RI - DNMS Licensee Event Report Disposition

Licensee: Bayhealth Medical Center

Event Description: Medical Event

License No: 07-14850-01 Docket No: 03007565 MLER-RI: 2006-024

Event Date: 06/12/06 Report Date: 6-12-06 HQ Ops Event #: 42634

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [ ] Other
- [ ] 10 CFR 30.50 Report
- [X] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date:
- [X] Special Inspection — Inspector/Date: Gabriel/Simmons 6-16-06
- [X] Telephone Inquiry — Inspector/Date: Gabriel 6-13-06
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:
- [ ] Daily Report
- [ ] 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
- [X] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] 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)

- [X] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [X] Medical Consultant Used-Name of Consultant/Date of Report: Dr. Nag, 7-3-06
- [ ] 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

[X] Non-Public

[ ] Public-SISP REVIEW COMPLETE

Inspector Signature: Sandra Gabriel Date: 7-12-06

Branch Chief Initials: ALN Date: 7/29/06

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

Rev. 02/25/05

Bayhealth Medical Center

Oncology Services
Department of Radiation Oncology
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REPORT AND NOTIFICATION TO NRC OF MEDICAL EVENT

License Number: 07-14850-01

Licensee's Name: Bayhealth Medical Center
640 South Queen Street
Dover, DE 19904

Authorized User: John Lahaniatis M.D.

Date / Time of Medical Event: 6/12/2006, 3:00PM

Description of Event:
On 6/12/06 at approximately 3:00 PM, an I-125 prostate seed implant was performed in the operating room at Bayhealth Medical Center/Kent General Hospital. At the end of the procedure John Lahaniatis, MD, Radiation Oncologist and authorized user, reviewed the documentation and wrote a note on the Operative Note Sheet indicating the isotope type, number of seeds, number of needles used, individual seed activity, total activity implanted and other patient-related parameters. At this time, it was determined that the implanted activity was different from the planned activity; the total activity calculated was 27 mCi and implanted activity was 34 mCi. This dose was 26% higher than intended.

Reason Why Event Occurred:
The event occurred due to incorrect entry of units of dose and activity into the treatment planning computer system.

With prostate seed implants, the total number and placement of radioactive seeds and subsequent computer calculations for dose distribution within the patient are performed in "real time." In order to do this computerized calculation as to how the seeds will be implanted, a physicist using a laptop in the Operating Room, enters specific information related to the type and radioactivity of the seeds, manufacturer, etc.

In this regard there are two options from which to choose: mCi or U. When seed activity is entered in either of the above option "boxes," the alternate unit is calculated and displayed on the following line. It is at this point that the software provides the opportunity to compare the numbers for agreement with the seed activity received from the vendor.

The seed activity ordered was 0.34 mCi per seed. However, the activity entered in software was 0.34 U per seed. The discrepancy was not noted. Therefore, the computer

calculated the number of seed required for activity 0.27 mCi per seed, while the activity actually implanted was 0.34 mCi per seed.

It was determined that the total activity implanted was 34 mCi which is 26% more than the planned activity of 27 mCi.

Effect on Patient:
Patient may be at risk for long term complications related to higher than planned dose to the rectum and urethra. Therefore the patient will be monitored by Drs. Vallorosi and Lahaniatis on a long-term basis, including physical examinations and appropriate imaging and other medical studies as needed.

Actions Taken to Prevent Recurrence:
To confirm radioactive seed information accuracy, a "time out" will be incorporated in the policy #B9810.24 titled "Prostate Implants using I-125 or Pd-103."

The "time out" will take place using a checklist to verify that the correct isotope and source strength have been entered. A second person—a physician, second physicist, dosimetrist or nurse—will verbally call out the numbers entered on the laptop screen. The physicist will then compare those numbers to the vendor's calibration certificate. The Radiation Oncologist will proceed only when the prescribed radioactivity data has been confirmed in the calculations.

Certificate that Licensee Notified Patient:
Letter was sent to patient on 6/16/06 from Dr. Lahaniatis.

Actions Taken:
All variations in dose delivery above 20% are considered misadministration per NRC 10CFR35.3045(a)(1)(ii) and NRC needs to be notified immediately.

The following actions were taken on 6/12/06:

1. Participating Urologist, Christopher Vallorosi, MD was notified in-person by John Lahaniatis, MD Radiation Oncologist immediately following the implant.

2. Rachael Taylor, MD, Radiation Safety officer was notified in-person by Dr. Lahaniatis.

3. Dr. Lahaniatis notified hospital administration by telephoning Donna Stinson, Administrative Director of Operations, Oncology Service line at 4:00 PM on 6/12/06.
    a. Ms. Stinson interviewed Sapna Paramale, Medical Physicist at 4:10 PM in the Dover Cancer Center for her description of the event.

4. Drs. Lahaniatis and Vallorosi met with patient's wife and described the event by 4:30 PM.

5. Raji Subramanyam, PhD, Chief Medical Physicist telephoned the NRC King of Prussia office at approximately 5:00 PM and was instructed by voice message to contact the Washington, DC office, where a verbal report was taken.

6. Dr. Lahaniatis telephoned the Seattle Prostate Institute. During the follow-up telephone conversation on 6/13/06, a Seattle-based Radiation Oncologist, requested the post implant dosimetry (with patient identifiers removed) to be sent to him via overnight express service for his review. He agreed to telephone Dr. Lahaniatis with his assessment before 6/16/06.

7. JoAnn Davis, Director of Risk Management was also notified of event by 6:00 PM.

Rachel Taylor M.D.
Radiation Officer

Rachel Taylor M.D.

JUN 26 2006