiation safety program for all departments involved in the RSL procedure, including the pathology laboratory, addressing:
Safety procedures and instructions, including receipt and survey procedures;
Specifying the individuals that must be physically present during implantation and explantation;
Source accountability, including maintaining a record of brachytherapy source accountability, and leak testing;
Calibration measurements of the brachytherapy sources;
Procedures to minimize puncturing the seed(s);
Surveys to detect leakage or lost seeds;
Storage;
Security; and
Disposal.

Surveys must be performed after source implant and removal (35.404 and record keeping requirements in 35.2404 and 35.2310, or equivalent Agreement State regulations). If the licensee intends to transfer the radioactive tissue samples to an outside pathology laboratory, the licensee must submit a description of the program to ensure the samples are transferred to an NRC or Agreement State licensed laboratory authorized to receive the seeds or radioactive tissue. The package must also be properly prepared for shipping.

Provide a copy of the written emergency procedures for responding to an abnormal situation to include:

- Instructions for responding to a source ruptured (e.g., cut by scalpel) during surgical removal to include procedures for retrieval of leaking/cut sources and mitigation of the I-125 uptake and decontamination of the patient and area from the ruptured source;
- Instructions to pathology personnel for responding to a leaking/cut and decontamination of personnel and the area;
- The process for restricting access to and posting of the implantation/explantation/pathology area in the event of an unaccounted for or ruptured source to minimize the risk of inadvertent exposure from seeds;
- Patient follow up should they not return for explantation; and
- Names and telephone numbers of the authorized users and the Radiation Safety Officer to be contacted.

Notes to Licensees

Change in physical conditions of use.

Because the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate due to the sources not having been tested
for puncture, the limited specific medical use licensee should request an amendment for the new conditions. Certain states will not allow variations in the physical conditions of use unless the original SSD certificate is amended or a custom evaluation is performed. A broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences. Licensees should submit documentation that addresses the safe use of the source in the normal and emergency conditions associated with this 35.1000 use. This documentation may be, but is not limited to, an engineering, historical, or scientific analysis of the surgical removal of these sources.

Suggested Revisions to existing iodine-125 and palladium-103 seed localization programs to conform to this licensing guidance.

(Note: Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes" or equivalent Agreement State regulations, to the RSL safety program that might otherwise require a license amendment).

The above licensing guidance may be revised as additional experience is gained regarding medical use of RSL. A licensee already authorized to use iodine-125 and/or palladium-103 seeds for RSL and is committed by license condition to follow the provisions in the existing guidance, must apply for and receive an amendment to its license in order to make changes to conform to the revised provisions.

An applicant initially applying for authorization for medical use of RSL (or a licensee applying later for an amendment to conform with revisions in this guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

(1) The revision is in compliance with the regulations of the NRC or Agreement State;
(2) The revision is based on NRC's current guidance for RSL 35.1000 use posted on the NRC website;
(3) The revision has been reviewed and approved by the licensee's Radiation Safety Officer, Radiation Safety Committee, and management;
(4) The affected individuals are instructed on the revised program before the change is implemented;
(5) The licensee will retain a record of each change for 5 years; and
(6) The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and
approved the change.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

The above guidance for changes to conform with the revised provisions does not prevent Agreement States from requiring the licensee request an amendment for each change to its radiation safety program if that is their policy.
ADMIN CLOSING/ ACTION ITEMS

NO HANDOUT
MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes
FROM: Thomas H. Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety, NMSS
SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE APRIL 20-21, 2005 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations from the April 20-21, 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.

MEDICAL EVENTS INVOLVING I-131

ACMUI recommendation: To reduce the number of medical events involving I-131, NRC staff should consider incorporating the following practices in licensees' procedures:

1. Patient verification procedures similar to blood administration (i.e., the patient's identity is verified by two different individuals prior to administration) could be considered.
2. Verbal orders should not be permitted in any step of the therapeutic dosage administration process.
3. The dosage to be administered must be verified against the written directive prior to administration.
4. Re-verify the therapeutic dosage in a dose calibrator on site prior to administration.
5. Communication between the Authorized User (AU) and the individual administering the dosage should be strengthened.

Contact: Angela R. McIntosh, NMSS/IMNS
(301) 415-5030
NRC staff response: It appears the ACMUI tailored its response to focus on reducing the incidence of medical events in general. While the staff appreciates the ACMUI's efforts, the staff's original intent was to acquire recommendations that would reduce the incidence of medical events involving 1-131 administrations where diagnostic administrations were intended, but activities which require a written directive were administered.

In an August 1, 2005 teleconference, staff discussed this issue with the Chairman of the 1-131 Medical Events Subcommittee, Dr. Douglas Eggli. During the discussion, Dr. Eggli stated that the subcommittee was not clear about the staff's request for recommendations. Dr. Eggli stated that he would re-engage the subcommittee to formulate recommendations for NRC staff consideration at the October 2005 ACMUI public meeting.

MEDICAL EVENTS INVOLVING PERMANENT IMPLANT BRACHYTHERAPY

Remarks: During discussion of this topic, the ACMUI recommended to NRC staff language that it believed would more accurately capture medical events resulting from permanent brachytherapy implants. This language is in the two proposed recommendations below. With respect to writing the actual rule, the ACMUI suggested that the NRC staff take the following approach: (1) Select Proposed Recommendation #1 as the new rule language, or (2) Select Proposed Recommendation #2 as the new rule language, or (3) Combine the language in Proposed Recommendations 1 and 2, and use the combined language to draft a new rule to capture medical events resulting from permanent brachytherapy implants.

ACMUI Proposed Recommendation #1: Any permanent implant in which there is no occurrence of seed migration and patient intervention, is a medical event if:

a) The total source strength implanted anywhere in the patient exceeds the written directive by more than 20 percent or;

b) The total source strength implanted in the target volume deviates from the written directive by more than 20 percent. That ACMUI be provided with a copy of the research protocol for review, before making recommendations on guidance regarding the use of 1-125 seeds as markers in breast tumors.

ACMUI Proposed Recommendation #2: Any permanent brachytherapy is a medical event, excluding seed migration and patient intervention, if a total source strength implanted in the treatment site in the patient varies from the written directive by more than 20 percent.

NRC staff response: Subsequent to the ACMUI's submission of these recommendations to the NRC staff, the ACMUI developed a different approach to defining medical events resulting from permanent brachytherapy procedures. Rather than recommending that the staff choose between Proposed Recommendations 1 and 2 above, the ACMUI's Medical Events Subcommittee (MESC) decided that it would develop a set of principles that it would recommend that the staff use to create a definition of medical events resulting from permanent brachytherapy procedures.

Toward this end, the ACMUI and the staff conducted a June 28, 2005, public teleconference meeting. During the teleconference, the MESC forwarded to the ACMUI the set of principles.
The ACMUI discussed and refined the principles with the MESC, then voted to approve the principles. The ACMUI will formally present these principles to the staff in a memorandum.

Once the staff has received the principles, the staff will use these principles as the basis for part of a Commission paper on medical event definition and conveying risk information to the public. The paper will recommend to the Commission whether the staff should use these principles as a guide for writing rule language that will define permanent implant brachytherapy medical events.

MAINTAINING THE 20% THRESHOLD FOR REPORTING MEDICAL EVENTS NOT INVOLVING PERMANENT IMPLANT THERAPY (BRACHYTHERAPY)

ACMUI recommendation: That as long as medical event reporting is not automatically treated as an indicator of potential patient harm, ± 20 percent remains a reasonable action level for reporting events of Quality Assurance significance to NRC for the following modalities: temporary implants, external beam treatments and unsealed radiopharmaceutical administrations.

NRC staff response: During previous rulemaking efforts, NRC staff has communicated the concept that the purpose of medical event reporting is to keep the NRC informed of the occurrence of these events, but that their occurrence is not necessarily indicative of actual patient harm.

In the Statements of Consideration contained within the Federal Register notification published May 14, 1980, (i.e., 45 FR 31701), the Commission published a final rule in 10 CFR Part 35, which stated, in part, that the NRC amended its medical regulations to require prompt reporting of medical events (then referred to as medical "misadministrations"). In that publication, the Commission acknowledged that misadministrations could occur without actual harm done to the patient.

In the Statements of Consideration contained within the Federal Register published July 25, 1991, (i.e., 56 FR 34104), the Commission published a final rule to 10 CFR Part 35, which stated that the NRC amended its regulations to include the requirement for a quality management program that was intended to ensure that byproduct material was administered as directed by the authorized user (AU). In the publication of 56 FR 34104, the NRC noted that there exists the possibility that medical events may cause patient harm, but also acknowledged that the "overall significance" of medical events is that they "indicate a breakdown in the licensee's program for ensuring that byproduct material or radiation is administered as directed by the AU."

Thus, the NRC has historically acknowledged that the presence of medical events is not necessarily indicative of patient harm, and continues to adopt this stance.

1The requirement for a Quality Management Program was rescinded with the publication of the rule in 10 CFR Part 35, that became effective October 24, 2002.
MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

April 20-21, 2005

MEETING SUMMARY

PURPOSE: To discuss issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

OUTCOME: The Nuclear Regulatory Commission (NRC) staff gained more understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. Staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

TUESDAY, APRIL 20, 2005

ACMUI REVIEW OF MEDICAL EVENTS INVOLVING I-131

Douglas F. Eggli, MD, ACMUI, presented this topic to the ACMUI. This presentation was given so that the ACMUI Subcommittee on Review of Medical Events Involving I-131, could forward to the full committee its recommendation(s) on what licensees can do to help reduce the number of medical events involving I-131.

The Subcommittee reviewed several I-131 medical events, to discover the general nature of the events and to recommend actions that licensees, and/or the NRC can take to help reduce their number. The Subcommittee found that the number of I-131 medical events was small, compared to the total number of therapeutic administrations of radioactive material. Most of the events were attributable to human error related to: failure to pay attention to detail; failure to follow established policies and procedures; and miscommunication among key personnel.

To help reduce the number of medical events involving I-131, the Subcommittee forwarded several recommendations to the main ACMUI. The Subcommittee clarified that it is not its intent that these recommendations should be implemented via changes to the 10 CFR Part 35 rule.

ACMUI Subcommittee Recommendations

To reduce the number of medical events involving I-131, NRC staff should consider incorporating the following practices in licensees procedures:

1. Patient verification procedures similar to blood administration could be considered.
2. Verbal orders should not be permitted in any step of the therapeutic dosage administration process.
3. The dosage to be administered must be verified against the written directive prior to administration.
4. Re-verify the therapeutic dosage in a dose calibrator on site prior to administration.
5. Communication between the Authorized User (AU) and the individual administering the dosage should be strengthened.

Additional recommendation: That the subcommittee's recommendations be endorsed by the full committee and forwarded to NRC staff. Motion was seconded and passed.

The ACMUI also recommended that documentation of events in the Nuclear Materials Events Database be revised to include causes and contributing factors to events.

CASE EXPERIENCE USING I-125 SEEDS AS MARKERS

Richard J. Vetter, PhD, ACMUI, presented some actual findings, from Mayo Clinic, of the off-label use of I-125 seeds as markers for breast cancer tumors. Mayo Clinic uses I-125 seeds to define the border of breast cancer tumors as an alternate to the traditional method, which is the use of wires (called “wire localization.”) Dr. Vetter reported that a small study was conducted at Mayo Clinic, in which the use of I-125 seeds as markers was compared to the traditional use of wires as markers. Mayo found that the use of I-125 seeds has certain advantages, including: the ability to implant the seeds up to 5 days before surgery, thereby minimizing scheduling conflicts; the ability to bracket lesions; the ability to perform post-localization mammograms without being impeded by wires; and reduced cost. Mayo’s conclusion was that the use of I-125 seeds as markers was easier, more convenient, preferred by physicians, and a more accurate method to mark breast cancer tumors than is the use of wire localization.

FDA RADIATION DOSE LIMITS FOR HUMAN RESEARCH SUBJECTS USING CERTAIN RADIOLABELED DRUGS

Orhan Suleiman, PhD, ACMUI, made a presentation designed to explain the current FDA thinking in terms of human research issues; specifically radiation dose limits, for a certain class of radiolabeled drugs.

Dr. Suleiman explained that the FDA is revisiting the dose limits allowed to persons participating in research involving radiolabeled drugs. FDA is revisiting this issue because dose limits have changed since the FDA first promulgated its rules in the use of human research subjects, back in 1975. The concept of effective dose is now in place, there’s more scientific data regarding radiation risk, and there are also new human research regulations for institutional review boards. As a result of these advances, FDA is now proposing updated dose limits for human research subjects.

Dr. Suleiman explained there were some challenges in trying to determine appropriate dose limits. Following are specific questions FDA is attempting to answer: Are the current dose limits still appropriate for research conducted under 21 CFR 361, “Radioactive drugs for certain
research uses"? If not, what dose limits are appropriate? Taking into account the risk of radiation exposure (which is higher for the very young and the very old) should there be different dose limits for different adult age groups? Regarding pediatric doses, should these considerations be taken into account as well? The ACMUI commented that it may be appropriate to devise a weight-based or age-based sliding scale of doses, to take into account the risk of exposure to different age groups.

**ESTABLISHING GUIDANCE ON EXCEEDING DOSE LIMITS FOR MEMBERS OF THE PUBLIC**

Sami Sherbini, PhD, NRC, made a presentation to inform the ACMUI of the NRC staff's approach to creating guidance that would allow members of the public to receive radiation doses in excess of that in the regulations, when caring for sick relatives who are hospitalized. Staff took action to create this guidance, based upon comments the ACMUI made at the October 13-14, 2004, ACMUI public meeting:

Dr. Sherbini explained that the current dose limit for members of the public is 100 millirem (although, under certain conditions, the 100 millirem limit may be raised to 500 millirem). Dr. Sherbini explained that in drafting guidance that would allow members of the public to receive higher than the current 100 millirem limit, staff reviewed several existing guidelines and criteria, to see if they could assist staff in creating a higher limit that would be reasonable, but not inappropriately high. Among these existing guidelines and criteria were National Council on Radiation Protection and Measurements standards, and emergency dose limits.

Staff found that existing guidelines and criteria did not suggest an ideal dose limit, higher than the current limit, that would be appropriate to the unique situation of members of the public exposed to radiation as care givers to sick relatives. Therefore, staff concluded that the best approach would be to let the licensee determine the dose limit, based upon each unique situation, then obtain NRC approval, via a license amendment, to allow the member of the public to receive that limit for that specific situation. That is the approach staff forwarded to the Commission for approval.

ACMUI expressed concern that seeking approval via license amendment may not be an expedient approach. In response, Dr. Sherbini explained that the process would be set up in such a way that it is anticipated that an amendment will take no more than a few days. Furthermore, if a licensee demonstrates a need to have this authority on a regular basis, it might be possible to put this provision directly in the license so that no amendment would be necessary.

**STATUS OF RULEMAKING, PART 35 - TRAINING AND EXPERIENCE**

Roger Broseus, NRC, gave an update on the status of the 10 CFR Part 35 rulemaking effort. Dr. Broseus stated that the rule was published March 30, 2005, with an effective date of April 29, 2005. However, licensees have until October 24, 2005, to implement the changes in the rule, and Agreement States have three years to implement the rule.
Dr. Broseus explained that the purpose of his presentation was to give an overview of the key changes to the rule. An abbreviated list of these changes include:

- Revision of requirements for specialty board recognition
- Revision of some requirements to obtain recognition via the alternate training pathway
- Revising the preceptor statement to require preceptors to "attest" to competency rather than to "certify" competency
- Removal of requirement that Authorized Users gain experience with elution of generators

One ACMUI member expressed concern about the revision to the requirement to obtain recognition via the alternate training pathway. This member believed the revision was too prescriptive, in this regard. There was also some concern that certain terms were not well-defined in the rule.

Dr. Broseus acknowledged the hard work that ACMUI undertook, particularly the Subcommittee on Training and Experience, to help staff complete the complex, multiyear effort to put into place regulations and requirements for the training and experience of radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, and authorized users. Dr. Broseus personally thanked the ACMUI for its efforts in this undertaking, and stated that thousands of licensees, NRC staff, and Agreement State staff will benefit from these changes.

THURSDAY, APRIL 21, 2005

STATUS AND UPDATE: REDEFINING MEDICAL EVENTS

This presentation was given so that the ACMUI Subcommittee on Redefining Medical Events could discuss its progress on redefining medical events, and submit to the full ACMUI any recommendations it has to redefine medical events within 10 CFR Part 35. The Subcommittee discussed four major areas to be considered for revision:

1. Redefinition of medical events involving permanent radioactive seed implant therapy (otherwise known as permanent "brachytherapy.")
2. Clarifying the conclusion of the procedure in the written directive.
3. Effectively communicating to the patient, risks associated with medical events.
4. Redefinition of medical events for modalities other than radioactive brachytherapy.

Regarding the first major area, redefinition of medical events involving brachytherapy, the ACMUI Subcommittee forwarded the following recommendation.

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1 In SRM MO40302B, the Commission instructed staff to provide the Commission with recommendations concerning the current definition of medical events and how to communicate effectively to the public associated risks, if any. In developing recommendations, the staff should confirm that there was an appropriate basis for applying the 20% reporting threshold for medical events to each modality, in the final Part 35 rule that became effective in October 2002. Furthermore, the staff should involve the ACMUI in the development of these recommendations.
Proposed Brachytherapy Medical Event Definition #1:

- Any permanent implant in which there is no occurrence of seed migration and patient intervention, is a medical event if:
  a) The total source strength implanted anywhere in the patient exceeds the written directive by more than 20 percent or;
  b) The total source strength implanted in the target volume deviates from the written directive by more than 20 percent.

There was much discussion of the use of the terminology “target volume.” One committee member believed this term should be replaced with the term “treatment site” because there are different definitions for the term “target volume.” Thus, a second definition of medical event was proposed.

Proposed Brachytherapy Medical Event Definition #2:

- Any permanent brachytherapy is a medical event, excluding seed migration and patient intervention, if a total source strength implanted in the treatment site in the patient varies from the written directive by more than 20 percent.

As the ACMUI continued discussing this definition, it commented on the challenge in proposing a sound medical event definition that is firm enough to capture events where it is evident that radioactive sources were mistakenly implanted outside of the intended treatment site, yet flexible enough to not count as medical events, instances where practitioners purposely implant sources in tissues slightly outside of the treatment site, in order to achieve good treatment coverage.

As the ACMUI continued to discuss how to draft such language, it agreed that an advisable next step would be to circulate the draft language among its colleagues, to get other professional opinions about how to make the definition flexible, yet capture egregious errors. Toward this goal, the ACMUI formulated the following action items.

ACTION ITEM: The ACMUI will circulate the draft language in Proposed Definitions #1 and #2, among other professional colleagues, to get insights on crafting language that will give physicians flexibility to treat slightly outside the perimeter of the treatment site, yet capture egregious errors where tissue clearly outside the intended treatment site was implanted.

ACTION ITEM: Dr. Nag will e-mail the other ACMUI members and NRC staff a copy of some slides he created, which gives his opinion on how to best define medical events involving permanent brachytherapy. The ACMUI will consider Dr. Nag's opinions as it moves forward toward drafting the language for medical events involving permanent brachytherapy.
ACTION ITEM: The NRC liaison to the Medical Event Subcommittee, Dr. Ronald Zelac, will obtain feedback from NRC staff, regarding whether to accept Proposed Definition #1, or Proposed Definition #2, or some combination of the two, as a definition that would provide necessary physician flexibility yet capture gross implantation errors.

Regarding the second major area, defining the conclusion of the brachytherapy procedure in the written directive, the ACMUI agreed that this must be done without a major rule change in 10 CFR Part 35. To help obtain this objective, the following action item was adopted.

ACTION ITEM: The NRC staff, with input from the ACMUI, will create a generic communication that defines the conclusion of the permanent implant procedure.

Regarding the third major area considered for revision, communicating risks to patients, the Medical Event Subcommittee agreed that after a medical event has occurred, the appropriate approach to informing risks to patients would be to honor the performance-based intent of 10 CFR Part 35. This could be done by creating language that would define a clinical outcome that every practitioner would recognize as necessary for reporting the event to the patient. The ACMUI prefers this approach, because every situation with each patient has enough variables to render impractical a precise, prescriptive definition requiring patient notification. The Subcommittee still needs to develop draft language that will honor this approach to patient notification of medical events.

Regarding the fourth major area considered for revision, the redefinition of the medical event criteria for modalities other than permanent brachytherapy, the Medical Event Subcommittee did not recommend any change to the current rule criteria. Instead, the Subcommittee affirmed the adequacy of the current criteria, and stated the philosophical approach it believed the NRC should use so that the current threshold of plus or minus 20% is appropriately applied. This is the philosophical approach the ACMUI endorsed:

The current threshold of plus or minus 20% of the intended dose is a reasonable action level for reporting medical events involving temporary implants, external beam treatments, and unsealed radiopharmaceutical administrations, as long as any event reporting is not automatically treated as an indicator of potential patient harm.

Thus, the Subcommittee advanced its belief that NRC should view medical events strictly as performance indicators that may warrant further Agency response. However, the occurrence of medical events are not, of themselves, evidence of patient harm.

The ACMUI made the following recommendation:

As long as medical event reporting is not automatically treated as an indicator of potential patient harm, (plus or minus) 20 percent remains a reasonable action level for reporting events of Quality Assurance significance to NRC for the following modalities:
temporary implants, external beam treatments and unsealed radiopharmaceutical administrations.

Additional recommendation: That the subcommittee's recommendations be endorsed by the full committee and forwarded to NRC staff. Motion was seconded and passed.

PATIENT SAFETY ISSUES WITH GAMMA STEREOTACTIC RADIOSURGERY

Douglas Kondziolka, MD, of the International Radiosurgery Association (IRSA), presented IRSA's views and recommendations on physician presence and responsibilities during gamma stereotactic radiosurgery (GSR). Dr. Kondziolka is a professor of neurological surgery, and of radiation oncology. He is also the current president of IRSA and a past president of the American Society for Stereotactic and Functional Neurosurgery.

Dr. Kondziolka stated that his experience with GSR administration includes over 3,000 patient treatments. At the University of Pittsburgh, his current institution, he stated that over 7,000 gamma knife treatments have been performed.

NRC's regulations in 10 CFR Part 35.600 currently require the presence of a team of individuals to administer GSR: the radiation oncologist and the medical physicist. Dr. Kondziolka affirmed NRC's regulatory approach that a team of trained professionals is needed to safely and effectively deliver GSR treatments, and stated that in the team approach, no individual is more important than any other individual, as all bring strengths related to efficacy and safety.

However, Dr. Kondziolka believed that neurosurgeons, trained in GSR, are also essential members of the GSR team, and stated that NRC's regulations are remiss in not requiring the presence of the trained neurosurgeon, along with the radiation oncologist and medical physicist. He stated that the neurosurgeon is the physician primarily responsible for the patient's treatment, and therefore, should be a member whose presence is required during the GSR administration. Dr. Kondziolka further stated that radiation oncologists are not trained in many components of radiosurgery, as are neurosurgeons. Therefore, there is increased risk to patients when neurosurgeons' presence is not required.

Dr. Kondziolka recommended the following changes to 10 CFR Part 35, which he believes will serve to augment patient safety:

- The term "authorized user" in 10 CFR Part 35 should be replaced with the terms authorized neurosurgeon, and authorized radiation oncologist.
- Clean and concise regulations for GSR are needed; regulations that are distinct from cobalt teletherapy and reflect how this procedure was performed.
- Either the neurosurgeon or the radiation oncologist should be present at the console during dose delivery, taking care of their joint patient.
- Authorized medical physicists should be in the vicinity, but should not be required to be at the console, since they are not medically trained.

THE IMPORTANCE OF RADIATION ONCOLOGIST PRESENCE AND AUTHORIZED USER STATUS FOR GAMMA STEREOTACTIC SURGERY PROCEDURES
David Larson, MD, representing the American Society of Therapeutic Radiology and Oncology (ASTRO) gave a presentation on ASTRO’s views regarding radiation oncologists’ presence during GSR. Dr. Larson is past president of IRSA, and a professor of radiation oncology. Dr. Larson is also a non paid scientific advisor of the Elektra Scientific Board (Elektra manufactures a GSR unit). Dr. Larson stated that he holds a PhD in high energy physics in addition to his medical degree.

Dr. Larson stated that ASTRO has long maintained a collegial and clinically cooperative relationship with neurosurgeons, for the administration of GSR since the inception of this procedure. Several organizations, including ASTRO, affirmed that GSR should be performed by both neurosurgeons and radiation oncology participants. However, ASTRO feels compelled, according to Dr. Larson, to address what he characterized as “gross misrepresentations” made by IRSA. Dr. Larson stated that ASTRO “absolutely” supports NRC’s current regulations, which requires only the presence of radiation oncologists and medical physicists during GSR, as adequate for patient safety.

Dr. Larson stated that radiation oncologists receive comprehensive training to handle all aspects of treatment planning, delivery and safety. Furthermore, ASTRO objects to IRSA’s position regarding medical physicists’ presence, which ASTRO believes is essential during GSR.

Accompanying Dr. Larson was Dr. Paul Wallner, senior vice president of 21st Century Oncology, and the previous chief of the Clinical Radiation Oncology branch of the National Cancer Institute. Dr. Wallner stated that IRSA is a “trade organization” who joined with several individual neurosurgeons to petition a change to 10 CFR Part 35.960, and, in doing so, has demonstrated a “basic lack of understanding of the entire authorized user issue.” Dr. Larson stated that ASTRO has never suggested that neurosurgeons should not be part of the GSR team, and that this whole issue is really a credentialing and privileging issue, and not a safety issue. Dr. Wallner stated that he “completely disagreed” with IRSA’s remarks regarding the training and qualifications of radiation oncologists, in relation to their ability to safely administer GSR treatments to patients.

The ACMUI questioned the representatives from IRSA and ASTRO, but made no recommendation for a change to the physical presence rule in 10 CFR part 35.600.

ADMINISTRATIVE CLOSING

Angela McIntosh, NRC, lead the discussion on this topic. During this discussion, the Ms. McIntosh and the ACMUI reviewed the recommendations and action items arising from this meeting, and discussed proposed meeting dates for the Fall 2005 meeting. The proposed meeting date for the fall meeting is October 25-26, 2005.

The meeting was adjourned at 4:44 p.m.
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<tr>
<td>Oct 2004</td>
<td>2005-01R</td>
<td>X</td>
<td>MRST</td>
<td>RADIOIMMUNOTHERAPY AND MICROSPHERE THERAPY</td>
<td>Y</td>
<td>Staff agrees with the ACMUI and was aligning the guidance for the Seed Selectron closer to the requirements in 35.400 rather than 35.600. However, the development of the guidance is on hold because of lack of licensing requests for this device.</td>
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Remarks: During the presentation of this topic, the discussion shifted to the Seed Selectron permanent implant remote after loader device, and the ACMUI made a recommendation regarding the Seed Selectron device. No recommendation was made regarding radioimmunotherapy and microsphere therapy.

The ACMUI recommended that NRC staff continue to regulate permanent prostate brachytherapy in 10 CFR 35.100, but use 35.400 as the regulatory framework for creating guidance, while adding elements of 10 CFR 35.600, as necessary, to that guidance.
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<tr>
<td>Oct 2004</td>
<td>2005-02R</td>
<td>X</td>
<td>MRST</td>
<td>RADIATION SAFETY ASPECTS OF I-125 THERAPEUTIC SEEDS USED AS MARKERS IN BREAST CANCER TUMORS That the ACMUI be provided with a copy of the research protocol for review, before making recommendations on guidance regarding the use of I-125 seeds as markers in breast tumors.</td>
<td>N/A</td>
<td>Staff requests that the ACMUI provide a recommendation at the Spring 2005 meeting. Robert Gallagher provided a copy of the research protocol in an e-mail on 12-2-04. NRC staff forwarded the research protocol to the ACMUI on December 2, 2004. Staff requests that the ACMUI review the protocol and provide a recommendation to staff at the Spring 2005 ACMUI public meeting. April 2005 update: Staff will schedule a teleconference call between the Spring and Fall 2005 meetings, for the ACMUI to forward its recommendations to staff. Mr. Gallagher will be invited to participate in the teleconference. May 2005 update: ACMUI will comment on the draft guidance being prepared by the Organization of Agreement States, once the guidance is made available to NRC staff. ACMUI notified of this action by e-mail on 5/28/05.</td>
<td>CLOSED OUT AS A RECOMMENDATION. Converted to an Action Item. See Action Item 2005-A16.</td>
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<td>Oct 2004</td>
<td>2005-03R</td>
<td>X</td>
<td>RGB</td>
<td>DIDACTIC HOURS OF TRAINING</td>
<td>That the number of didactic hours of training in the draft final 10 CFR 35.390 be reduced from 200 to 80, with the total number of hours of training under 35.390 remaining at 700 hours. This motion passed with one abstention.</td>
<td>N/A</td>
<td>Staff will consider this recommendation with all other comments submitted by stakeholders, during the formal comment period.</td>
<td>CLOSED</td>
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<td>Oct 2004</td>
<td>2005-04R</td>
<td>X</td>
<td>RGB</td>
<td>GRANDFATHERING MEDICAL PHYSICISTS IN HDR, IVB, AND TELETherAPy</td>
<td>That the draft language in 10 CFR 35.57 be modified to read as follows: That physicists who have been authorized to serve the function of authorized medical physicists for high dose rate brachytherapy, gamma stereotactic radiosurgery, and teletherapy be grandfathered to be allowed to serve as authorized medical physicists for those respective modalities.</td>
<td>N/A</td>
<td>Staff will consider this recommendation with all other comments submitted by stakeholders, during the formal comment period.</td>
<td>The discussion that led to this recommendation centered around the appropriateness of grandfathering an AMP working under a broad scope license. Such a person would not be named on the license, but would have been designated an AMP by the local Radiation Safety Committee. The ACMUI believes such Individuals are entitled to being grandfathered, in the same manner as AMPs who are named on Type A licenses.</td>
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<td>Oct 2004</td>
<td>2005-05R</td>
<td>RECOMMENDATION TO IMPLEMENT THE DRAFT FINAL 10 CFR 35</td>
<td>RGB</td>
<td>N/A</td>
<td>The Draft Final 10 CFR 35 will move forward in the finalization process in accordance with Agency procedure. All recommendations made in association with the Draft Final 10 CFR 35 will be processed in accordance with Agency procedure.</td>
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<td>Oct 2004</td>
<td>2005-06R</td>
<td>PROPOSED CHANGE TO ABNORMAL OCCURRENCE CRITERIA (FOR MEDICAL EVENTS)</td>
<td>Mclnosh</td>
<td>N</td>
<td>Staff has given further consideration of the types of anticipated therapies that will be encountered in the future. After consideration of the nature of future therapies, the staff has determined it is best to leave the expression of dose in the AO medical event criteria in terms of absorbed dose (rad) rather than dose equivalent (rem). Furthermore, so that the AO criteria is aligned with the medical event criteria in 10 CFR 35, the staff believes it is best that the AO criteria keep its existing language that requires reporting of medical events, rather than &quot;events involving the medical administration&quot; of material.</td>
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<td>Oct 2004</td>
<td>2005-07R</td>
<td>ACMUI Recommendation (R)</td>
<td>N/A</td>
<td>2005 ICRP RECOMMENDATIONS</td>
<td>CLOSED</td>
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<td>ACMUI Action Item (SA)</td>
<td>N/A</td>
<td>That the International Commission on Radiological Protection (ICRP) maintain in its recommendations the current occupational exposure of 500 millirem to pregnant occupational workers.</td>
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<td>Staff Accepted Recommandation?</td>
<td>Y, N, N/A or Partially</td>
<td>Dr. Richard Vetter, ACMUI, presented this topic to the ACMUI to gain their committee's perspective on the ICRP's draft recommendations. At the October 19, 2004 meeting to discuss the ICRP recommendations (held at NRC HQ by the Advisory Committee on Nuclear Waste) Dr. Vetter forwarded the ACMUI's recommendation, as stated to the left. No further action is required by NRC staff.</td>
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<td>ACMUI Action Item (SA)</td>
<td>N/A</td>
<td>Staff accepted ACMUI recommendation. TAR is viewable in ADAMS under accession # ML042090505.</td>
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<td>Oct 2004</td>
<td>2005-A02</td>
<td>ACMUI Recommendation (R)</td>
<td>N/A</td>
<td>DOSE RECONSTRUCTION</td>
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<td>ACMUI Action Item (SA)</td>
<td>N/A</td>
<td>That the NRC staff provide the ACMUI a copy of the staff's conclusion of its dose reconstruction effort.</td>
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<tr>
<td>Oct 2004</td>
<td>2005-A03</td>
<td>X</td>
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<td></td>
<td>MEDICAL EVENT REVIEW OF I-131 MEDICAL EVENTS</td>
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<td>Staff requests that ACMUI limit its review to only those medical events staff provided to ACMUI at the Oct 2004 ACMUI public meeting. Staff notified ACMUI that the new due date is December 28, 2004. Dec 20, 2004 update: ACMUI has agreed to provide a response to staff by January 5, 2005. April 2005 update: ACMUI is scheduled to provide the NRC staff its recommendations to reduce I-131 medical events, at the April 20, 2005 ACMUI public meeting. May 2005 update: the ACMUI provided recommendations to staff at the April 20, 2005 meeting. CLOSED OUT</td>
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<td>Oct 2004</td>
<td>2005-A04</td>
<td>R</td>
<td>A</td>
<td>N/A</td>
<td>MEDICAL EVENT REVIEW - ADDITIONAL ACMUI ACTION</td>
<td>N/A</td>
<td>May 2005 update: The Medical Event Subcommittee as a whole has taken responsibility for review and comment.</td>
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<td>Ralph Lieto, ACMUI, will search the NRC's Nuclear Materials Events Database for events related to medical events, and provide feedback that will help structure the ACMUI's review of medical events, and will also participate in an ACMUI subcommittee to review medical event trending.</td>
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<td>Oct 2004</td>
<td>2005-A05</td>
<td>R</td>
<td>X</td>
<td>N/A</td>
<td>MEDICAL EVENTS CRITERIADEFINITION-SUBCOMMITTEE FORMATION</td>
<td>N/A</td>
<td>Subcommittee was formed at the Oct 2004 meeting. Members include Mr. Lieto and Drs. Nag, Diamond, and Williamson, with Dr. Williamson serving as Chair.</td>
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<td>The ACMUI will form a subcommittee to more closely review the 20% dose threshold, as applied to medical events. The subcommittee will include Mr. Lieto and Drs. Nag, Diamond, and Williamson, with Dr. Williamson serving as Chair.</td>
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<td>Oct 2004</td>
<td>2005-A06</td>
<td>MEDICAL EVENTS CRITERIA</td>
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<td>Zelac</td>
<td>N/A</td>
<td>NRC staff gave the ACMUI pertinent data at the Oct 2004 meeting. Staff will provide further data, as needed, upon ACMUI request.</td>
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<td>NRC staff will provide pertinent data for the subcommittee to begins its work (e.g., background data on the genesis of the 20% threshold). Furthermore, NRC will provide a staff member to act as liaison to the subcommittee.</td>
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<td>Oct 2004</td>
<td>2005-A07</td>
<td>REDLINE/STRIKEOUT COPY</td>
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<td>RGB</td>
<td>N/A</td>
<td>The deadline for comment submission toward the draft final rule was Oct 18, 2004, only 4 days before ACMUI made this recommendation. Staff was unable to produce the latest version of a redline/strikeout draft rule, approved by the Commission, within such a severe time limit. However, staff anticipates the ability to publish a redline/strikeout version of the draft final rule by (DATE)</td>
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<td>OF DRAFT FINAL 10 CFR 35</td>
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<td>The NRC staff will obtain the Commission's permission to publish a redline/strikeout copy of the draft final rule to the NRC website.</td>
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<td>Nov 2004</td>
<td>2005-A08</td>
<td>R</td>
<td>A</td>
<td>Zelate</td>
<td>N/A</td>
<td>May 2005 update: The ACMUI provided staff with 2 proposed recommendations at the April 20, 2005 public meeting. As a result, 4 Action Items were established. See Action Items 2005-A11, 2005-A12, 2005-A13, and 2005-A14. Also, ACMUI made another recommendation regarding medical event reporting, as applied to modalities in general. See Recommendation 2005-08R. July 25 Update: Subsequent to the ACMUI's submission of these recommendations to the NRC staff, the ACMUI developed a different approach to defining medical events resulting from permanent brachytherapy procedures. Rather than recommending that the staff choose between Proposed Recommendations 1 and 2 above, the ACMUI's Medical Events Subcommittee (MESC) decided that it would develop a set of principles that it would recommend that the staff use to create a definition of medical events resulting from permanent brachytherapy procedures. Toward this end, the ACMUI and the staff conducted a June 28, 2005, public teleconference meeting. The ACMUI forwarded the principles to staff in a July 19, 2005 memorandum.</td>
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**TELECONFERENCE DISCUSSION:**
**UPDATE TO MEDICAL EVENT CRITERIA DEFINITION**

An ACMUI subcommittee will hold an information gathering and discussion (i.e., non-public) teleconference discussion to determine if the 20% dose threshold is an appropriate threshold for medical events. A second charge is to develop a strategy for effectively communicating to the public the risks, if any, associated with all classes of medical events.

The teleconference held Dec 7. Items discussed and/or needing further investigation include:
* permanent implant - when is treatment over?
* how criteria is applied to determine when the wrong site is treated (prostate brachytherapy)
* 20% - can't be viewed as indicator of patient harm
* need to close "loop hole" that allows AUs to make mistakes.

A follow up, non-public teleconference was conducted on Jan 13, 2005, 4-6p.m.
A public teleconference has been scheduled for Jan 18, 2005.

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<tr>
<td>Dec 2005</td>
<td>2005-A09</td>
<td>X</td>
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<td>COMMENT ON OPTIONS PAPER: VISITOR RECEIPT OF DOSE IN EXCESS OF REGULATORY LIMITS. Staff e-mailed ACMUI a draft options paper that gives guidance to licensees on allowing certain visitors of patients to receive exposure in excess of regulatory limits.</td>
<td>N/A</td>
<td>Staff requested comments by January 17, 2005.</td>
<td>CLOSED</td>
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<td>March 2005</td>
<td>2005-A10</td>
<td>X</td>
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<td>COMMENT ON GENERIC ISSUES PROGRAM. Staff in Nuclear Regulatory Research requested comments from the ACMUI on the revised Generic Issues Program.</td>
<td>N/A</td>
<td>Comments requested by March 23, 2005. ACMUI Coordinator sent e-mail notification on March 14, 2005.</td>
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<td>April 2005</td>
<td>2005-A11</td>
<td>X</td>
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<td>CIRCULATE PROPOSED LANGUAGE TO REDEFINE MEDICAL EVENTS INVOLVING PERMANENT BRACHYTHERAPY</td>
<td>N/A</td>
<td>July 25, 2005 update: July 25 Update: Subsequent to the ACMUI's submission of these recommendations to the NRC staff, the ACMUI developed a different approach to defining medical events resulting from permanent brachytherapy procedures. Rather than recommending that the staff choose between Proposed Recommendations 1 and 2 above, the ACMUI's Medical Events Subcommittee (MESC) decided that it would develop a set of principles that it would recommend that the staff use to create a definition of medical events resulting from permanent brachytherapy procedures. Therefore this action is rescinded.</td>
<td>CLOSED</td>
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<tr>
<td>Date</td>
<td>Item Number</td>
<td>ACMUI Recommendation (R)</td>
<td>ACMUI Action Item (AA)</td>
<td>Staff Action Item (SA)</td>
<td>Staff Accepted Recommendation?</td>
<td>Staff Disposition/ Response</td>
<td>Remarks/ Follow-up/ CLOSED OUT</td>
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<td>SLIDES</td>
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Dr. Subir Nag, ACMUI, will e-mail the other ACMUI members and NRC staff a copy of some slides he created, which gives his opinion on how to best define medical events involving permanent brachytherapy. The ACMUI will consider Dr. Nag's opinions as it moves forward toward drafting the language for medical events involving permanent brachytherapy.
<table>
<thead>
<tr>
<th>Date</th>
<th>Item Number</th>
<th>ACMUI Recommendation (R)</th>
<th>ACMUI Action Item (AA), Staff Action Item (SA)</th>
<th>Name and Description of Recommendation or Action Item</th>
<th>Staff Accepted, Recommendation?</th>
<th>Staff Disposition/ Response</th>
<th>Remarks/Follow-up/ CLOSED OUT</th>
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<tbody>
<tr>
<td>April 2005</td>
<td>2005-A13</td>
<td>X</td>
<td>OBTAIN NRC STAFF FEEDBACK ON PROPOSED RECOMMENDATIONS 1 AND 2 (RE: MEDICAL EVENT DEFINITION FOR PERM. BRACHYTHERAPY)</td>
<td>The NRC liaison to the Medical Event Subcommittee (MESC), Dr. Ronald Zelac, will obtain feedback from NRC staff, regarding whether to accept Proposed Definition #1, or Proposed Definition #2, or some combination of the two, as a definition that would provide necessary physician flexibility yet capture gross implantation errors.</td>
<td>N/A</td>
<td>June 7, 2005 update: The ACMUI MESC has changed its approach to addressing this issue. The MESC no longer believes it is necessary that staff review Proposed Definitions 1 and 2, with the purpose of drafting an appropriate definition of medical events involving permanent implant brachytherapy. Rather, the MESC has decided to form principles for defining this type of medical event. Therefore, with regard to perm. implant brachytherapy, the principles would state (a) what the MESC believes should be changed in the current rule, and (b) what the content of a new rule should be. The MESC plans to forward these principles to NRC staff, and asks that staff review them and draft new rule language based upon the principles.</td>
<td>June 7, 2005: The MESC will hold a June 13, 2005 non-public teleconference to draft principles that would communicate: what the MESC believes should be changed in the current rule, and (b) what the content of a new rule should be. CLOSED</td>
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<tr>
<td>Date</td>
<td>Item Number</td>
<td>ACMUI Recommendation (R)</td>
<td>ACMUI Action Item (AA)</td>
<td>Staff Action Item (SA)</td>
<td>Name and Description of Recommendation or Action Item</td>
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<tr>
<td>April 2005</td>
<td>2005-A14</td>
<td></td>
<td>X</td>
<td>McIntosh</td>
<td>GENERIC COMMUNICATION THAT DEFINES CONCLUSION OF PERMANENT IMPLANT BRACHYTHERAPY</td>
<td>N/A</td>
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<tr>
<td>June 2005</td>
<td>2005-A15</td>
<td></td>
<td>X</td>
<td>McIntosh</td>
<td>COMMENT ON DRAFT RIS RE: DOSE TO VISITORS</td>
<td>N/A</td>
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<tr>
<td>Date</td>
<td>Item Number</td>
<td>ACMUI Recommendation (R)</td>
<td>ACMUI Action Item (AA)</td>
<td>Staff Action Item (SA)</td>
<td>Staff Disposition/ Response</td>
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<td>April 2005</td>
<td>2005-08R</td>
<td>X</td>
<td>MAINTAINING THE 20% THRESHOLD FOR REPORTING MEDICAL EVENTS NOT INVOLVING PERMANENT IMPLANT THERAPY (BRACHYTHERAPY)</td>
<td>Staff Recommendations?</td>
<td>N/A or Partially</td>
<td>CLOSED</td>
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As long as medical event reporting is not automatically treated as an indicator of potential patient harm, (plus or minus) 20 percent remains a reasonable action level for reporting events of Quality Assurance significance to NRC for the following modalities: temporary implants, external beam treatments and unsealed radiopharmaceutical administrations.

July 25, 2005 update: During previous rulemaking efforts, NRC staff has communicated the concept that the purpose of medical event reporting is to keep the NRC informed of the occurrence of these events, but that their occurrence is not necessarily indicative of actual patient harm. In the Statements of Consideration contained within the Federal Register notification published May 14, 1980, the Commission published a final rule in 10 CFR Part 35, which stated, in part, that the NRC amended its medical regulations to require prompt reporting of medical events (then referred to as medical "misadministrations"). In that publication, the Commission acknowledged that misadministrations could occur without actual harm done to the patient.
<table>
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<tr>
<th>Date</th>
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<th>Staff Disposition/ Response</th>
<th>Remarks/Follow-up/ CLOSED OUT</th>
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<tr>
<td>May 2005</td>
<td>2005-A16</td>
<td>RADIATION SAFETY</td>
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<td>N/A</td>
<td>Staff notified ACMUI by e-mail on 5/26/05. Update (9/23/05): Robert Gallagher to present the draft guidance to the ACMUI, for comment, at the October 26, 2005 ACMUI meeting.</td>
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<td>guidance to ACMUI for</td>
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<td>comment. See Recommendation 2005-02R.</td>
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<td>July 2005</td>
<td>2005-A17</td>
<td>COMMENT ON RIS RE:</td>
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<td>N/A</td>
<td>Request comments NLT 22 July.</td>
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<td>ASSESSMENT AND CONTROL</td>
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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 (IMNS), Office of Nuclear Material Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, IMNS

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

From March 18, 2004, to March 18, 2006

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

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

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

U.S. Nuclear Regulatory Commission

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

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

a. $160,000.00 (includes travel, per diem, and compensation)

b. Total staff-year of support: 1.5 Full Time Equivalent
8. **Estimated number of meetings per year:**

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

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

March 18, 2006

10. **Filing date:**

March 18, 2004

/RA/
Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the Commission
U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
BYLAWS
CONTENTS

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2. Minutes....................................................................... 2
3. Appointment of Members......................................... 3
4. Conduct of Members.................................................... 4
5. Amendments.............................................................. 5
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.
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
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.
human environment. Thus, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Further Information


If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at (600) 307–4209, (301) 415–4737 or by e-mail to pdr@nrc.gov. Documents may also be viewed electronically on the public computers located at the NRC’s PDR, O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Lisle, Illinois, this 12th day of September 2005.

James L. Cameron,
Chief, Decommissioning Branch, Division of Nuclear Materials Safety, RII.

[FR Doc. 05–18664 Filed 9–19–05; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

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

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 25 and 26, 2005. A sample of agenda items to be discussed during the public sessions includes: (1) Discussion of the Energy policy Act of 2005, which provides for NRC regulation of accelerator-produced radioactive material and discrete sources of Ra–226; (2) Status of Specialty Board applications for NRC recognition; (3) Electronic signature in written directives; (4) Revision of NRC Form 313A; (5) RIS on dose control and assessment; (6) Review of the medical events definition commission paper. To review the agenda, see http://www.nrc.gov/reading-rm/docs/collections/acmui/agenda/ or contact, via e-mail MSS@nrc.gov.

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

Date and Time for Closed Session Meeting: October 25, 2005, from 8 a.m. to 10 a.m. This session will be closed so that NRC staff can brief the ACMUI on information relating solely to internal personnel rules.

Dates and Times for Public Meetings: October 25, 2005, from 10 a.m. to 5 p.m.; and October 26, 2005, from 8 a.m. to 5 p.m.

Address for Public Meetings: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Room T2B3, 11545 Rockville Pike, Rockville, MD 20852–2738.

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. Submittals must be postmarked by October 3, 2005 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) 397–4205, on or about January 26, 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.

4. Attendees are requested to notify Mohammad S. Saba at (301) 415–7608 of their planned attendance if special services, such as for the hearing impaired, are necessary.

Dated at Rockville, Maryland, this 14th day of September, 2005.

For the Nuclear Regulatory Commission.

Andrew L. Bates, Advisory Committee Management Officer.

[FR Doc. 05–18652 Filed 9–19–05; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meetings

DATES: Weeks of September 19, 26, October 3, 10, 17, 24, 2005.

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

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of September 19, 2005

There are no meetings scheduled for the Week of September 19, 2005.

Week of September 26, 2005—Tentative

There are no meetings scheduled for the Week of September 26, 2005.

Week of October 3, 2005—Tentative

There are no meetings scheduled for the Week of October 3, 2005.

Week of October 10, 2005—Tentative

There are no meetings scheduled for the Week of October 10, 2005.

Week of October 17, 2005—Tentative

Tuesday, October 18, 2005

9:30 a.m. Briefing on Decommissioning Activities and Status (Public Meeting)

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

Week of October 25, 2005—Tentative

Wednesday, October 26, 2005

1:30 p.m. Discussion of Security Issues (Closed—Ex. 1)
PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of October 3, 2005
- There are no meetings scheduled for the Week of October 3, 2005.
- Week of October 10, 2005—Tentative
- Week of October 17, 2005—Tentative

Tuesday, October 18, 2005
9:30 a.m.—Briefing on Decommissioning Activities and Status (Public Meeting)
- This meeting will be webcast live at the Web address: http://www.nrc.gov.

Week of October 24, 2005—Tentative
Wednesday, October 26, 2005
1:30 p.m. Discussion of Security Issues (Closed-Ex. 1)

Thursday, October 27, 2005
10 a.m. Discussion of Security Issues (Closed-Ex. 1)

Week of October 31, 2005—Tentative
Tuesday, November 1, 2005
9:30 a.m.—Briefing on Implementation of Davis-Besse Lessons Learned Task Force (DBLLTF) Recommendations (Public Meeting)
- This meeting will be webcast live at the Web address: http://www.nrc.gov.

Week of November 7, 2005—Tentative

There are no meetings scheduled for the Week of November 7, 2005.

The schedule for Commission Meetings is subject to change on short notice. To verify the status of meetings call (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. braile, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301-415-7080, TDD: 301-415-2100, or by e-mail at aks@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).

In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to dkw@nrc.gov.

Dated: September 29, 2005.

Debra L. McCain,
Office of the Secretary.

[FR Doc. 05-19920 Filed 9-30-05; 9:58 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION


AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and request for comments.

DATES: Written comments must be provided by November 30, 2005.

Background: In support of an effort to develop a risk-informed revision of the emergency core cooling system (ECCS) requirements for commercial nuclear power plants, estimates of loss-of-coolant accident (LOCA) frequencies have been developed which will enable redefinition of the design-basis break size for these requirements. These LOCA frequency estimates have been developed using an expert elicitation process by consolidating service history data and insights from probabilistic fracture mechanics (PFM) studies with knowledge of plant design, operation, and material performance. This expert elicitation to develop LOCA frequency estimates is described in draft NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process" (June 2005).

The ECCS requirements in the United States are contained in 10 CFR 50.46, Appendix K to Part 50, and General Design Criterion (GDC) 35. Specifically, ECCS design, reliability, and operating requirements exist to ensure that the system can successfully mitigate postulated LOCAs. Consideration of an
Palisades Plant, located in Van Buren County, Michigan. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would exempt NMC from the requirements of 10 CFR 50.68, “Criticality Accident Requirements,” Subsection (b)(1) during the handling and storage of spent nuclear fuel in a 10 CFR part 72 licensed spent fuel storage container that is in the Palisades' spent fuel pool. The proposed action is in accordance with NMC's application of June 21, as supplemented August 25, 2005.

The Need for the Proposed Action

Under 10 CFR 50.68(b)(1), the Commission sets forth the following requirement that must be met, in lieu of a monitoring system capable of detecting criticality events:

Plant procedures shall prohibit the handling and storage at any time of more fuel assemblies than have been determined to be safely subcritical under the most adverse moderation conditions feasible by unborated water.

Section 50.12(a) allows licensees to apply for an exemption from the requirements of 10 CFR part 50 if the regulation is not necessary to achieve the underlying purpose of the rule and other conditions are met. NMC stated in its August 25, 2005, letter that applying the 10 CFR 50.68(b)(1) criticality prevention standards to dry shielded canister loading operations, conducted in connection with a 10 CFR part 72 license would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated.

Environmental Impacts of the Proposed Action

The NRC has completed its evaluation of the proposed action and concludes that if the exemption described above is not granted, it would result in an undue hardship. The details of the NRC staff's safety evaluation will be provided in the exemption that will be issued as part of the letter to the licensee approving the exemption that will be issued as part of the letter to the licensee approving the proposed action (i.e., the "no-action" alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

The action does not involve the use of any different resources than those previously considered in the Final Addendum to the Final Environmental Statement Related to Operation of the Palisades Nuclear Plant dated February 1978.

Agencies and Persons Consulted

On September 30, 2005, the staff consulted with the Michigan State official, Mary Ann Elzerman, of the Michigan Department of Environmental Quality, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see NMC's letter of June 21, as supplemented August 25, 2005. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site, http://www.nrc.gov/reading-rm/adams.html. 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 at 1-800-397-4209 or 301-415-4737, or send an e-mail to pdr@nrc.gov.

Dated at Rockville, Maryland, this 30th day of September 2005.

For the Nuclear Regulatory Commission.

L. Raghavan,
Chief, Section 1, Project Directorate III,
Division of Licensing Project Management,
Office of Nuclear Reactor Regulation.

[FR Doc. 05-19921 Filed 10-3-05; 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 October 21, and 26, 2005. A sample of agenda items to be discussed during the public sessions includes: (1) Discussion of the Energy policy Act of 2005, which provides for NRC regulation of accelerator-produced radioactive material and discrete sources of Ra-226; (2) Status of Specialty Board applications for NRC recognition; (3) Electronic signature in written directives; (4) Revision of NRC Form 313A; (5) RIS on dose control and assessment; (6) Review of the medical events definition commission paper. 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: October 25, 2005, from 8 a.m. to 11 a.m. This session will be closed so that NRC staff can brief the ACMUI on discussing information relating solely to internal personnel rules.

Dates and Times for Public Meetings: October 25, 2005, from 11 a.m. to 5 p.m.; and October 26, 2005, from 8 a.m. to 5 p.m.

Address for Public Meetings: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Room
# ACMUI MEMBERS

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