RI - DNMS Licensee Event Report Disposition

Licensee: West Virginia University Hospital

Event Description: Dose <> Prescribed dosage

License No: 47-23066-02 Docket No: 03-02023 LER-RI: 2010-008

Event Date: 1/20/10 Report Date: 7/7/10 HQ Ops Event #:

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [N/A] Other
- [ ] 10 CFR 30.50 Report
- [X] 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:
- [ ] Daily Report
- [ ] Review at Next Inspection

3. REPORT EVALUATION

- [X] Description of Event
- [X] Levels of RAM Involved
- [X] Cause of Event – inconclusive
- [X] Corrective Actions
- [X] Calculations Adequate
- [X] Additional Information Requested from Licensee – received 10/12/10

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [N/A] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [N/A] 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) – identified during inspection
- [N/A] Medical Consultant Used-Name of Consultant/Date of Report: underdose
- [N/A] Medical Consultant Determined Event Directly Contributed to Fatality
- [X] Device Failure with Possible Adverse Generic Implications – inconclusive
- [N/A] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

See inspection report for full details

☐ Non-Public

[X] Public-SUNSI REVIEW COMPLETE

Inspector Signature: Date: 11-4-10

Branch Chief Initials: Date: 11/8/10

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

Rev. 02/25/05

Event Notification Report for July 14, 2010

U.S. Nuclear Regulatory Commission
Operations Center

Event Reports For
07/13/2010 - 07/14/2010

** EVENT NUMBERS **

46074 46078 46081 46086 46089 46090 46091

TOP

Hospital	Event Number: 46074
Rep Org: WEST VIRGINIA UNIVERSITY HOSPITAL Licensee: WEST VIRGINIA UNIVERSITY HOSPITAL Region: 1 City: MORGANTOWN State: WV County: License #: 47-23066-02 Agreement: N Docket: NRC Notified By: NASSER RAZMIANFAR HQ OPS Officer: MARK ABRAMOVITZ	Notification Date: 07/07/2010 Notification Time: 11:37 [ET] Event Date: 01/20/2010 Event Time: [EDT] Last Update Date: 07/07/2010
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): ANTHONY DIMITRIADIS (R1DO) ANGELA MCINTOSH (FSME)

Event Text

MEDICAL TREATMENT TERMINATED PRIOR TO ADMINISTERING FULL DOSE

A patient's liver was being treated using SIR-Spheres through a catheter. During the administration of the Y-90 SIR-Spheres, the physician believed that there was leakage around the stopper and halted the medical procedure with only 21.9 mCi administered instead of the complete dose of 30.7 mCi i.e. 71% of the prescribed dose. The manufacturer was notified of the potential manufacturing defect and the hospital was directed to ship the delivery apparatus (as is) back to the manufacturer after the Y-90 had decayed. The equipment was returned to the manufacturer on April 5, 2010 and a report was received from the manufacturer on June 21, 2010. "The manufacturer noted that there was leaking but could not conclude that it was a manufacturer defect or if the physician applied too much pressure to the V-vial during the procedure." The patient was notified of the dose received.

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.

WestVirginiaUniversity
RADIATION SAFETY DEPARTMENT

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

July 21, 2010

Attn: Penny Lanzisera
Health Physicist
Medical Branch
Division of Nuclear Material Safety

Subject: Report regarding Y-90 medical event.

West Virginia University Hospitals Inc.
License No. 47-23066-02 Docket No. 03-020233

Dear Ms. Lanzisera,

Prescribing physician: Dr. Carl Jueng

On January 20th, 2010 a patient was prescribed to receive 30.7 mCi of Y-90 in a Sirtex Microsphere procedure. The Patient only received 21.9 mCi of Y-90. The Patient had only received 71% of the prescribed dose, when the procedure was stopped.

During the procedure the physicians believed that the V-Vial was leaking. So they terminated the procedure.

The Vial was sent for testing by the manufacturer, they confirmed that the vial leaked but could not confirm whether it was from excessive manual pressure, or if it was due to manufacturer defect.

The following corrective actions have been made.

Corrective action (a): Refresher training was given by the manufacturer

Corrective action (b): Dose preparation form has been modified to flag if the dose delivered is less than 80% of the prescribed dose. This will then require signatures of the Authorized User and Interventional Radiologist the same day of the procedure to determine if the dose differs from the prescription because of stasis or if a medical event declaration needs to be made.

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West Virginia University
WVU Hospitals

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Morgantown, WV 26506-9006

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RADIATION SAFETY DEPARTMENT

Corrective action (c): Meeting with RSO and Physicians to take place before any future procedures to discuss the event and information contained in 10 CFR 35.3045

The Individual was not informed of the medical event. The patient has since passed away. The referring physician was aware of the patient not receiving the full prescribed dose. The referring physician was the Interventional Radiologist who assisted on the case.

Sincerely yours,

Nasser Razmianfar
Director and Radiation Safety Officer

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