

September 19, 2008

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Subject: 10 CFR Part 20.2201: Report of loss of licensed material

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

One I-125 sealed source ("seed") intended for permanent prostate implantation on 9/8/08 cannot be located definitively inside the patient or inside the hospital and is assumed lost. The calibrated activity was 0.481 mCi on 8/25/08.

(ii) Description of the circumstances under which the loss occurred

On the morning of 9/8/08, a permanent prostate implant was performed in our high dose rate (HDR) treatment room in Radiation Oncology under sterile conditions. The implant was to consist of 62 seeds, in twenty needles each containing a varying number of seeds of 0.408 millicurie of I-125. Seventy I-125 seeds were ordered and pre-loaded in a cartridge and were received sterilized from Isotron. Prior to treatment one of the seeds was expelled from the cartridge and used for calibration. It was stored in a separate shielded container, and not used in the patient treatment.

The written directive and treatment plan intended implantation of 62 I-125 seeds into a patient's prostate for the treatment of cancer. Using the Nucletron seedSelectron remote afterloading system each needle was placed under ultrasonic guidance in the patient's prostate. The seedSelectron was connected to each needle and the seeds ejected from the cartridge into the needle. This procedure was performed for each of the twenty needles with only one needle being implanted at a time injecting a total of 62 seeds. The treatment progressed normally as planned and was successfully completed. At the conclusion of the treatment, X-rays were taken to verify the number of seeds implanted, and the count of 61 instead of 62 was confirmed radiographically. Prior to exiting the room, all staff (radiation oncologist, nurse, physicist, brachytherapy specialist) completed the routine required survey which included the soles of the shoes.

(iii) A statement of disposition, or probable disposition, of the licensed material involved

The residual seeds in the cartridge were x-rayed and seven I-125 seeds were identified by at least 3 medical physicists. At least 3 medical physicists and the authorized user examined the patient's x-rays, and each could clearly identify only 61 seeds in the patient. The one I-125 seed used for calibration was accounted for in the inventory. The patient was scheduled to return for bi-plane views on 9/10/08, so that additional radiographs could potentially identify the missing seed. When the patient returned on 9/10/08, he had excreted four I-125 seeds which were properly handled and placed in the secure designated storage area. On the follow up x-rays, only 57 seeds were clearly identified. The anatomy surrounding the prostate was also imaged, but only 57 seeds were clearly identified. The entire pelvic region, abdomen and chest were also imaged with no results. It is possible that the seed may have migrated to an area inside the patient which was not included on the follow up x-rays.

The pre-loaded cartridge of seeds was not x-rayed prior to the treatment, so the presence of all 70 seeds was not confirmed prior to the treatment. It is conceivable that only 69 seeds

were shipped. We contacted Isotron and they provided us with their documentation showing that they shipped 70 seeds. Please see the attachments.

The most probable disposition is that the seed is located inside the patient, but has migrated to an area which does not allow us to confirm its presence radiographically. The second most likely explanation is that we only received 69 seeds instead of 70 seeds. It is unlikely that the seed is lost inside our HDR suite, given the normal progression of the implantation procedure and the thoroughness of our search. It is very unlikely that the seed was disposed of in the landfill or sewer, since it was not detected when the team of medical physicists individually surveyed each item of linen and trash, and thoroughly surveyed the sink.

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

No exposure of individuals to radiation from the one missing I-125 in restricted and unrestricted areas is expected.

(v) Actions that have been taken to recover the material

A thorough search was initiated immediately, using a pancake thin end window Geiger-Mueller detector in the micro-R/hr range (Ludlum Model 14C calibrated on June 4, 2008). The surgical table, floor, each item of trash, each item of linen and all personnel were carefully surveyed. All cartridges and needles were rechecked several times. A thorough survey of the surgical table was conducted, urine collection bag and patient (even near the pelvis, although exposure from the implant made detection in this vicinity unlikely). The low survey readings in adjacent areas of the patient made it unlikely that the seeds were on the patient. The patient was released and removed from the HDR room and transferred to Phase I recovery. The survey also included the entire entrance hallway to the HDR room and the radiation oncologist's office. The Radiation Safety Officer designate for Radiation Oncology was notified and an additional survey of the room was conducted with the Johnson survey instrument (GSM-15) with a plastic scintillator (GLE-1) calibrated with an I-125 source on January 4, 2008. The surface of the floor including the small cracks in the floor covering and at the baseboards was surveyed. Each item of trash and linen was checked separately. The Corporate Radiation Safety Officer was notified and conducted an independent search with the Johnson survey instrument which included the entire floor, baseboards, sink, each item of equipment in the HDR room, the linen and trash. When nothing was found, the room was released so that patient treatments could be resumed in the room. A repeat survey of the patient using a Geiger-Mueller detector in the $\mu\text{R/hr}$ range (Victoreen model 190 with pancake probe calibrated April 24, 2008) as well as the areas surrounding the patient, trash and linens was performed in the Phase I area. All readings were low indicating the source was not in the vicinity. The patient was then discharged to Phase II. A survey including the patient, stretcher, linens, trash, urinary catheter, urinary bag and area was performed in Phase II. Low readings were again observed indicating the source was not in the area. The unused seeds were returned to the locked cabinet in the other HDR room for inventory and storage.

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

(1) All personnel involved with prostate implants will receive refresher training regarding proper procedure. (2) An image of the loaded cassette will be taken to verify the receipt of the correct number of seeds. This image will be retained along with the patient records. In the event the seed count on the image does not agree with the count per the manufacturer, the situation will be reconciled prior to treatment. (3) Every effort will be made to obtain a seed count that accounts for all of the seeds received from the manufacturer prior to the discharge of the patient.

For additional information, please contact Cheryl Culver Schultz, M.S. at 248-551-0548.



Cheryl Culver Schultz, M.S.
Corporate Radiation Safety Officer

cc. Alvaro Martinez, M.D. Di Yan, Ph.D.
 Lisa Burgess, M.S. Evelyn Sebastian

selectSeed Verpackung Protocol

Class:	6	SelectSeed I-125 Batch # :	83320
Rack:	X11		
Position:	D7		

#	ILSA Parcel ID #	Cartridge oder Container Nr.	Daten / Zahlen / Bemerkungen	Pass, Angelegenheit #...
1.	1013 776	1300056 065298		<input type="checkbox"/> Pass <input type="checkbox"/> ...

Material	Part # + Rev ...	Lieferant	Verwendung	Chargen #
Sterilisationstüten 110x160mm Blau farbig	4FKFB019210	VP Stericlin	<input checked="" type="checkbox"/> Cartridge <input type="checkbox"/> ...	C054830032
Sterilisationstüten 140x240mm Blau farbig	4FKFB019211	VP Stericlin	<input checked="" type="checkbox"/> Cartridge <input type="checkbox"/> Bulk Container <input type="checkbox"/> ...	C054830021
Sterilisationstüten 100x200mm Blau farbig	4FKB000541	VP Stericlin	<input type="checkbox"/> Bulk Container <input type="checkbox"/> ...	

#	Item	Criteria	Daten / Zahlen / Bemerkungen	Pass, Angelegenheit #...
2.	Lagerverwaltung Seed Zähler	ISO0517DE rev: ISO0518DE rev: Bearbeiter (+ Trainer) : Datum:	04 04 C13 28.08.08	
3.		aus dem Tresor entnommen	120	
4.		benötigt	70	
5.		vorbereiteter CLD Topf	Transport Behälter: 3 Pos: 1	
6.		abgezählt	70	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
7.		zurück in den Tresor:	50	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
8.	Rundförderer ist nach der Beendigung zu leeren.	• O.k.	Förderer leer	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
9.	Capintec	ISO0524DE rev:	00	<input checked="" type="checkbox"/> Pass
10.	Benutzung Umfüllstation Seed Zähler Nur für Befüllung von selectSeed container	ISO0518DE rev: • Name : • Datum :	<input type="checkbox"/> Container vorhanden & sauber <input type="checkbox"/> Passing entfernt <input type="checkbox"/> Container fixiert <input type="checkbox"/> Container Deckel entfernt <input type="checkbox"/> Laminierten Container Siegel	<input type="checkbox"/> Pass <input type="checkbox"/> ...
11.	Kontrolle beim Befüllen	• Nur ein CLD Topf vorhanden	<input type="checkbox"/> Topf in Container entleert <input type="checkbox"/> Deckel zugeschraubt <input type="checkbox"/> Fixierung entfernt <input type="checkbox"/> Container Siegel aufgeklebt	<input type="checkbox"/> Pass <input type="checkbox"/> ...
12.	Kontrolle nach Befüllen	• O.k.	<input type="checkbox"/> Keine Seeds beim Umfüllstation <input type="checkbox"/> Kein Messergebnis Kontamat <input type="checkbox"/> Container nach CLD-Raum transportiert (weiter bei Punkt 17)	<input type="checkbox"/> Pass <input type="checkbox"/> ...
13.	Benutzung der Verpackungsanlage Nur für Befüllung von Cartridges	• CLD box • Name : • Datum :	ISO0519DE rev: 00 115 28.08.2008	
14.		• BUCL Einsatz in Box 6 notwendig? • Name : • Datum :	ISO0520DE rev:	
15.	Kontrolle am Anfang	• O.k.	<input checked="" type="checkbox"/> Hilfsmaterialien bereit <input checked="" type="checkbox"/> Installation komplett und überprüft <input type="checkbox"/> Kommunikation PC-CPU ok	<input type="checkbox"/> Pass <input checked="" type="checkbox"/> ...
16.	Kontrolle nach Befüllen	• O.k.	<input checked="" type="checkbox"/> Keine Seeds in der Box <input type="checkbox"/> Seeds für nächsten Auftrag <input type="checkbox"/> Restseeds ausgeschleust	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
17.	Kontrolle (QA) Label		<input checked="" type="checkbox"/> Label drucken <input checked="" type="checkbox"/> Label auf Lesbarkeit kontrollieren <input type="checkbox"/> Cartridge-Label aufgeklebt und mit Schutzfolie überklebt	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...

selectSeed I-125
Manufactured by
ISOTRON
www.isotron.com

Ref No: 133002-00
Batch No: 83320
Number of Seeds: 70
App. Nom. Act: 0.481 mCi
App. Tot. Act: 33.7 mCi
Act. Reference Time: 2008 Aug 25 12:00 CET
Parcel ID No: 1013776

Container hier

#	Item	Criteria	Daten / Zahlen / Bemerkungen	Pass, Angelegenheit #...
18.	Sterile Verpackung	ISO0521DE rev: Bearbeiter (+ Trainer): Datum:	OO TIS 28.08.2007	
19.	Kontrolle Aktivierung des Siegelgerätes	Temp: $\geq 80^{\circ}\text{C}$ F: 90-110N	<input type="checkbox"/> Kontrolle der eingestellten Daten <input checked="" type="checkbox"/> Seal check	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
20.	Versiegelung	• O.k.	<input checked="" type="checkbox"/> Cartridge in Tüten 11x16cm und 14x24cm Tüten versiegeln <input type="checkbox"/> Container in Tüten 10x20cm und 14x24cm Tüten versiegeln	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
21.	Angegebene Siegeldruck	Angabe darf 90-110N nicht unter- oder überschreiten	Druck: 93 N(ewton)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
22.	Kontrolle Label	• O.k.	mittelgrosses Label auf die grosse Tüte kleben	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
23.	Vollständigkeitskontrolle	• O.k.	<input checked="" type="checkbox"/> Siegelnaht <input checked="" type="checkbox"/> sterile Verpackung auf Beschädigungen prüfen <input checked="" type="checkbox"/> Keine Fremdkörper sichtbar	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
24.	Sterilisation	ISO0522DE rev: Bearbeiter (+ Trainer): Datum:	OO TIS 26.08.2007	
25.	Aktivierung des Sterilisators: • Vor jedem Arbeitsbeginn ist täglich sicher zu stellen:	• O.k.	<input checked="" type="checkbox"/> Genügend pyrogenfreies Wasser <input checked="" type="checkbox"/> Kondensatbehälter leer <input checked="" type="checkbox"/> Entlüftungstest durchgeführt <input checked="" type="checkbox"/> Letzter Vakuumtest < 30 Tage <input checked="" type="checkbox"/> Druckverlauf in Steri-Kammer o.k.	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
26.	Sterilisierung	• O.k.	<input checked="" type="checkbox"/> Fute mit Label nach oben <input checked="" type="checkbox"/> Ablagebleche füllen mit max. 2x4 Cartridges oder Containern <input checked="" type="checkbox"/> Prüfkörper mit Chemo-Indikator: o.k. <input checked="" type="checkbox"/> Cartridges/Container mit der Papierseite nach unten einlegen <input type="checkbox"/> Standard-Programm 121°C	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
27.	Sterilisation kontrolle	O.k. • Temperature and pressure follows profile • range: sterilization temp + 3 degrees • fluctuation: max +- 1 degree • fluctuation temp points: max 2 degree difference • Equilibration time : max. 15 sec	<input checked="" type="checkbox"/> Temperatur, Zeit -und Druckverlauf gem. Sterilisationsdaten (siehe Zyklusdiagramm GA s. 29) <input checked="" type="checkbox"/> Sterilisations Protokoll ausdrucken und kontrollieren	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
28.	Nach der Sterilisation	O.k.	Messen und Entsorgung des Restkondensates	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
29.	Cartridge einlagern oder für Versand vorbereiten		Sterilisierte Cartridges/Container den (übrigen) Labels zuordnen und in die Schleuse legen oder im Tresor einlagern	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...
30.	Final Verpackung	ISO0523DE rev: Bearbeiter (+ Trainer): Datum:	OO V 29. AUG. 2008	
31.	Protokoll Anlage(n)	• Protokolle als Anlage beifügen um Rückverfolgbarkeit zu ermöglichen	<input checked="" type="checkbox"/> ILSA Pickliste(n) <input checked="" type="checkbox"/> WEBECO Steri-Protokoll <input checked="" type="checkbox"/> selectSeed Verpackungs- Detail Protokoll(e)	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> ...

#	Angelegenheiten	Getroffene Maßnahmen	Genehmigt
1.	Sollwert 0,466 eintragen	Istwert 0,438 c/B	
2.	Datenübertragung Time out	keine neue cartridge Nr.	TIS



selectSeed Cartridge Detail Verpackung Protocol

Class:	6	SelectSeed I-125 Batch # :	83320
Aktivität: (ART)	0,481 mCi	Kalibrierdatum:	2008 Aug 25
Rack:	XII	Position:	D 1
Messdatum:	2008 Aug 13	1.Messaktivität:	0,546 mCi

#	Cartidge #	Parcel ID #	Anzahl Seeds
1.	1300056065299	1013776	70

#	Item	Criteria	Daten / Zahlen / Bemerkungen
2.	Lagerverwaltung Seed Zähler	Bearbeiter: Datum:	LBr 2008 Aug 28
3.	Capintec	Bearbeiter: Datum:	LBr 2008 Aug 28
4.	Prüfung der Seeds (10%):	Sollwert (von-bis):	0,445 ... 0,483 mCi
			01) 0,472 mCi 02) 0,453 mCi 03) 0,446 mCi 04) 0,450 mCi 05) 0,450 mCi 06) 0,471 mCi 07) 0,471 mCi 08) mCi 09) mCi 10) mCi
5.	CLD-Box	Bearbeiter: Datum: Uhrzeit Ende Befüllung:	TSc Handeing. Cart-IDNr 2008 Aug 28 00 : 00 : 00
6.	Versiegelung	Bearbeiter: Datum:	TSc 2008 Aug 28
7.	Sterilisation	Bearbeiter: Datum:	TSc 2008 Aug 28
	Pfad Sterilisationsdatei	\\Cld-nu\FestplatteC\Programme\Webeco\SteriDoc\00093604\002945.txs	
8.	Kontaminationsprüfung	Ergebnis protokollieren (kleiner 0,20 Bq/mL = keine Kontamination).	0,15 Bq/ml
9.	Bemerkungen	Datenübertragung Time out	

Beaumont® Hospital
Royal Oak

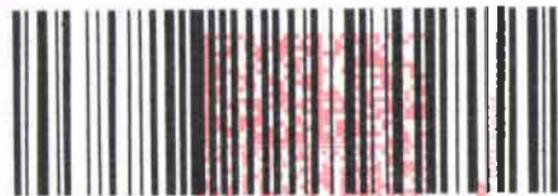
3601 West Thirteen Mile Road
Royal Oak, Michigan 48073-6769

01-78060

**RETURN RECEIPT
REQUESTED**

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

CERTIFIED MAIL™



049J82031829

\$05.490

09/23/2008

Mailed From 48073

7007 1490 0000 3657 4627

US POSTAGE

