

General Information or Other	Event Number: 40943
Rep Org: NY STATE DEPARTMENT OF HEALTH Licensee: Region: 1 City: State: NY County: License #: Agreement: Y Docket: NRC Notified By: ROBERT DANSEREAU HQ OPS Officer: JEFF ROTTON	Notification Date: 08/12/2004 Notification Time: 17:12 [ET] Event Date: 08/10/2004 Event Time: [EDT] Last Update Date: 08/12/2004
Emergency Class: NON EMERGENCY 10 CFR Section: AGREEMENT STATE	Person (Organization): RAYMOND LORSON (R1) DANIEL GILLEN (NMSS)

Event Text

<p>AGREEMENT STATE REPORT - CONTAMINATED BRACHYTHERAPY SEEDS</p> <p>"A New York State Department of Health licensee reported on 8/10/04 that prostate seed implant needles were found to be contaminated during a post implant radiological survey in the operating room. Two post implant urine samples from the patient were saved and were found to be contaminated as well. Radiograph of the prostate post implant indicated all seeds were implanted. Hospital staff believed that the contamination was attributable to the implant procedure as the patient had not received a diagnostic nuclear medicine procedure and there was no evidence of any other source for the contamination. The radiation oncologist contacted the patient and was able to administer KI [Potassium Iodide] later in the day, and he will evaluate the need for ongoing treatment with KI.</p> <p>"New York State Department of Health staff went to the hospital on 8/11/04 to investigate this incident. Confirmatory measurements were made and the plastic needle packing tray, needles, lead pouch and urine samples were found to be contaminated. A third urine sample was obtained from the patient on 8/11/04, which also is contaminated. The radiation oncologist who performed the procedure stated that there were no problems with the needles or the implant procedure. The needles were examined and no bends, crimps or damage were observed. The hospital, has notified the pharmacy that had provided the preloaded sterile needles. NRC Region 1 staff were contacted by phone and were given the name of the pharmacy.</p> <p>"The Radiation Safety Officer took the initial urine sample to another New York State Department of Health licensee on 8/11/04 for nuclide identification and rough quantification using a HPGe detector. The isotope in the urine was identified as I-125 and the activity was estimated to be 34 nanocuries per cc (volume of urine sample collected was 200 cc). The patient's urine samples will be sent to DOH Wadsworth Laboratories for analysis. Future samples are expected to be collected and analyzed.</p> <p>"The brachytherapy seeds were manufactured by Mills Biopharmarmaceuticals, Inc., sold by Mentor MBI (Oklahoma City, OK) and loaded into needles by the pharmacy. Brachytherapy seed specifics are: Model: 125SL Lot Number: 042814 Batch Number: IB040142N Seed activity on 8/10/04: 0.405 millicuries"</p>
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A/5

Full Report

08/11/2009

Item Number: 040583

Last Updated: 01/24/2005

Narrative:

The licensee reported that a patient was implanted with I-125 seeds that were leaking. During a post implant radiological survey in the operating room, the licensee found radioactive contamination on the implant needles. Two post implant urine samples from the patient also contained radioactive contamination. The licensee attributed the contamination to the implant procedure because the patient had not received any other radiological procedure. The patient was given potassium iodide later in the day. Confirmatory measurements of the plastic needle-packing tray, needles, leak pouch, and urine samples by the New York State Department of Health on 8/11/2004 confirmed the presence of radioactive contamination. A third urine sample was obtained from the patient on 8/11/2004, which also contained radioactive contamination. The radiation oncologist stated that there were no problems with the needles or the implant procedure. The needles were examined and no bends, crimps, or damage was observed. The licensee notified the pharmacy that provided the preloaded sterile needles (Advanced Care Medical in Oxford, Connecticut). The RSO took the initial urine sample to another New York State Department of Health licensee on 8/11/2004 for radionuclide identification and rough quantification. The radionuclide in the urine was identified as I-125 with an activity of 1,258 Bq/cc (34 nCi/cc) in 200 cc of urine. The patient's urine samples will be sent to the Department of Health Wadsworth Laboratories for further analysis. Future samples will be collected and analyzed. The brachytherapy seeds were manufactured by Mills Biopharmaceuticals, Incorporated, sold by Mentor MBI, and loaded into needles by Advanced Care Medical. Each seed (model 125SL, lot #042814, batch #IB040142N) contained an activity of 14.99 MBq (0.405 mCi) on 8/10/2004. Advanced Care Medical stated that leak tests and contamination surveys of the seeds prior to shipment were negative. An NRC inspection of Advanced Care Medical identified seed strand production issues involving temperature and cutting/sizing that may affect the integrity of the seeds. The INL has requested additional information for this event.

Event Date: 08/10/2004

Discovery Date: 08/10/2004

Report Date: 08/10/2004

Licensee/Reporting Party Information:

Agreement State Regulated: YS

Reciprocity: NONE

License Number: NY-0025

Name: OUR LADY OF LOURDES HOSPITAL

NRC Docket Number: NA

City: BINGHAMTON

NRC Program Code: NA

State: NY Zip Code: 13905

Responsible NRC Region: 1

Site of Event:

Site Name: BINGHAMTON

State: NY

Additional Involved Party:

License Number: 06-30764-01

Name: ADVANCED CARE PHARMACY LLC

NRC Docket Number: 03036099

City: OXFORD

NRC Program Code: 02513

State: CT Zip Code: 06478

Responsible NRC Region: 1

Other Information:

NRC Reportable Event: Y

Abnormal Occurrence: N

Agreement State Reportable Event: Y

Investigation: Y

Atomic Energy Act Material: Y

NMED Record Complete: R

Consultant Hired: N

Event Closed by Region/State: N

Event Type:

EQP - EQUIPMENT

LKS - LEAKING SOURCE

MD2 - MEDICAL EVENT

Event Cause:

EQP

Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

Old Cause: DEFECTIVE OR FAILED PARTS

LKS

Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

Old Cause: DEFECTIVE OR FAILED PARTS

MD2

Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

Old Cause: DEFECTIVE OR FAILED PARTS

Corrective Actions Information:

Action Number: Corrective Action:

EQP

1 NOT REPORTED

LKS

1 NOT REPORTED

MD2

1 NOT REPORTED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 08/10/2004

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: NA

Effect on Patient:

Source of Radiation:

EQP

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY

Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: MILLS BIOPHARM.

Activity: 0.000405 Ci 0.014985 GBq

Model Number: 125SL

Serial Number: NA

LKS

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY

Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: MILLS BIOPHARM.

Activity: 0.000405 Ci 0.014985 GBq

Model Number: 125SL

Leak Test Result: NR uCi NR kBq

Serial Number: NA

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY

Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: MILLS BIOPHARM.

Activity: 0.000405 Ci 0.014985 GBq

Model Number: 125SL

Serial Number: NA

Device/Associated Equipment:

EQP

Device Number: 1

Device Name: APPLICATOR

Model Number: NR

Manufacturer: NR

Serial Number: NR

LKS

Device Number: 1

Device Name: APPLICATOR

Model Number: NR

Manufacturer: NR

Serial Number: NR

MD2

Device Number: 1

Device Name: APPLICATOR

Model Number: NR

Manufacturer: NR

Serial Number: NR

Reporting Requirements:

EQP

Reporting Requirement: 30.50(b)(2)(ii) - old - (SUPERSEDED) EQUIPMENT IS DISABLED OR FAILS TO FUNCTION AS DESIGNED WHEN THE EQUIPMENT IS REQUIRED TO BE AVAILABLE AND OPERABLE WHEN IT IS DISABLED OR FAILS TO FUNCTION.

LKS

Reporting Requirement: 35.67(e) - Medical source leak test revealed the presence of 185 Bq (0.005 uCi) or more of removable radioactive material.

MD2

Reporting Requirement: 35.3045(a)(2)(v) - Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN40943	08/17/2004		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML042290191	09/02/2004		RLS	OTHER
ML042390364	09/13/2004		RLS	CONFIRMATORY ACTION LETTER
ML042520340	09/29/2004		RLS	LICENSEE REPORT
ML042680349	09/29/2004		RLS	LICENSEE REPORT
ML042730411	10/12/2004		RLS	CONFIRMATORY ACTION LETTER
ML042740225	10/12/2004		RLS	LICENSEE REPORT
ML042240017	11/15/2004		RLS	ADAMS DOCUMENT PACKAGE
ML042750328	11/15/2004		RLS	NRC LETTER
ML043070554	11/15/2004		RLS	CONFIRMATORY ACTION LETTER
LTR050124	01/24/2005		DCH	NRC LETTER



Redacted Copy

115 Hurley Road Building 3A Oxford, CT 06478

~~CONFIDENTIAL CORRESPONDANCE~~

George Pangburn, Director
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: Confirmatory Letter No. 1-04-007

Dear Mr. Pangburn,

We would like to thank you for bringing this discrepancy in the Sealed Source Device Registry as it relates to the Mentor brachytherapy seed to our attention. We endeavor to maintain the highest standards of compliance to all regulations and requirements as it relates to our products.

In our initial license application we stated that in our production processes:

"Neither the sealed sources nor the "seed spacers" are modified in a way that would allow them to react or interact in a way that they were not intended to. Connecting the "seed spacers" to the ends of the sealed sources do not change the intended form fit or function of the original NRC registered devices."

We stand by this statement and would like to take this opportunity to present the technical basis for this claim.

The issue at hand is the information stated in the Sealed Source Device Registry filed by Mills Biopharmaceuticals for its seeds. In the registry a temperature and pressure limitation of 280.4° F at no more than 35 PSI pressure is placed on their sealed source. Although not stated, it would appear than these specification limitations refer to typical Autoclave sterilization cycle parameters and not process temperatures.

Advanced Care Medical has established a criterion that all seeds used in our program will comply with ISO 2919-199E. This standard states that the design and testing criteria for sealed sources require that the source withstand temperatures of 800° C or 1472° F for a one hour soak time and then be plunged into water at 15° C for thermal shock. These criteria are the same for ANSI N44.1-1973.

Our process exposes the sealed sources to a temperature of [REDACTED] for only a few seconds. Cooling begins [REDACTED] and the time the source is exposed to a temperature above [REDACTED] [REDACTED]. A [REDACTED] return to ambient temperature occurs over the following [REDACTED]. See the comparison chart below:

	Temperature	Time	Return to Ambient
ISO 2919-199E	1472° F	One Hour	0 Minutes
ANSI N44.1-1973	1472° F	One Hour	0 Minutes
Advanced Care Medical	[REDACTED]	[REDACTED]	[REDACTED]

Our process temperature and times were established by using [REDACTED] in maximum temperature and a [REDACTED] in elapsed time to establish our safety margins. Thermal shock was [REDACTED] to ambient temperature.

Further, our internal process controls ensure complete line clearance between each order. Processing equipment and tools are wipe tested and results logged to determine that no leakage has occurred before the next order is processed.

In the last two years we have delivered over [REDACTED] sources that have gone through our process without a single incidence of reported leakage prior to this event.

Beyond the technical basis that supports our processes we also check each Seed Vendor for regulatory compliance. Seed Vendors who enter into our program on a full time basis generally sign our standard Service Agreement which outlines their product compliance as stated in paragraph 3.2b:

"Manufacturer hereby represents, warrants and covenants to ACM as follows:

that the Products provided will be of a professional quality, conforming, in all material respects, to generally accepted industry standards and practices for similar products, and shall comply with ISO 2919-199E classification C53X42. The Manufacturer, without any expense to ACM, shall obtain all required licenses and permits, and shall obey and abide by all applicable laws, regulations, ordinances and other rules of the United States or the state in which the Products are being provided, or any other duly constituted public authority as applicable to this Agreement."

The determination of whether a Seed Vendor meets this criterion is based on evidence of one or more of the following requirements:

1. Evidence of a current CE mark for their product (CE requires compliance with ISO 2919-199E) and/or
2. Copies of their ISO 2919-199E on file at our offices and/or
3. A signed copy of our service agreement as referenced above, stating that they comply with ISO 2919-199E

Mentor is a limited user of our program. When Mentor requested us to process their sealed sources for a limited number of their accounts we check to see if Mentor had a CE Mark on their product. The fact that Mentor had a valid CE Mark met one of the criteria we have established above and it was determined that the Mentor seed was compliant with ISO 2919-199E based on that criteria.

In reading the Mills Biopharmaceuticals Sealed Sources Device Registry, it appears that some references to temperature are ambiguous, and/or unclear. It is not clear whether the limitations on high temperature and pressure are related to Autoclave sterilization cycle limitations that would be used by the end user or are written to modify the overall test criteria in their Prototype Testing section of ANSI N44.1-1973.

All other Sealed Source Device Registry's for our other Seed Vendors refer to an Autoclave temperature and pressure limitation but go on to reference the acceptable high temperature for their sealed source device ranging from 400° C to 800° C. This may be an oversight or unintended omission during the registry of the Mills Biopharmaceuticals sealed source.

We have contacted Mentor and asked for clarification in this matter and they have responded with the attached letter and relevant ANSI standard. Mentor states in this letter in point number two that the Mills Biopharmaceuticals sealed sources comply with ANSI N44.1-1973 integrity and testing specifications which includes testing the sources to temperatures of 1472° F for the appropriate cycle times mentioned above. This information from Mentor assures us that their sealed sources are equivalent to our other Seed Vendors products and are safe to use in our manufacturing processes.

We hope this clarifies the situation and if further information is required from us we are at your service.

I have included the ANSI Standard for your review and a redacted copy of this letter that can be published to the appropriate public websites.

Sincerely,



Richard Terwilliger
Advanced Care Medical
Vice President / Technical Director

Encl.: Mentor letter dated 9-2-04
Copy of the ANSI 44.1-1973 standard
Redacted copy of response for public site



"Michele Burgess"
<MLB5@nrc.gov>
01/24/2005 01:12 PM

To <DHUN@inel.gov>, <SMITTW@inel.gov>, <ZAP@inel.gov>
cc "Angela McIntosh" <ARM@nrc.gov>, "Aaron McCraw"
<ATM@nrc.gov>, "Linda Gersey" <LMP1@nrc.gov>
bcc

Subject Fwd: EN 040583 - RI confirms is reportable

Please see attached. RI confirms that 040583 is reportable. If you have any questions, let me know. Thanks.

----- Message from "Duncan White" <ADW@nrc.gov> on Mon, 24 Jan 2005 13:56:28 -0500 -----

To: "Linda Gersey"
<LMP1.twf4_po.TWFN_DO@nrc.gov>
cc: "Aaron McCraw" <ATM@nrc.gov>
Subject : EN 040583

This event occurred in NY State in August 2004. It also relates to a NRC license (Advance Medical in CT). This is a reportable event.