Status of Medical Events & Other Reported Events

ACMUI Meeting
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Division of Materials Safety and State Agreements

Status of Medical Events

- 31 Medical Events Reported - FY 2008
  FY 2008 Change
  35.200 3 + 2
  35.300 (10) 4 - 2
  35.400 (109) 10 0
  35.600 10 - 5
  HDR 8
  Breast Balloon (3)
  Gamma Knife 1
  Teletherapy 1
  35.1000 Y-90 Microspheres 4 - 8

Diagnostic Medical Events

35.200 3
Communication errors
Intended I-123 gave I-131 2
Physician did not specify isotope
Verbal order for I-123, wrote I-123, but scheduled I-131
Intended 10 mCi I-131, wrote 10 μCi 1
I-131, but delivered 10 mCi I-131

Therapy Medical Events

35.300 3
3 Nal-131
Three capsules – gave 1
Switched patient dosages
Administered wrong drug to wrong patient – prescribed Bexxar

Sm-153
Wrong dose calibrator geometry
(8 patients)

Brachytherapy Medical Events

35.400 8
1 GYN (2 patients)
Treatment planning magnification error (2 patients)
9 PROSTATE (109 patients)
2 – Leaking sources (2 I-125, 1 Pd-103 Mck applicator)
1 – Treatment Plan Computer failure – went to default dose
3 – Less than 80% of dose (57, 7, or 3 patients) or wrong treatment site (55 patients)
3 – Wrong treatment site (misplacement, misidentification, displacement)
**HDR Medical Events**

35.600 HDR  
8  
- Equipment malfunction on 12 of 29 fractions  
- Manually entered wrong dwell time  
- Wrong dose reference point  
- Wrong source wire length and wrong applicator  
- Gave 1/10 dose each of fraction instead of 10 X dose

**HDR Medical Events cont.**

HDR Continued  
3 Balloon Breast Procedures SenoRx and MammoSite  
Source Position Simulator was checked and catheter had kink so wrong source wire length was used  
Source placement was dislodged by 2 cm physicist over rode alarm  
Attached HDR connector to inflation catheter – saline leaked out

**Gamma Knife Medical Events**

Gamma Knife  
1  
- MRI set up reversed left and right side  
- Wrong side of brain treated

**Teledotherapy Medical Event**

35.600 Teledotherapy  
1  
50 % of Dose and Time – Written directive called for 2 approximately equal split times for each anterior-posterior (AP) and posterior-anterior (PA) treatment but only one time per side was given

**Y-90 Microsphere Medical Events**

35.1000  
4  
- stopcocks put in backwards caused kink  
- set erroneously most of dose was collected in the vent vial  
- Did not turn stopcock on the delivery device dose went to waste vial instead of into the patient  
- faulty equipment or human error

**Other Reported Events**

Involving Patients  
4  
- 5 mCi I-131 after 150 mCi I-131 ablation  
- Patient intervention  
- Sr-90 eye applicator after calibration  
- F-18 infiltration
# MEDICAL RADIOACTIVE MATERIAL EVENTS

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ACMUI Meeting, Oct. 28, 2008

## Other Medical Radioactive Material Events

- **Categories**
  - Lost sources, sealed & unsealed – 12
  - Leaking sealed sources – 7
  - Fetal/embryo dose - 2

## Other Medical Radioactive Material Events

- **Categories**
  - Landfill Alarms - 4
    - Decay-In-Storage (DIS) waste
    - Unknown origin
    - Released patient (10 CFR 35.75) waste
  - Miscellaneous
    - Equipment Malfunction – 3
    - Packaging - 4
    - Overexposure -1

## Lost Sources - Sealed & Unsealed

1. I-131 capsule (0.055 mCi) from thyroid neck phantom
2. Ir-192 seed ribbon (6 mCi) missing from post-treatment inventory; found 3 days later in off-site laundry
3. I-125 seed (0.157 mCi) for breast tumor localization lost via suction canister after removal.
4. I-125 seed (0.33 mCi) lost when pig of 20 seeds overturned during autoclaving process.
5. 18 I-125 seeds (5 mCi) unused after implant disposed by improperly trained technologist via nuclear medicine decay-in-storage waste.
6. Two I-125 seeds (1 mCi) unused after implant, improperly left in applicator; during cleaning, seeds ejected and flushed down drain.
7. I-123 capsule (200 mCi?) lost when pig not returned to proper storage location.
8. I-125 seed (0.161 mCi) lost after implant removal via general trash.
Lost Sources - Sealed & Unsealed

9. Two Gd-153 transmission sources (194 mCi total) lost when gamma camera disposed to scrap recycler.
10. Five Ir-192 seeds (2.95 mCi) in ribbon lost during temporary implant.
11. 114 Pd-103 seeds (126.5 mCi) unused for implant, lost during storage in area undergoing renovation prior to return.
12. I-125 seed (0.49 mCi) unused for implant missing after inventory of six non-implanted seeds.

Leaking Sealed Sources

Excludes leaking sources reported under medical event (ME)

1. Five seeds unused after implant; wipe testing of storage pig, loading cartridge and one seed found contaminated. Return to vendor for analysis found seed damaged, likely during use in applicator.
2. I-125 seed jammed in applicator. Technician unloaded seed from cartridge with bare hands; survey found cartridge & hands contaminated.

Leaking Sealed Sources

3. Vendor during I-125 seed strand assembly damaged a seed causing contamination of working/crimping tool.
4. Five I-125 seeds/two different lots unused after implant found leaking & visibly damaged; no patient or work area contaminated. Cause was excessive force on stacked seeds during cartridge loading.
5. I-125 seed ruptured by cauterization tool 3 days after implant. Patient & equipment contaminated; thyroid bioassay < 1 rem (cSv).

Leaking Sealed Sources

6. Vendor reported leaking I-125 seed cross-contaminated potentially 1500 seeds shipped to multiple customers.
7. Licensee reported at least one I-125 seed leaking after survey of group of seeds for removable contamination; found after autoclaving & cartridge loading. Analysis by vendor of returned seeds found surface contamination but no defects (welds, encapsulation).

Fetal/Embryo Dose

1. Patient received 149 mCi I-131 NaI two days after negative HCG pregnancy test. Patient informed pregnant 2 months after administration; 32 cGy (rad) estimated embryo dose. Event discovered during NRC inspection. No adverse effects expected because of stage of pregnancy.
2. Patient received 134 mCi I-131 NaI after two negative HCG pregnancy tests done within 5 days prior to administration. Patient informed pregnant 3 weeks later; 35 cGy (rad) estimated embryo dose. Patient failed to follow instructions.

Landfill Alarms

- Four event reports
  ➢ 2 events – Waste origin unknown
  ➢ 2 events - Improper disposal of hospital LLRW; (source unknown in 1 event)
- All involved I-131
- All events reported from Agreement States (CA, AL)
### Miscellaneous - Machine Malfunctions

1. Gamma Knife shielding doors failed to close after treatment; manually closed by medical physicist with negligible dose. No deviation from written directive.
2. High Dose Rate (HDR) source failed to retract properly during testing by manufacturer's field engineer. Source disconnected & top of source capsule clipped off by closing vault door.

### Miscellaneous - Packaging

1. Inner pig with 51 I-125 seeds opened during shipment. Exposure levels significantly exceed limits; no contamination or loss or overexposures occurred.
2. Three packages of Co-57 flood sources received with removable contamination of the surfaces exceeding reportable limits. Contamination was Tc-99m; source unspecified.

### Miscellaneous - Overexposure

- Two workers for a radiopharmacy received extremity overexposures in the making of I-131 capsules. Doses ranged 53-105 rem (cSv). Lack of written procedures & proper handling tools cited.

### Miscellaneous - Machine Malfunctions

3. During HDR source exchange by field engineer, old source failed to enter exchange container. Cause was dummy & active sources extended into same pathway became stuck outside safe. Vendor source recovery team sent to successfully retract source after engineer cuts wrong source (dummy instead of active) wire to place in emergency shielded container.

### Miscellaneous - Packaging

3. Five packages found with removable Tc-99m contamination exceeding limits. Cause was cross-contamination from radiopharmacy courier who handled empty contaminated containers from previous stop. Significant vehicle and skin contamination.
4. A package of Tc-99m radiopharmaceuticals found with significant removable surface contamination. Package from centralized radiopharmacy.

### Comparison Radioactive Material Events

<table>
<thead>
<tr>
<th>Lost sources – sealed &amp; unsealed</th>
<th>FY08</th>
<th>FY07</th>
<th>FY06</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaking sealed sources</td>
<td>7</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Landfill Alarms</td>
<td>4</td>
<td>6</td>
<td>27</td>
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<tr>
<td>Miscellaneous</td>
<td>8</td>
<td>7</td>
<td>6</td>
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</tbody>
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Observations

- Multiple search queries needed to capture all reported events involving medical use of radioactive material, especially those other than MEs.
- Suggested NMED improvement is search capability with multiple key words.