RI - DNMS Licensee Event Report
Disposition

Licensee: St. Mary's Medical Center

Event Description: Medical event

License No: 47-01576-01 | Docket No: 03007358 | MLER-RI: 2008-001

Event Date: 10/15/08 | Report Date: 10/22/08 | 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
- [ ] Other
- [ ] 10 CFR 30.50 Report
- [x] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [x] Immediate Site Inspection — Inspector/Date: Richard McKinley 10/29/08
- [ ] Special Inspection — Inspector/Date: Farah Tarkins 10/29/08
- [ ] Telephone Inquiry — Inspector/Date:
- [ ] Preliminary Notification/Report
- [ ] 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

- [N/A] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality

If any of the above are involved:

- [ ] Considered Need for IIT

Decision/Made By/Date:

- [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
- [ ] Considered Need for AIT

N/A

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: Edward Silberstein, MD 12/15/08
- [N/A] 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

[ ] Non-Public — Inspector Signature: Richard W. McKinley — Date: 01/08/09

[x] Public-SUNSI REVIEW COMPLETE — Branch Chief Initials: PL for — Date: 01/08/09

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

Rev. 02/25/05

ST. MARY'S MEDICAL CENTER

2900 FIRST AVENUE
HUNTINGTON, WV 25702

October 22nd, 2008

Sent via email to hoo.hoc@nrc.gov

Medical Branch, Division of Nuclear Materials Safety
U.S. NRC Region I
Nuclear Materials Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: Medical Event for NRC RAML#: 47-09576-01

To Whom It May Concern:

This report is to document the details and meet the reporting requirements related to the medical event that occurred at our facility on 10/15/2008. I became aware that a medical event had likely occurred at approximately 6pm on 10/21/2008. At 10:15am on 10/22/2008, I contacted the NRC Operations Center at 301-951-0550 to report the event and spoke to Jason Kozel.

Name of Licensee:
St. Mary's Medical Center
2900 First Avenue
Huntington, WV 25702
NRC RAML#: 47-09576-01

Name of Prescribing Physician:
Tipu Fiaz Saleem, MD

Name of Authorized User:
Abid Yaqub, MD

Description of Event:
This incident occurred during a therapeutic administration of one 150 mCi I-131 capsule on 10/15/2008 at our facility. This was a post thyroidectomy and ablation therapy on a patient who has an esophageal stricture. Prior to administration, the patient was questioned by the nuclear medicine staff and the authorized user as to if she felt that she could swallow the standard ¾" capsule to which she indicated "Yes". At approximately 11:00am, the patient attempted to swallow the capsule but it lodged in the patient's upper esophagus. In an effort to wash the capsule down, applesauce and then soda were given to no avail. The patient coughed up the applesauce and soda. The materials coughed up were surveyed and found to be radioactive. Decontamination procedures were initiated and the Radiation Safety Officer and Authorized User were called. A calibrated GM survey meter was used to confirm that the capsule was indeed lodged in the upper esophagus at about the mid-cervical level. It was decided that retrieving or pushing the capsule through would be potentially harmful to the patient, would result in significant exposure to personnel, and would create a large contamination problem. We felt that the best option would be to try using more soda (Coke/Pepsi) to dissolve the capsule

enough for it to pass through into the stomach. The patient agreed with this course of action and swallowed small amounts of soda. Eventually at around 2:00 pm, the capsule made it down to the stomach as confirmed by GM survey meter readings at the throat and stomach. All radioactive and decontamination material was gathered and placed in a 2-gallon container. Otherwise, the therapy was uneventful. The total time that the capsule was lodged in the patient's throat was approximately 2.5 hours.

Dosimetry:
To determine if a medical event had occurred as defined by 10CFR35.3045, the following evaluation was performed.

The 2-gallon container was surveyed post-cleanup to measure 2 mR/hr at 1 meter. Using the I-131 gamma factor @ 1 meter (Rad Health Handbook), we estimate the activity not administered to be approximately:

2 mR/Hr / 0.28 mR/Hr/mCi = 7.14 mCi.

The difference between the prescribed dose (150 mCi) and the administered dose (150 – 7.14 = 142.9 mCi) is therefore estimated to be:

1 – (142.9/150) = 0.047, or 4.7%.

This difference is less than the 20% threshold and the authorized user for this therapy does not deem this difference to be significant in achieving the objective of the therapy.

This event was discussed with Mr. Michael Stabin, of Vanderbilt University and the ICRP, who noted that there is currently no esophagus-to-esophagus MIRD S-Factor for I-131. Given the lack of appropriate dose conversion factors, he agreed that the approach taken below is reasonable.

Using the I-131 gamma factor @ 1 centimeter (NUREG Appendix U) to represent the local esophageal dose in the area adjacent to the capsule in an effort to determine a conservative estimate of the esophagus dose:

2.2 R/Hr/mCi (2.5 Hr) (142.9 mCi) = 786 rad.

This dose is more than 50 rem to an organ or tissue.

Using the package insert, we can compare this dose to that received by the thyroid bed @ 5% uptake:

260 rad/mCi (142.9 mCi) = 37,154 rad.

In an attempt to estimate what the esophageal dose would have been from the thyroid and extrathyroidal uptake only, for a "perfect administration" without the lodged I-131 capsule, we performed the following calculation based on Equation B-5 of NUREG Appendix U:

$$D(\infty) = \frac{34.6\Gamma Q_0}{(r)^2}\left\{E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff}\right\}$$

= 1043 R (0.97 rad/R) = 1012 rad.

Where:
D(∞) = Accumulated dose to infinity
34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ = Exposure rate constant for I-131 point source = **2.2 R/mCi-hr at 1 cm**
Qo = Initial activity at the start of the time interval = **150 mCi**
Tp = Physical half-life in days, I-131 = **8.04 days**
r^2 = Inverse square where r is distance in centimeters of thyroid bed to esophagus = **3 cm**
E1 = Occupancy factor for the first 8 hours = **1**
E2 = Occupancy factor from 8 hours to total decay = **1**
F1 = Extrathyroidal uptake fraction, **0.95** based on Medical Condition
F2 = Thyroidal uptake fraction, **0.05** based on Medical Condition
T1eff = Extrathyroidal Effective Half-Life, **0.32** days based on Medical Condition
T2eff = Thyroidal Effective Half-Life, **7.3** days based on Medical Condition
0.97 = Roentgen-to-rad conversion factor for keV > 200

The estimated esophageal dose from the period that the capsule was lodged plus the dose from the thyroid therapy is estimated to be:

786 rad + 1012 rad = 1799 rad.

This corresponds to an additional dose to the esophagus of:

1- (1799 rad / 1012 rad) = 0.778, or 77.8%

This exceeds by 50% or more the esophageal dose expected from the therapy had the capsule not lodged in the throat.

Note that the Nuclear Medicine staff involved in the administration and cleanup of the event performed bioassay testing using a thyroid uptake probe between 24 and 48 hours later with negative results.

Why Event Occurred:
Patient and staff assumed capsule would pass through to the stomach.

Effect on the Patient:
The patient had no ill effects at the time other than the discomfort associated with having a capsule lodged in her throat. Our radiation oncologist indicates that a dose of this magnitude and duration could result in temporary localized esophagitis and possible future radiation fibrosis.

As of 10/22/08, the patient has no such specific symptoms. We will continue to follow-up with the patient.

Actions to prevent reoccurrence:
Please note that this was a very unusual situation that had not previously happened at our facility or elsewhere in the experience of all those involved. We will caution our referring physicians and authorized users to evaluate patients known to have difficulty swallowing for possible pretherapy esophageal dilatation, or possible use of liquid iodine 131, prior to performing radioiodine therapy capsule administration. Swallowing a dummy capsule such as a multivitamin could also be tried as part of the pretherapy assessment.

Notification of the Patient:
On 10/22/08, the authorized user verbally notified the patient that her esophagus received approximately 80% more dose than would have otherwise been received had the capsule not lodged in her throat. Possible effects were also discussed. The patient was informed that a written description of the event could be obtained, if requested.

Notification of Referring Physician:
The referring physician was notified verbally and will receive a copy of this report with patient name and identifier appended within 15 days of the incident (by October 30, 2008).

Notification of NRC:
I initially understood that the capsule had been lodged for approximately 1.5 hours which corresponds to an esophageal dose of approximately 495 rad (less than 50% above expected dose). As previously mentioned, this was an unusual situation that had not previously happened in the experience of all those involved and no guidance is available. In worked through this evaluation, I contacted Ms. Sandy Gabriel at NRC Region 1 on 10/17/2008. Ms. Gabriel discussed our circumstances with NRC Headquarters and determined, based on the information that I provided at that time, that this was not a medical event reportable to the NRC. However, a report of the event was requested. It was in reviewing the therapy documentation and interviewing all those involved that I realized that the capsule was actually lodged for approximately 2.5 hours. I then revised the dosimetry assumptions and estimates and determined that it appeared that the criterion of a medical event has indeed been met. The next morning, I again notified Ms. Gabriel, as she was my original point of contact, and called the NRC Operations Center.

We hope that this report meets with your satisfaction. Please contact me if there are any questions or if I may be of assistance. Thank you.

Sincerely,

James Norweck, MS, DABR
Radiation Safety Officer
Office: 304-522-1550 x234
Cell: 304-710-0172
FAX: 304-522-0704
jnorweck@radiology-inc.com