RI - DNMS Licensee Event Report
Disposition

Licensee: Mercy Health Partners

Event Description: Lost Iodine Seeds

License No: 37 01374-03 | Docket No: 03 00 2983 | MLER-RI: 2006-002

Event Date: 1-20-06 | Report Date: 1-26-06 | HQ Ops Event #: 42284

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [X] 10 CFR 20.2201 Theft or Loss
- [X] 10 CFR 20.2203 30 Day Report
- [ ] Other

- [ ] 10 CFR 30.50 Report
- [ ] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [ ] Special Inspection — Inspector/Date
- [ ] Telephone Inquiry — Inspector/Date
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:

R. McKinley / TBD 4/10-11/06

- [ ] Daily Report
- [X] Review at Next Inspection

3. REPORT EVALUATION

- [X] Description of Event
- [X] Levels of RAM Involved
- [X] Cause of Event
- [X] Corrective Actions
- [X] Calculations Adequate
- [ ] Additional Information Requested from Licensee — N/A

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION — N/A

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only) — N/A

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS Event inspected 4-10 to 11-06 and appears that licensee ~~Event License To be addressed during routine inspection scheduled for 2nd qtr 2006~~ inspected

[X] Non-Public — Inspector Signature: Richard C. McKinley — Date: 4/19/06

[ ] Public-SISP REVIEW COMPLETE — Branch Chief Initials: PC — Date: 4/19/06

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05

never received 2 sources

Mercy Health Partners
746 Jefferson Avenue
Scranton, Pennsylvania 18501

Donna Janda, Health Physicist
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Janda,

Per 10 CFR 20.2201 (b)(2)(ii) this report is being filed with your office as you were my contact by phone during this incident.

On 1/20/06 I notified Peter Snyder at the NRC Hotline about the loss of two (2), I-125 seeds to be utilized for a Prostate brachytherapy implant. These were sealed sources with an apparent activity of 0.3467 mCi per seed as of 1/20/06, but an actual activity of 1.26 millicuries for both seeds, thus prompting the call as the actual activity exceeded the 1 millicurie activity level listed in appendix C of 10 CFR Part 20.
Initial requests from G.E. Healthcare and Anazao Health for reports were made. Anazao Health called us and confirmed that they conducted the 10% seed calibration, but did not conduct a full inventory of the seeds. We were unable to obtain an immediate report from G.E. Healthcare.

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form:

The seeds in question were sealed sources manufactured by G.E. Healthcare (Model 6711(OncoSeed)). These sealed sources had an apparent activity of 0.3467 millicuries per seed as of 1/20/06, but an actual activity of 0.63 millicuries per seed for a total of 1.26 millicuries for both seeds.

(ii) A description of the circumstances under which the loss or theft occurred; and (iii) A statement of disposition, or probable disposition, of the licensed material involved:

On Thursday January 12, 2006 our medical physics staff ordered 88 seeds from G.E. Healthcare to be implanted into a patient on 1/20/06. The seeds, by contract, are sent to Anazao Health for inventory, assay confirmation and sterilization for patient implant. Because the seeds were pre-sterilized, we were unable to do a manual inventory count of the seeds until they were opened under sterile conditions in the OR during the actual patient procedure.

During the procedure, 68 seeds were placed into the patient, the remaining seeds were counted and a total of 18 seeds were counted, thus two (2) seeds were not present. Following the seed placements, we were able to count 67 seeds in the patient by radiographic imaging, and one seed was passed by the patient and retrieved, for a total of 68 seeds. We had a total of 18 seeds left over from the procedure, thus only a total of 86 seeds were accounted for following our post study inventory.

Our medical physics staff confirmed that no seeds were lost during the procedure and as is our policy, conducted a complete survey of the OR utilized for the procedure following the seed placement. No seeds were found and the survey was negative. The physics staff then contacted me to advise me of the missing seeds. I then requested that a second and third survey be conducted. Again, no seeds were found and all survey results were negative. I then advised the medical physics staff to release the OR for use.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas:

There were no unusual exposure levels noted to staff and all surveys conducted were negative.

(v) Actions that have been taken, or will be taken, to recover the material:

Multiple surveys were conducted with a Victoreen Model #: 270 (SN 91537) with an end window probe calibrated specifically for I-125 sources on 9/07/05. Thus we our sure we never received the full inventory of 88 seeds.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material:

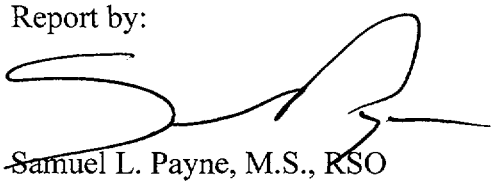
Because we now have adequate procedures in place, we will request that Anazao Health confirm a full inventory of all seeds ordered.

Conclusion:

Although both G.E. Healthcare and Anazao Health will not admit to the loss of these seeds from their end, we do not believe that we, as the end user, obtained the full order of 88 seeds and only received 86 seeds. We can not account for the missing seeds from our end and multiple counts of the seeds and surveys conducted by our staff confirm that there was no loss of seeds at our facility. As Anazao Health did not confirm by a full inventory count that they were in receipt of the full inventory of seeds ordered from GE Healthcare, I believe they would be in a better position than we, as the end user, to account for the missing seeds, if they were all sent in the first place. I have attached the following documents for your review:

1. Letter from Warren Keller, medical physics, Mercy Hospital dated 2/15/06 (2 pages)
2. Assay process from Anazao Health faxed to us on 2/3/06 (2 pages)
3. Seed Certificaltion from Anazao Health (2 pages)
4. Package Insert for OncoSeed (Iodine-125 Seeds) (4 pages), and
5. Incident Report from GE Healthcare (3 pages).

Report by:



Samuel L. Payne, M.S., RSO
Mercy Health Partners
Scranton, Pennsylvania

cc. Radiation Safety Committee Mercy Hospital
Warren Keller, Medical Physics Mercy Hospital

February 15, 2006

Samuel Payne, MS RSO
Mercy Hospital
Scranton, PA 18510

Dear Sam:

On Thursday January 12, 2006 we received a shipment of I-125 seeds ordered from Oncura Inc. a division of Amersham Health sent to Anazao Health for sterilization, and a third party independent 10% assay and count.

The implant was on Friday January 20, 2006. The Real Time procedure which means it was planed in the OR and the seeds had to be loaded in the OR. Since the seeds arrive sterile we could not open the package ahead of time. The package was opened in the OR and we counted the seeds as we loaded them into the needles and then counted the left over seeds. A total of 88 seeds were ordered. 68 seeds were implanted into the patient with 18 seeds left over, a total of 86 seeds. We then did a recount of the left over seeds and recount of the seed implanted according to the plan and still came up with 86 seeds. We did a survey of the Lead Pig the seeds came, the glass vial that held the seeds, the packaging they came, sterile table we were working off of and the floor around the table. No loose seeds were found as a result of this survey. We surveyed all areas of the OR and found no loose seeds. We also performed a survey of all staff and also performed a second survey of every one before they were permitted to leave the OR. The patient was transferred from the OR table to a cart, leaving behind all the sheets that were underneath the patient while he was on the OR table. The OR patient table, instrument tables, the table we had used to load the seeds, suction, instruments, pails, trash, linens and surgical gowns were surveyed and no loose seeds were found. We did a survey of the foley catheter that was removed from the patient and found one seed. This was a seed that had already been implanted. The entire room from corner to corner, side to side and top to bottom was surveyed four times after the case was finished and no loose seeds were found. We had X-ray films of the patient pelvis taken and did a count of the seeds. The X-ray film showed a total of 67 seeds of the 68 that were implanted. The survey meter utilized for all surveys performed was a **Victoreen** Model #: 290 Serial #: 91537 last calibrated on 09/07/2005 specifically calibrated for I-125 sources.

67 seeds shown on the X-ray Film
1 seed recovered from the foley catheter
18 seeds left over

86 total seeds

I contacted the RSO as soon as we verified from the X-ray films that there were 67 seeds in the patient. I then notified Amersham Health and Anazao Health of this situation. I was contacted by Hal Weaver from Anazao Health and Subash Patel from Amersham Health that they would start a check at their ends. Also notified was C.J. Urlaub Chief

Administrative Officer of Mercy Hospital. The Or room was quarantine until it is released by the RSO. We notified the OR staff that the room was restricted and quarantined until it is released by the RSO. On Sunday January 22, 2006 we performed two more surveys going corner to corner, side to side and top to bottom of the quarantined room still not finding any loose unaccounted for seeds the RSO stated that we could release the room and all the contents, instruments, linens, trash, surgical gowns and X-ray equipment.

On February 3, 2006 I received a copy of the procedure that Anazao Health uses to process the seed orders. They do not count the seeds when they receive a shipment nor count them before they send them out. All though they send a certificate that shows the 10% assay results and gives the number of seeds in the shipment. They actually do not know how many seeds that they had received from Amersham or how many seeds they then sent on to us after they did the assay and sterilization.

We are still waiting for Amersham Health to send a report of the results of their investigation into this situation. Although their initial findings called to me by Mr. Patel, on February 9, 2006, he stated they had no extras seeds at their facility after preparing our order and that their records show they had sent out 88 seeds to Anazao Health as the Third Party to sterilize, 10% assay and count.

Attached are the two documents: one from Amersham Health Ocura Division and one from Anazao Health.

What I find most troublesome is that Anazao Health certificate shows 88 seeds but they did not count the seeds when they received them nor did they count them after assaying the 10% and returning them with the rest of the seeds to then sterilize them before shipping the seeds to us. It is possible that Anazao Health never received 88 seeds from Amersham or if they did that in fact receive 88 seeds from Amersham that they may not have actually send us the 88 seeds, since they never did a count.

Warren S. Keller
Radiation Safety Tech.
Medical Physics Dept.
Mercy Hospital
746 Jefferson Ave.
Scranton, PA 18510

10% Assay Process – Work Instructions

Purpose:

The purpose of these instructions are to detail the steps taken by AHC for manual 10% assay, verification of seed activity, for Brachytherapy seed orders.

Getting Started:

- Prior to performing any assaying processes, the assay equipment needs to have had the Daily Channel Checks completed. This process is done at the beginning of the first shift of everyday. For detailed instructions refer to Assay Machine and Station Prep for Assays - Work Instructions.
- Clear individual workstation of all materials from any previous job, or any miscellaneous materials not associated with this job. The workstation should be free and clear of ANY paperwork or materials from any other job.
- Radioactive Survey of workstation has been performed to verify that no radioactive materials have been left from previous job.
- Prior to processing seeds for each job, order must be entered into computer and pharmacy labels generated for each loading job to be completed.
- Retrieve a container from the cart containing Jobs for 10% Assay and place the container at the work station.
- This process can be used for manual 100% assay of stranded seeds, IBt Strands or Rapid Strands (seeds that arrive pre-stranded). Follow all instructions listed below, except assay all strands (100% manual assay) and retrieve job from Rapid Strand Jobs to be Assayed and Cut cart.
- Review prescription order and confirm that this job requires 10% Assay.

Paperwork Setup:

- Record survey results and job information on the Work Station Log.
- Record all data for Batch Control and Assay Record from customer supplied documents. This data includes confirmation number(s), header information, service(s) requested and assay data. Assay data consists of:
  - Verification of survey of work area – Has the area been surveyed and cleared of any other radioactive material.
  - Total seeds ordered – Total amount of seeds with job.
  - Seed quantity to assay – If the job is loose seeds for 10% Assay, seeds quantity will be 10 seeds or 10% of the seeds, the greater quantity of the two. For example if the amount of seeds is 66 the amount for assay will be 10 seeds and if the amount of seeds is 131 the amount for assay will be 14 seeds (Always round up).
  - Dial setting – Setting for each source. Use chart located in the work station for this dial setting.
  - Assay Date – Day of assay.
  - Assay Time – Time when assay was started.

Issued By: _____ Title: Brachytherapy Mgr Date: 3/7/2005

Approved By: _____ Title: President Date: 3/7/2005

10% Assay Process – Work Instructions

- Desired activity on the assay date – Mean activity of the seeds on the day of assay, plus 5% and minus 5%.
- Assay Station ID – The station ID, what machine was used.

Assay Process:

- Perform wipe and confirm that there is no contamination.
- Check that the dial setting, of the assay machine, is set on the correct number.
- Pour out the desired amount of seeds that will be needed for the assay, if the seeds are supplied loose, or unload the amount seeds from a preloaded Mick cartridge that will be needed for the assay. Be sure to shield all the loose seeds.
- Place one seed at a time into the dose calibrator and record the reading on to the Batch Control and Assay Record.
- When finished assaying all seeds, return the seeds back to the vial and proper shielding or reload the Mick cartridge and place back in original packaging.

Finishing Assay:

- Survey the work area and record results on the Work Station Log.
- Perform a wipe of the station once the job is complete and have someone re-survey the station. Record re-survey data on the Work Station Log and record wipe data on the Batch Control and Assay Record.
- Sign appropriate document, Batch Control and Assay Record when finished.
- Move container to Jobs for RX Script / 10% Assay Processing cart.

Medi-Physics, Inc.
3350 North Ridge Ave.
Arlington Heights, IL 60004 USA

Certification

Iodine-125 Sealed Sources for Medical Uses

The following specified radioactive sources manufactured by Medi-Physics, Inc. have been subjected to the tests described below and have been given the results listed.

Reference Date (Y/M/D): 2006/01/13	Order Reference No: 1180843	Order ID No: 81494360

Container Number	1	1				
Model Number	6711	6711				
Quantity of Seeds	70	18				
Air Kerma Strength in μGym²/h*	0.486	0.486				
Total Air Kerma Strength in μGym²/h	34.020	8.748				
Apparent Activity in mCi*	0.383	0.383				
Total Apparent Activity in mCi	26.810	6.894				
Leak Test Date (Y/M/D)	2005/11/24	2005/11/24				
Expiration Date (Y/M/D)	2006/05/19	2006/05/19				
Specified Implant Date (SID) (Y/M/D)	2006/01/16	2006/01/16				
Apparent Activity on (SID) mCi	0.370	0.370				
Air Kerma Strength on (SID)μGym²/h	0.470	0.470				

NS+: Not Specified

All seeds have passed a leakage and contamination test showing less than 0.185 kBq, 0.005 μCi of removable Iodine-125 activity. No other certification is to be implied.

"Total" is defined as the quantity of seeds in the lot multiplied by stated air kerma strength or stated apparent activity of that lot.

*"Air kerma strength", and "apparent activity" are descriptive of the radiation output and not the content activity. For accounting and regulatory purposes calculate the content activity of Model 6702, Model 6711 (OncoSeed™) and 6733 (EchoSeed™) seeds by multiplying the "Total apparent mCi" by 1.34, 1.78 and 1.78, respectively. Multiply the content activity in milliCuries (mCi) by 37 to obtain the SI value in MegaBecquerels (MBq).

Read the reverse side of this form for information about source description; physical characteristics of I-125; specification of source; method of calibration; and accuracy.

*Apparent Activity & Air Kerma Strength on Customer Specified Implant Date (SID) are decay correction calculations from the reference date to the date as provided by the customer.

Quality Control: Catherine G. Conley	Date: 09Jan06

43-6708I
Revised March 2004

AnazaoHealth™
Brachytherapy | Create. Heal. Live™

5710 Hoover Boulevard | Tampa, Florida 33634
800.995.4363 Telephone | 800.697.5250 Facsimile
www.anazaohealth.com

I-125 Sealed Source Calibration Certificate

Account: Mercy Hospital **Amersham** **Model 6711** **Quantity:** 88 seeds

Patient Name: Kinback, George **Source Lot Number:** **Mean:** 0.383 mCi
Implant Date: 1/16/2006 81494360

AHC Analyst: Miranda **Manufacturers** **Total Apparent Activity:** 33.70 (mCi)
Date Assayed: 1/10/2006 **Cal.Date:** 1/13/2006

Test Number	Amersham Mean mCi Activity	Air Kerma Activity	AHC Assayed mCi Activity	Decay Factor	Assay mCi Amersham Calibration Date	Air Kerma Activity	Percent to Mean	Decay Factor from cal to Implant	Assay mCi Implant Date	Air Kerma Activity
1	0.383	0.485	0.390	0.9656	0.377	0.476	-1.7%	0.9656	0.364	0.460
2	0.383	0.485	0.378	0.9656	0.365	0.462	-4.7%	0.9656	0.352	0.446
3	0.383	0.485	0.389	0.9656	0.376	0.475	-1.9%	0.9656	0.363	0.459
4	0.383	0.485	0.389	0.9656	0.376	0.475	-1.9%	0.9656	0.363	0.459
5	0.383	0.485	0.384	0.9656	0.371	0.469	-3.2%	0.9656	0.358	0.453
6	0.383	0.485	0.401	0.9656	0.387	0.490	1.1%	0.9656	0.374	0.473
7	0.383	0.485	0.386	0.9656	0.373	0.471	-2.7%	0.9656	0.360	0.455
8	0.383	0.485	0.399	0.9656	0.385	0.487	0.6%	0.9656	0.372	0.471
9	0.383	0.485	0.387	0.9656	0.374	0.473	-2.4%	0.9656	0.361	0.456
10	0.383	0.485	0.393	0.9656	0.379	0.480	-0.9%	0.9656	0.366	0.464

Irving Green
Nuclear Pharmacist

Iodine 125	
DAY	DECAY FACTOR
-4	1.0478
-3	1.0356
-2	1.0236
-1	1.0117
0	1.0000
1	0.9884
2	0.9769
3	0.9656
4	0.9544
5	0.9434
6	0.9324
7	0.9216

Amersham Health

OncoSeed (Iodine-125 Seeds)™

Model 6711
Non-Sterile OncoSeed
Model 6715
Sterile Convenience Pack

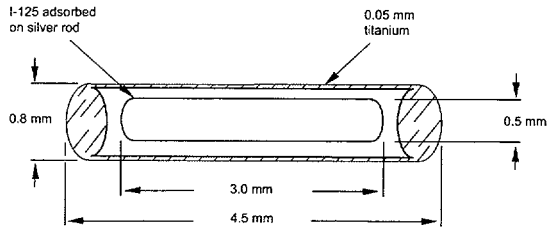
R_x ONLY

Device Description

Model No. 6711

OncoSeed seeds consists of a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod.

ONCOSEED DIAGRAM



Model No. 6715

The OncoSeed Sterile Convenience Pack contains fifteen OncoSeed Seeds (Model 6711) loaded into a Mick® Disposable Cartridge and steam sterilized Ready to Use.

Physical Properties

- Principle Radionuclide: ^{125}I (Iodine)
- Radionuclide Purity: > 99.9% ^{125}I; < 0.005% ^{126}I
- Half-life of ^{125}I: 59.43 days
- Types of Radiation: X-ray and Gamma
- Energy Level:

Photon	27.4 keV
X-ray	31.4 keV
Gamma	35.5 keV
Fluorescent X-Rays from the Silver Rod	22.1 keV and 25.2 keV

- Decay Mode: ^{125}I decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of an OncoSeed.

Shelf Life

The useful "shelf life" of the source and convenience pack can be calculated by considering the day of use after the assay date and corresponding value of decay factor. Unused seeds must be disposed of within six months of the leak test date shown on the certification form accompanied with the product.

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below:

Iodine-125 Decay Chart (59.43 day Half-Life[1])

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.657
2	0.977	38	0.642
4	0.954	40	0.627
6	0.932	42	0.613
8	0.911	44	0.599
10	0.890	46	0.585
12	0.869	48	0.571
14	0.849	50	0.558
16	0.830	52	0.545
18	0.811	54	0.533
20	0.792	56	0.520
22	0.774	58	0.508
24	0.756	60	0.497
26	0.738	62	0.485
28	0.721	64	0.474
30	0.705	66	0.463
32	0.689	68	0.452
34	0.673	70	0.442

Intended Use/Indications

OncoSeed seeds with apparent activities from 0.191 to 1.01 mCi are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

OncoSeed seeds with total apparent activities greater than 1.01 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

OncoSeed seeds are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with OncoSeed seeds.[10, 11]

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g., ulcerated) is not recommended with OncoSeed seeds.

Warnings

1) Do not use visibly damaged seeds for implantation.
2) Do not apply excessive force during loading/removing of seeds.
3) Do not pick up seeds with the fingers, use forceps.
4) Do not use dry heat or chemical sterilization.
5) To minimize radiation exposure, use vented chemical hood and proper shielding in handling of seeds.
6) Caution should be exercised in performing Transurethral Resection (TURP) with electrocautery in patients who have undergone prostatic radioactive seed implantation. Because the integrity of the seed capsule can potentially be breeched by electrocautery, the patient and surgical personnel should be monitored for any possible radioactive contamination after the procedure. Additionally the radioactive half-life of the seed should be considered prior to the use of electrocautery.

Precautions

1) Loading/Unloading of Seed

Sterile Convenience Pack (Model 6715) is loaded Ready to Use. No special loading/unloading is required.

Do not force an OncoSeed into (or from) any implant tube, needle, or cartridge; doing so may damage the wall or end welds of the seed, potentially causing release of I-125 into the environment and into body fluids should the seed be implanted. UNDER NO CIRCUMSTANCES SHOULD VISIBLY DAMAGED SEEDS BE IMPLANTED.

When loading or removing an OncoSeed from plastic or rubber afterloading catheters, it is advisable to use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. If a chemical hood is not available, a plastic glove box specifically designed for work with radioactive iodine may be substituted, provided it is properly vented.

If a razor blade, scalpel, or other sharp tool is used to remove an OncoSeed from the afterloading catheters, use extra care to avoid contacting or cutting a seed. A seed which has been damaged (nick, cut, slice, or other type of damage) will release I-125 into the environment.

To assure that seeds have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30 keV photons. This survey should include wipe (or leak) tests of seeds and an overall area survey. For seed leak test details, contact Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. Residents of Canada call 905-847-1166 or 1-800-387-7146.

2) Seed Corrosion

The titanium shell of an OncoSeed has excellent corrosion resistance under normal use. However, do not expose a seed to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

3) Personnel Monitoring

OncoSeed seeds are radioactive, and appropriate precautions must be taken when handling the sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel.

Personnel monitoring is required. Typically a film badge or TLD dosimeter worn on the body and a ring badge (during seed handling) is adequate.

4) Storage and Transportation

The lead seed container effectively shields >99.9% of the photons from I-125. The lead seed container may be used for storage and transport of seeds.

5) Seed Handling

OncoSeed seeds should be handled behind shielding of adequate thickness. Forceps, either reverse or normal action, should be used to maintain operator to seed distance. If normal action forceps are used, gentle pressure should be applied so that seeds are not damaged. ONCOSEED SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

OncoSeed Convenience Pack is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use. No special handling is required.

6) Seed Sterilization

OncoSeed seeds are not sterilized when shipped and must be sterilized prior to use. Only the steam sterilization method must be used

Sterile Convenience Pack is shipped sterilized. In the event resterilization is required, only the steam sterilization method must be used using the following conditions: 120°C-122°C, 14-18 psi, 30-33 minutes

DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

7) Accidental Damage to Seed

Although an OncoSeed has a high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing to rupture a seed causing it to release "free" I-125. If this happens, the area of the accident should be closed off, the seeds should be sealed in a lead container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

Adverse Reactions

General

Since I-125 seeds deliver radiation to the target tissue in order to provide therapy, any adverse effect associated with tissue radiation damage theoretically may be associated with their use. The potential for and symptoms of such damage will vary depending on the nature and location of the target tissue.

Prostate Brachytherapy

The following adverse event information has been derived from published articles listed in the reference section.

Immediately subsequent to transperineal seed implantation for prostate brachytherapy, there is often procedure-related bleeding or burning beneath the scrotum, or passage of blood in the urine.[12] These symptoms are usually treated supportively. Incidents of asymptomatic seed embolization to the lungs have been noted in the literature.[13]

Short-term irritative or obstructive urinary symptoms, such as frequent, urgent or uncomfortable urination, dribbling, or difficulty voiding, may be experienced after implantation, and may last for several weeks to a few months.[14-18] Generally, these are transient, mild effects which resolve spontaneously (as seed radiation levels decrease) or require minor intervention.

Impotence has been noted as a long-term adverse effect, with an incidence ranging from 6-30%, as published by some groups.[14, 18-20] The risk of impotence may be age-related.[18] Proctitis may occur, with several groups reporting a 2-6% incidence.[15, 18, 21,22] Long-term incontinence is uncommon,[14, 18, 21] although patients who have previously undergone transurethral resection of the prostate (TURP) are at a higher risk.[23,24] Urethral stricture has been reported in a small percentage of cases.[14, 15, 18]

Patient Counseling Information

All patients should be informed of the nature of OncoSeed seed implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received an OncoSeed seed implant. Guidelines for necessary precautions have been established.[25]

All patients should be advised of the possibility that, during a course of treatment, one or more OncoSeed seeds might slough off and become detached as a tumor regresses and becomes smaller. Under these circumstances, any bandages or linens which come into contact with the site of the implant should be scrutinized for small metallic seeds (1/4 of an inch long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon and placed in a jar or other container, and placed in an inaccessible area in the home. The radiation center should be notified of such an event as soon as possible after its occurrence.

How Supplied

Model No. 6711 OncoSeed seeds are shipped in a shrink wrapped, screw-cap glass vial which is inside a sealed lead "securitainer" The lead securitainer can be opened by pulling off the plastic ring seal. OncoSeed seeds are supplied non-sterile and loose with apparent activities from 0.191 to 6.24 mCi per seed and, by special request, from 6.24 to 40 mCi per seed. Please contact Amersham Health (Medi-Physics, Inc.), Customer Service for further details.

Model No. 6715 OncoSeed seeds in the Sterile Convenience Pack contains fifteen Model 6711 OncoSeeds loaded into a Mick Disposable Cartridge and steam sterilized Ready to Use. Each Sterile Convenience Pack is placed in a primary sterility barrier and held in a lead container, which holds a maximum of ten convenience packs. OncoSeed Sterile Convenience Pack are available with apparent activities from 0.27 mCi to 0.673 mCi per seed. Please contact Amersham Health (Medi-Physics, Inc.), Customer Service for further details.

Both seed models are packaged with labeling information on air kerma strength and apparent activity per seed, total air kerma strength and apparent activity, reference date, number of seeds, and order I.D. number. Air kerma strength is specified in units of microGray meter squared per hour ($\mu Gym^2/h$), and apparent activity has units of milliCurie (mCi). The label contains precautionary regulatory statements pertaining to licensing of the seeds. Any discrepancies noted upon receipt of the product, from that which was ordered, must be reported immediately to Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. In Canada call 905-847-1166 or 1-800-387-7146.

Leak Testing

OncoSeed seeds are leak tested prior to shipment and have passed a leak test showing <0.005 µCi of removable I-125 as required by Illinois Department of Nuclear Safety 32 Ill. Adm. Code Part 335, Subpart C, 335.2050. This leak test value is printed on the Certification form that accompanies each shipment.

OncoSeed seeds that retain clinical utility for more than six months must be leak tested at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State, except for sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer, as prescribed in Illinois Department of Nuclear Safety 32 Ill. Adm. Code Part 335, Subpart C, 335.2050.

OncoSeed seeds intended for temporary implants (1 to 40 mCi) might fall into the above category and, if so, would need to be leak tested. Additionally, since the higher activity seeds are often reused, leak testing at more frequent intervals is recommended. For leak test details, contact Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. Residents of Canada can call 905-847-1166 or 1-800-387-7146.

Unused OncoSeed seeds intended for permanent implants (nominal strength of 0.50 mCi) will not require additional leak testing providing they are disposed of within six months of the date shown on the Seed Certification form.

Licensing

The Illinois Department of Nuclear Safety (IDNS) has approved this sealed source for distribution to persons licensed pursuant to 32 Ill. Adm. Code 330.260(a) and Part 335 Subpart H 335.7010 or under equivalent licenses of the USNRC or an Agreement State, and outside the United States, to persons authorized by the appropriate authority.

Directions for Use

General

OncoSeed seeds and Convenience Pack should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Radiation detection equipment, capable of detecting 30 keV photons, should be available whenever I-125 Seeds seeds are being handled. The seeds are quite small and it may be difficult to locate a dropped seed visually.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.[28-31]

OncoSeed seeds can be implanted directly with an 18 or larger gauge needle or using a seed applicator attached to the needle. Common seed applicators are the Mick, Henschke and Scott. The Royal Marsden Gold Grain gun can be used to implant seeds provided a special modification is requested of the manufacturer.

For temporary implant, OncoSeed seeds are usually loaded into plastic tubing or other devices (e.g., gold eye plaques) to facilitate afterloading procedures and seed recovery.

OncoSeed seeds are shipped with a source output strength certificate. However, if verification of source output is considered necessary, the AAPM guidelines should be followed.[7]

OncoSeed Convenience Pack (Model 6715) is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use.

Steam Sterilization (autoclave):

Model 6711

Use the normal cycle (121 degrees C at 15 psi for 15 to 30 minutes) or the flash cycle (133 degrees C at 30 psi for about 3 minutes). DO NOT EXPOSE SEEDS TO TEMPERATURES AND PRESSURES IN EXCESS OF 138 DEGREES C and 35 PSI. Autoclaves should be equipped with traps or other means to prevent seed loss through the drain hole.

When in doubt about compatibility of steam heat with various seed containers, load them with non-radioactive seeds to determine the effect of steam on the container material and on seed recovery.

Model 6715

Sterile Convenience Pack is shipped sterilized Ready to Use. Refer to the Precautions section, item six, for resterilization.

Dosage and Administration

The total activity of OncoSeed seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice [5-9, 26, 27] should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution around each individual seed is not isotropic.[2-9] This anisotropy should be considered in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility, and together with the silver rod, results in a total self-absorption of approximately 35%.

Iodine-125 has a 59.43 day half-life. Decay corrections must be made in order to properly calculate the activity of the seeds on the day they are implanted.

ACCOUNTABILITY/DISPOSAL

Iodine-125 is an accountable radioactive material. OncoSeed seeds should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the appropriate federal or state licensing agency.

When disposal is indicated, OncoSeed seeds should be transferred to an authorized radioactive waste disposal agency. OncoSeed seeds should never be disposed of in normal waste.

If a seed has been visibly damaged in any way, seal it in a container and discard it immediately to radioactive waste and check the area for contamination.

An OncoSeed disposal service is provided by Amersham Health (Medi-Physics, Inc.). Customers wishing to dispose of OncoSeed seeds in this manner must contact Amersham Health (Medi-Physics, Inc.), Customer Service for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR Parts 171-177) regarding packaging and labeling,

Shipments are to be directed to: Amersham Health (Medi-Physics, Inc.), 3350 N. Ridge Ave., Arlington Heights, IL 60004.

REFERENCES

1. "X-Ray and Gamma Standards for Detector Calibration," International Atomic Energy Agency, Tech Doc-619, September, page 149 (1991).
2. Schell MC, Ling CC, Cromadzki ZC, and Werking KR, Dose Distributions of Model 6702 I-125 Seeds in Water *Int J Radiat Oncol Biol Phys* 13: 795-799 (1987).
3. Ling CC, Schell MC, and Yorke ED, Two-dimensional Dose Distribution of I-125 Seeds. *Med Phys* 12, no. 5: 652-655 (1985).
4. Ling CC, Anderson LL and Shipley WU, Dose Inhomogeneity in Interstitial Implants Using I-125 Seeds. *Int J Radiat Oncol Biol Phys* 5: 419-425 (1979).
5. Nath R, Anderson LL, Luxton G, Weaver KA, Williamson JF, and Meigooni AS, "Dosimetry of interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43," *Med Phys* 22, 209-234 (1995).
6. Bice WS, Prestlidge BR, Prete JJ, and Dubois DF, "Clinical impact of implementing AAPM Task Group 43 on permanent prostate brachytherapy using I-125," *Int J Radiat Oncol Biol Phys* 40, 1237-1241 (1998).
7. Nath R, Anderson LL, Meli JA, Olch AJ, Stitt JA, and Williamson JF, "Code of Practice for Brachytherapy Physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56," *Med Phys* 24, 1557-1648 (1997).
8. Kubo HD, Coursey BM, Hanson WF, Kline RW, Seltzer SM, Shuping RE, and Williamson JF, "Report of the Ad Hoc Committee of the AAPM Radiation Therapy Committee on ^{125}I Sealed Source Dosimetry," *Int J Radiat Oncol Biol Phys* 40, 697-702 (1998).
9. Williamson JF, Coursey BM, DeWerd LA, Hanson WF, Nath R, and Ibbott G, "Guidance to users of Nycomed Amersham and North American Scientific, Inc., I-125 Interstitial Sources: Dosimetry and calibration changes: Recommendations of the American Association of Physicists in Medicine Radiation Therapy Committee Ad Hoc Subcommittee on Low-Energy Seed Dosimetry," *Med Phys* 26, 570-573 (1999).
10. Hilaris BS, (ed.) *Handbook of Interstitial Brachytherapy.* Publishing Sciences Group Inc., Acton, Massachusetts (1975).
11. Marchese MJ, Hall EJ, Hilaris BS, Clinical, Physical and Radiobiological Aspects of Encapsulated Iodine-125 in Radiation Oncology. *Endocurietherapy/Hyperthermia Oncology* 1: 67-82 (1985).
12. Storey MR, Landgren RC, Cottone JL, et al. Transperineal ^{125}iodine implantation for treatment of clinically localized prostate cancer: 5-year tumor control and morbidity. *Int J Radiat Oncol Biol Phys* 1999; 43 (3): 565-570.
13. Tapen EM, Blasko JC, Grimm PD, et al. Reduction of radioactive seed embolization to the lung following prostate brachytherapy. *Int J Radiat Oncol Biol Phys* 1998; 42 (5): 1063-1067.
14. Stock RG, Stone NN, DeWyngaert JK, et al. Prostate specific antigen findings and biopsy results following interactive ultrasound guided transperineal brachytherapy for early stage prostate carcinoma. *Cancer.* 1996; 77 (11): 2386-2392.
15. Peschel RE, Chen Z, Roberts K, Nath R. Long-term complications with prostate implants: iodine-125 vs. palladium-103. *Radiat Oncol Invest* 1999; 7: 278-288.
16. Blasko JC, Grimm PD, Ragde H, Schumacher D. "Implant therapy for localized prostate cancer" in *Prostate Cancer,* (Ernstoff MS, Heaney JA, Peschel RE, ed.) Blackwell Science, Cambridge, Massachusetts, and Oxford, England (1998), p137-155.
17. Kaye KW, Olson DJ, Payne JT. Detailed preliminary analysis of iodine-125 implantation for localized cancer using percutaneous approach. *J Urol* 1995; 153: 1020-1025.
18. Strum SB, Scholz MC. Brachytherapy: Implantation of prostate cancer with radioactive isotopes - analysis of the Seattle experience: May 1996 update. Published at http://www.prostatepointers.org/seedpods/brachy07.html
19. Blasko JC, Grimm PD, Ragde H. Brachytherapy and organ preservation in the management of carcinoma of the prostate. *Sem Radiat Oncol* 1993; 3: 240-249.
20. Arterbery VE, Wallner K, Roy J, Fuks Z. Short-term morbidity from CT-planned transperineal I-125 prostate implants. *Int J Radiat Oncol Biol Phys* 1993; 25: 661-667.
21. Stone NN, Stock RG. Prostate brachytherapy: treatment strategies. *J Urol* 1999; 162: 421-426.
22. Wallner K, Roy J, Harrison L. Tumor control and morbidity following transperineal iodine-125 implantation for T1/T2 prostatic carcinoma. *J Clin Oncol* 1996; 14: 449-453.
23. Zelefsky MJ, Whitmore WF. Long term results of retropubic permanent 125 I implantation of the prostate for clinically localized prostate cancer. *J Urol* 1997; 158: 23-30.y
24. Ragde H, Blasko JC, Grimm PD, et al. Interstitial iodine-125 radiation without adjuvant therapy in the treatment of clinically localized prostate carcinoma. *Cancer.* 1997; 80: 442-453.
25. Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. *NCRP Report* No. 37, Washington, DC (1970).
26. Hilaris BS, "Brachytherapy Treatment Planning" in *Brachytherapy Oncology Update 1984,* (Hilaris BS and Nori D, ed.) Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY pp 5-10.
27. Anderson LL, Kuan HM, and Ding IY, "Clinical Dosimetry With I-125", in Modern Interstitial and Intracavitary Radiation Cancer Management, (FW George III ed.) MASSON Publishing USA, Inc., New York (1981), pp 9-15.
28. Protection Against Radiation From Brachytherapy Sources. *NCRP Report* No. 40, Washington, DC (1972).
29. Specification of Gamma-Ray Brachytherapy Sources. *NCRP Report* 41, Washington, DC (1974).
30. Radiation Protection for Medical and Allied Health Personnel. *NCRP Report* No. 48, Washington, DC (1976).
31. Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV. *NCRP Report* No. 49, Washington, DC (1976).

Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

Amersham Health

Amersham Health
Medi-Physics, Inc.
Arlington Heights, IL 60004 USA
Customer Service (800) 228-0126
Professional Services (800) 654-0118

CE 0086

Rev. May 2002
43-6711F

GE Healthcare

INCIDENT REPORT (LEVEL 1)

This Report was Printed on 26-Jan-2006 at 3:31:59PM by Michael Swabowski (PID-000684). This time represents the Reports Server time at UTC Time Zone

Site: Arlington Heights **Quality System:** Level 1 IR

Title:	Customer Complaint - Quantity discrepancy	**PR NUMBER:**	19210
Parent Id:		**Reference Number:**	BP-06-001 / NRC Eve
Assigned To:	Swabowski, Michael	**Responsible Department:**	QA
Date of Occurance:	20-Jan-2006	**Date Due:**	31-Jan-2006
Originator:	Swabowski, Michael	**Originator's Department:**	QA
Category:	Customer Complaint	**Classification:**	Device Product
Sub Category 1:	Complaint (Accountability)	**Sub Classification 1:**	N/A
Sub Category 2:	N/A	**Sub Classification 2:**	N/A
Sub Category 3:	N/A		
Tag No.(s):	N/A	**Procedure:**	N/A
Customer:	Mercy Hospital	**Probable Cause Category:**	Distributor
Product Family:	6711 I-125 Seeds	**Product Description:**	N/A
Lot / Batch No.:	E21808C E21810C	**Other Lot / Batch No.:**	N/A
Item Disposition:	N/A	**Package Size:**	N/A
C A Category:	N/A	**Status:**	Close - Completed

DESCRIPTION OF INCIDENT:

A customer reported to Oncura that 2 seeds were short (missing) at Mercy Hospital. Instead of 88 seeds they counted only 86 seeds. Since the activity is greater than 1.0 mCi, the RSO of Mercy Hospital has notified the NRC hotline.

GE Healthcare, Arlington Heights, IL shipped 88 seeds to AnazaoHelath on 1/09/06. AnazaoHealth performed an independent assayed, sterilized, and shipped 88 seeds to Mercy Hospital on 1/11/06.

Departments Accountable: N/A

IMMEDIATE ACTIONS TAKEN:

Arlington Heights QA, QC, Manufacturing, Order Fulfillment and Nuclear Assurance departments were notified of the incident.

This order, order number 81494360, was filled with seeds from two lots of OncoSeed, 70 seeds from lot E21808C and 18 seeds from lot E21810C. This lot of seeds was manufactured in the UK. The on-site paperwork (product release information) was reviewed by QA. There were no incident reports or laboratory investigations associated with the lot. The Iodine seed dispensary worksheet for this order was retrieved and reviewed. This order was documented correctly and filled as required.

The product dispensing records and cycle count data were reviewed. The both balances had zeroed out on 09Jan06. Therefore there was no remaining inventory to count to verify the quantity. However, if one less seed was dispensed to the order in question then the extra seed would have become apparent during the cycle count. No count discrepancies were reported for these lots of seeds as the balances had reconciled appropriately.

GE Healthcare

INCIDENT REPORT (LEVEL 1)

This Report was Printed on 26-Jan-2006 at 3:32:10PM by Michael Swabowsk (PID-000684). This time represents the Reports Server time at UTC Time Zone.

Location: N/A **Sub Location:** N/A

Regulatory Impact: Minor **Other Impact:** NA

Equipment ID(s) / Tag No.(s): N/A

ASSESSMENT IMPACT:

This order was for 88 seeds. The complaint stated that 68 seeds were implanted in the patient and the number of implanted seeds was verified using an x-ray. After the operation the hospital counted 18 remaining seeds for return shipment to the seed provider thus, 2 seeds were unaccounted for. There is no impact to the procedure, the hospital ordered extra seeds for the procedure and the procedure was able to be completed without incident.

Nuclear Assurance Assessment - Nuclear regulatory notification would not be required since the investigation concluded that it is unlikely that the count discrepancy originated during the order filling process. IEMA was provided an informal "heads up" due to the event being reported to NRC, and our agreement with IEMA is to alert them of these circumstances once we become aware of them. A follow up will be provided that describes the results of our investigation, and no additional action is expected from IEMA.

CAUSE ANALYSIS:

One possible explanation of this discrepancy would involve miscounting the amount of seeds when the order was filled at GE Healthcare.

Order filling is performed per approved SOP USHM-10-02-05. This procedure is in place to ensure that count discrepanci are accounted for at the time and after the order is filled. The workstations are surveyed with a NaI detector before and after the order filling procedure to ensure no loose seeds are present. No loose seeds were found around the time this order was filled. The seeds for each order are counted into a vial and verified by a second operator. The seed counters used in the order filling process are validated pieces of equipment and are checked daily to ensure accuracy and precision. The remaining seeds are then counted back into the stock vial when returning to inventory and quantities are verified. The seeds are counted again to verify proper quantities for the order, the vials are shrink wrapped and sealed in a securitainer. The entire order filling process is documented and the documents are reviewed by QC prior to packaging for shipment. These documents (Iodine Seed Dispensary Worksheet) were reviewed by QA during this investigation and all documentation was found to be appropriate. The cause of the missing seed from the order could not be attributed to the order filling process.

This order of seeds was sent to AnazaoHealth before it was shipped to the end customer. AnazaoHealth assayed, sterilized and then shipped the seeds to the end user. As all accountability at GE Healthcare was found to be complete and accurate, it is not likely that the two seeds were missing from the order when shipped to AnazaoHelath.

INCIDENT RESOLUTION:

Based on the investigation performed, QA cannot confirm this complaint. The product dispensing records and cycle count data indicate that these lots of seeds reconciled appropriately. In addition, proper procedures are in place to ensure the requested amount of seeds are placed into each order. All paperwork indicates that the proper amount of seeds were filled for this order.

Nuclear regulatory notificarion is not required since the investigation concluded that it is unlikely that the count discrepancy originated during the order filling process. IEMA was provided an informal "heads up" due to the event being reported to NRC, and our agreement with IEMA is to alert them of these circumstances once we become aware of them. A follow up will be provided that describes the results of our investigation, and no additional action is expected from IEMA.

ADDITIONAL ACTIONS:

Proper procedures are in place to ensure the requested amount of seeds are placed into each order. No additional actions required

GE Healthcare

INCIDENT REPORT (LEVEL 1)

This Report was Printed on 26-Jan-2006 at 3:52:10PM by Michael Swabowski (PID-000684) This time represents the Reports Server time at UTC Time Zone

Report Disposition: Accepted - No Additional Actions Required

REPORT DISPOSITION/CORRECTION:

Accepted, not further actions.

ADDITIONAL INFORMATION:

None

DEPARTMENT APPROVAL(S):

	Performed By	Date Performed
Mfg - Filling Operations Approval	Baron, Roger	25-Jan-2006 2:24 pm
QC Devices Approval	Luedtke, Pam	25-Jan-2006 2:48 pm
EHS - NERA Approval	London, Wayne	25-Jan-2006 3:12 pm
QA Approval	Datisman, Erik	25-Jan-2006 4:23 pm
Mfg - Seed Manufacturing Approval	Cornell, Rick	25-Jan-2006 4:33 pm

QA Final Approval: Terrier, Esther **Date:** 25-Jan-2006 5:05 pm

QA Comments
Approved for closure

PR CHILD INFORMATION:

PR ID	Quality System	Title

Hospital Event # 42281

Rep Org: MERCY HOSPITAL - SCRANTON, PA		**Notification Date / Time:** 01/20/2006 17:46	(EST)
Licensee: MERCY HOSPITAL - SCRANTON, PA		**Event Date / Time:** 01/20/2006 15:00	(EST)
		Last Modification: 01/20/2006	
Region: 1	**Docket #:**		
City: SCRANTON	**Agreement State:** No		
County:	**License #:** 37-01374-03		
State: PA			
NRC Notified by: SAMUEL PAYNE	**Notifications:** CHRIS HOTT		R1
HQ Ops Officer: PETE SNYDER	LAWRENCE KOKAJKO		NMSS
Emergency Class: NON EMERGENCY			
10 CFR Section:			
20.2201(a)(1)(i) LOST/STOLEN LNM>1000X			

This material event contains a "Less than Cat 3" level of radioactive material

!!! This is a draft document, do not release to the public !!!

LOST IODINE SEEDS

After an implantation procedure using Iodine 125 seeds was performed at 1500 at Mercy Hospital of Scranton, PA the staff became aware that there were potentially 2 seeds missing. The total activity of the 2 seeds is estimated to be 1.26 millicuries.

The hospital ordered 88 seeds for this operation. 68 seeds were implanted in the patient. The number of implanted seeds was verified using an x-ray. After the operation the hospital counted 18 remaining seeds for return shipment to the seed provider. The hospital performed surveys of the operating room and was unable to locate any other seeds. At the time of the report the operating room was quarantined for further investigation.

The hospital contacted the health services company that sterilized the seeds to determine if fewer seeds were provided but Anazao Heath was unable to provide an exact count of the seeds. On Monday 1/23/06 the Radiation Safety Officer plans to contact the seed provider, Amersham Health to determine an exact count of seeds shipped.

THIS MATERIAL EVENT CONTAINS A "LESS THAN CAT 3" LEVEL OF RADIOACTIVE MATERIAL

Sources that are "Less than IAEA Category 3 sources," are either sources that are very unlikely to cause permanent injury to individuals or contain a very small amount of radioactive material that would not cause any permanent injury. Some of these sources, such as moisture density gauges or thickness gauges that are Category 4, the amount of unshielded radioactive material, if not safely managed or securely protected, could possibly - although it is unlikely - temporarily injure someone who handled it or were otherwise in contact with it, or who were close to it for a period of many weeks.

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE CONVERSATION RECORD

Date: 01/24/2006

Time: 3:00 pm

Mail Control or Report No(s). NA

License No(s). 37-01374-03

Docket No(s). 03002983

Name of Licensee:	Mercy Hospital
Name of Participant(s):	Samuel Payne, RSO
Telephone No.	570-477-3925
Subject: (NOTE: This will be used as the Documents Title in ADAMS)	Follow up to Event Report # 42281

Summary:

Mr. Payne provided the following additional details regarding the 2 missing I-125 prostate implant seeds:

1. The seeds have not been located and he is waiting for Amersham to verify the number of seeds that were actually shipped; seed shipments are first sent from Amersham to Anazao to verify activity (on 10 percent of the ordered amount) and for sterilization.
2. The seeds are then sent to Mercy Hospital and delivered to the OR on the day they will be implanted. The seeds are not inventoried at Mercy Hospital prior to implantation.
3. A Victoreen Model 290 survey meter, calibrated for I-125, was used to perform the surveys. Four surveys were performed after the patient was moved to a holding area. The patient's bedding and bed were surveyed after the patient was moved out of the OR.

Mr. Payne will provide additional information on the survey meter efficiency for I-125 and Amersham's count of the number of seeds shipped.

Action Required: Wait for additional information for LER and determine need for follow up inspection.

Document Availability:

___ Publicly Available

√ Non-Publicly Available

√ Non-Sensitive

___ Non-Sensitive Copyright

___ Sensitive

___ Sensitive Copyright

___ Immediate Release

___ Normal Release

___ Delay Release Date

Prepared & SISP Review Completed By: **/ RA /** Donna M. Janda Date: 1/24/2006