

## RI - DNMS Licensee Event Report Disposition

Licensee:	Kennedy Memorial Hospital		
Event Description:	Shift of I-125 seeds after implantation		
License No:	29-13459-01	Docket No:	03009149
Event Date:	12/08/06	Report Date:	12/08/06
		MLER-RI:	2006048
		HQ Ops Event #:	43039

### 1. REPORTING REQUIREMENT

<input type="checkbox"/> 10 CFR 20.1906 Package Contamination	<input type="checkbox"/> 10 CFR 30.50 Report
<input type="checkbox"/> 10 CFR 20.2201 Theft or Loss	<input checked="" type="checkbox"/> 10 CFR 35.3045 Medical Event
<input type="checkbox"/> 10 CFR 20.2203 30 Day Report	<input type="checkbox"/> License Condition
<input type="checkbox"/> Other _____	

### 2. REGION I RESPONSE

<input type="checkbox"/> Immediate Site Inspection	Inspector/Date
<input checked="" type="checkbox"/> Special Inspection	Inspector/Date: Gabriel 12/12/06
<input checked="" type="checkbox"/> Telephone Inquiry	Inspector/Date: Gabriel 12/8/06
<input type="checkbox"/> Preliminary Notification/Report	<input type="checkbox"/> Daily Report
<input checked="" type="checkbox"/> Information Entered in RI Log	<input type="checkbox"/> Review at Next Inspection
Report Referred To: _____	

### 3. REPORT EVALUATION

<input checked="" type="checkbox"/> Description of Event	<input checked="" type="checkbox"/> Corrective Actions
<input checked="" type="checkbox"/> Levels of RAM Involved	<input checked="" type="checkbox"/> Calculations Adequate
<input checked="" type="checkbox"/> Cause of Event	<input type="checkbox"/> Additional Information Requested from Licensee

### 4. *N/A* MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/> Release w/Exposure > Limits	<input type="checkbox"/> Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/> Repeated Inadequate Control	<input type="checkbox"/> Pkgng Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/> Exposure 5x Limits	<input type="checkbox"/> Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/> Potential Fatality	<input type="checkbox"/> Unique Circumstances or Safeguards Concerns
If any of the above are involved:	
<input type="checkbox"/> Considered Need for IIT	<input type="checkbox"/> Considered Need for AIT
Decision/Made By/Date: _____	

### 5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

<input checked="" type="checkbox"/> Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)	
<input checked="" type="checkbox"/> Medical Consultant Used-Name of Consultant/Date of Report:	Subir Nag, MD 1/31/07
<input type="checkbox"/> Medical Consultant Determined Event Directly Contributed to Fatality	NO
<input type="checkbox"/> Device Failure with Possible Adverse Generic Implications	NO
<input type="checkbox"/> HQ or Contractor Support Required to Evaluate Consequences	NO

### 6. SPECIAL INSTRUCTIONS OR COMMENTS

<input checked="" type="checkbox"/> Non-Public	Inspector Signature: <u>Subir Nag</u>	Date: <u>2/1/07</u>
<input type="checkbox"/> Public-SUNSI REVIEW COMPLETE	Branch Chief Initials: <u>[Signature]</u>	Date: <u>2/5/07</u>

**KENNEDY**  
HEALTH SYSTEM

Department of Radiation Oncology  
900 Medical Center Drive  
Suite 100  
Sewell, NJ 08080  
Telephone: (856) 582-3008  
Fax: (856) 582-3009

December 20, 2006

United States Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

**ATTN: Sandra Gabriel, Ph.D.**

Dear Dr. Gabriel:

This report is submitted pursuant to 10 CFR 35.3045.

**The medical event occurred at the licensee facility:**

Kennedy Memorial Hospitals,  
435 Hurfville- Crosskeys Road,  
Turnersville NJ 08012

License No. ~~29-15439-01~~  
Docket No. 03002543

29-15439-01

**The prescribing physician:**

Carolyn Horowitz, M.D., Ph.D.

**Description of the medical event:**

On October 25, 2006, a patient was implanted with 104 iodine 125 brachytherapy sources for the treatment of prostate cancer. The total activity of the implanted source was 42.4 mCi. A post-plan CT scan was performed on December 8, 2006. Post-implant dosimetry done on that day using the CT data-set indicated that all the seeds had been misplaced approximately 1.5 cm inferior to the intended location.

**The probable cause of the medical event:**

There may have been inaccuracy in the localization of the base plane of the prostate in the volume study and/or inaccurate ultrasound localization of the base plane the day of the implant. This inaccuracy may have caused the I-125 to be implanted inferior to the target, in the perineum.

**The effect on the patient who received the administration:**

The effect of the administration in the short term may be itching in the perineal area. The long term effect may be the necrosis of the skin of the perineum. The prescribing physician will closely monitor the patient for potential side effects.

**Actions taken as of December 18, 2006 to prevent recurrence of the circumstances that led to the medical event:**

1. A radiologist will be reviewing the volume study performed by the urologist. After approval by the radiologist and radiation oncologist, the volume study will be input into the treatment planning computer.
2. The balloon used for the localization of the prostate in the O.R will be filled with contrast medium that will show more clearly the bladder/prostate interface, and thus the location of the base plane of the prostate.
3. Following the insertion of the initial trochars during the implant, fluoroscopy will be used to determine if the trochars were inserted up to the base plane of the prostate gland.
4. Additional actions to prevent recurrence may be taken pending the results of a root cause analysis (RCA). The RCA meeting is scheduled for January 3, 2007.

**Certification that the patient was notified of the medical event:**

On December 8, 2006, during a follow-up appointment, the patient was notified by the prescribing physician that the medical event had occurred.

If you require any additional information, please contact me.

Sincerely,



Lester Tripp  
Radiation Safety Officer

**From:** Sandra Gabriel  
**To:** Trisha Haverkamp  
**Date:** 12/16/2006 1:50:12 PM  
**Subject:** New LER

Would you please open a new LER package for Kennedy Memorial Hospitals based on Event Number 43039? Please see the event notification report from 12/12/06. This was a medical event. I have already done an on-site inspection. Licensee's 15-day written report is due on 12/23.

thank you!

Hospital	Event Number: 43039
Rep Org: KENNEDY MEMORIAL HOSPITAL Licensee: KENNEDY MEMORIAL HOSPITAL Region: 1 City: TURNERSVILLE State: NJ County: License #: 29-15459-01 Agreement: N Docket: NRC Notified By: LESTER TRIPP HQ OPS Officer: JASON KOZAL	Notification Date: 12/08/2006 Notification Time: 15:49 [ET] Event Date: 12/08/2006 Event Time: [EST] Last Update Date: 12/11/2006
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): MARVIN SYKES (R1) GARY JANOSKO (NMSS)

**Event Text****SHIFT OF I-125 SEEDS AFTER IMPLANTATION**

On 10/26/06 the licensee implanted a patient with 104 seeds of I-125 (total activity of 42.2 millicuries, manufactured by Bard, Inc.) to treat prostate cancer. The post implant CT performed on 12/08/06 indicated that the distribution of the seeds was inferior to the intended distribution. A percentage of the seeds had shifted approximately 1.5 cm inferior to what was intended. The licensee is still evaluating at this time what percentage of the seeds intended for the prostate were no longer in the prostate. The licensee immediately informed the patient and the prescribing physician. The patient has to this point shown no ill effects from the migration. However, a quantity of the seeds have migrated to the perineum. Due to the unknown quantity of seeds in the perineum the licensee is still investigating the amount of dose received in this area.

The licensee is investigating the cause of the migration. After the cause is determined they will put corrective actions in place to prevent reoccurrence. The licensee has performed multiple implants that were close to 100% successful since this occurrence. The licensee intends to supplement the patients treatment with an external bean in order to achieve the intended dose.

The licensee notified NRC Region 1 (S. Gabriel, P. Lanzisera)

\* \* \* UPDATE TO HUFFMAN FROM TRIPP AT 10:55 EST ON 12/11/06 \* \* \*

Based on discussion with NRC Region 1 (S. Gabriel), the licensee provided the following revision to the initial event report:

"On October 25, 2006, the licensee implanted 104 I-125 seeds into a patient for the treatment of prostate cancer. The total activity of the implanted seeds was 42.4 mCi. A post-implant CT performed on December 8, 2006, indicated that the seed were misplaced approximately 1.5 cm inferior to the intended position. The licensee is still evaluating the details of the post-implant dosimetry.

"Notifications pursuant to 10 CFR 35.3045 were made on December 8, 2006.

"The licensee is still evaluating the cause of the misplacement of the iodine seeds. After the cause(s) has been determined, corrective actions will be put in place.

"The patient will require further treatment of the prostate gland. External beam therapy will be used to supplement the dose to prostate."

R1DO (Conte) and NMSS EO (Morell) notified.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

## MEDICAL CONSULTANT REPORT (SHORT FORM)

(If site visit is not necessary)

Medical Consultants Name: Subir Nag, MD

Report Date: February 1, 2007

Signature:

Licensee's Name: Kennedy Memorial Hospitals, Turnersville, NJ

License No. ~~2912167-01~~ 29-15459-01

Docket No: 03002543

Facility Name: Kennedy Memorial Hospitals, Turnersville, NJ

Incident Date: 10/25/06

Prescribing Physician's Name: Carolyn Horowitz, MD

Referring Physician's Name: Marcella Nachmann DO, Urologist

Individuals contacted during investigation (by phone): Lester Tripp – Physicist/Radiation Safety Officer; Carolyn Horowitz, MD, Radiation Oncologist, Marcella Nachmann DO, Urologist

Records reviewed: NRC event report, patient chart, dosimetry, preplanning ultrasound images, post-implant CT scans.

Estimated Dose to Individual or Target Organ: Prostate D90 = 8 Gy (145 Gy prescribed)

Probable Error Associated with Estimation: Minimal

Prescribed Dose (Medical Administration Only): 145 Gy prescribed

Method Used to Calculate Dose: Treatment Planning Computer

Description of Incident: Patient was implanted with 104 I-125 seeds (42.4 mCi) to the prostate as per pre-plan. Preloaded needles were used. Post-implant CT based dosimetry revealed most of the seeds to be inferior to the prostate. Hence the dose to the prostate is estimated to be 8 Gy instead of the prescribed 145 Gy.

The most likely cause of this incident is that the prostate was not properly identified during the procedure. This could have been because the prostate was not well visualized or the urologist placing the needles had insufficient experience with ultrasound guided prostate implants. A remote possibility is that the patient moved superiorly by 2-3 cm during the procedure, after needle insertion but before seed deposition. The latter is a less likely scenario as (1) the physicians did not report any unusual patient movements and (2) the needles were placed row by row and the seeds were deposited before the next row of needles were inserted.

Current medical condition of the exposed individual: No adverse effect.

Based on your review do you agree with the licensee's written report in the following areas:

- a. Why the event occurred: Yes
- b. Effect on the patient: Yes
- c. Licensee's immediate action on discovery: yes
- d. Improvements needed to prevent recurrence: Yes.

Areas where you do not agree with the licensee's evaluation: None

Did the licensee notify the referring physician: Yes.

Did the licensee notify the patient: Yes

Why Site Visit is Not Required:

1. I have reviewed the necessary patient chart, dosimetry, planning ultrasound images, and post-implant CT scans.
2. Likelihood of patient harm is small.
3. The licensee has taken satisfactory corrective actions including:
  - a. having a radiologist review the volume study during implant procedure
  - b. filling foley catheter balloon with contrast to better identify prostate base
  - c. using fluoroscopy to confirm needle depth before depositing the seeds and fluoroscopic confirmation of seed position intermittently during the procedure.
  - d. The prostate dose of the affected patient will be made up by adding external beam dose using IMRT.

Assessment of probable deterministic effects of the radiation exposure on the individual: No significant adverse effect is expected.