RI - DNMS Licensee Event Report
Disposition

Licensee: MedStar Georgetown University Hospital

Event Description: Violation of Written Directive

License No:	08-30577-01	Docket No:	03035499	MLER-RI:	2016-009
Event Date:	05/19/16	Report Date:	06/28/16	HQ Ops Event #:	2

1. REPORTING REQUIREMENT

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

2. REGION I RESPONSE

- [ ] Immediate Site Inspection — Inspector/Date
- [X] Special Inspection Sometime in July 2016 — Inspector/Date
- [ ] 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

- [ ] 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 (NA)
- [ ] Considered Need for AIT (NA)

Decision/Made By/Date: Dwyer 6/30/2016

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

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] 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

Follow up to determine if event constitutes a medical event

___Non-Public

Inspector Signature: Date:

X Public-SUNSI REVIEW COMPLETE

Branch Chief Initials: Date: 7/1/2016

Location of File: G:\REFERENCE\BLANK FORMS\LER FORM.DOC

MedStar Georgetown
University Hospital

3800 Reservoir Rd
Washington, DC 20007
202.444.4637 PHONE
202.444. FAX
medstargeorgetown.org

David A. Smith, PhD
Director, Radiation Safety

Radiation Safety

June 28, 2016

ATTN: Ms. Tara Weidner
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
2100 Renaissance Blvd
Suite 100
King of Prussia, PA 19406-2713

SUBJECT: Notice of Possible Violation, NRC License 08-30577-01, Docket No. 030-35409

On 16 June 2016 I was notified by the Authorized User (AU) of an issue regarding the 19 May 2016 radioembolization of a patient. During the subsequent review of the patient's treatment plan in preparation for an additional radioembolization of the Right Hepatic Lobe (scheduled for 16 June 2016) the AU observed the 19 May 2016 Written Directive/treatment plan was completed for the Right Hepatic Lobe but treatment had been delivered to the Left Hepatic Lobe.

Review of the physician notes for the case reveal the intended primary treatment site, as noted by the Interventional Radiologist (IR) was the Left Hepatic Lobe, however, communication between the IR and AU requested a treatment plan for the Right Hepatic Lobe. On 16 June 2016 the AU confirmed with the IR that the Left Hepatic Lobe was indeed the intended treatment site for the 19 May 2016 procedure. Of note, the 19 May 2016 delivery was not completed as stasis was achieved.

The AU and Medical Physicist (MP) recalculated the 19 May 2016 treatment plan based on the administered activity and the treatment volume for the Left Hepatic Lobe. The resultant delivered dose was 119.4% of the prescribed dose. The AU determined there was no harm to the patient.

After review of the circumstances relative to the requirements stipulated in 10 CFR 35.3045, *Report and Notification of a Medical Event*, it does not appear this is a Medical Event and therefore, does not meet the reporting requirements of 10 CFR 35.3045. The dose was delivered to the Left Hepatic Lobe prior to the planned delivery to the Right Hepatic Lobe, i.e. both lobes were intended for treatment at different times; the original Written Directive was reviewed and corrected to account for the delivery to the Left Hepatic Lobe and the resultant dose did not exceed any thresholds specified in 10 CFR 35.3045.

Although not believed to be reportable as a Medical Event, this incident may be a violation of 10 CFR 35.40, *Written Directives*, paragraph (c) and/or 10 CFR 35.41, *Procedures for Administrations Requiring a Written Directive*, paragraphs (a)(2) and (b)(2). Therefore, I am submitting this report for your review.

Actions taken to preclude a recurrence:

1. A Time Out will occur wherein the AU, MP and IR communicate the specifics of the treatment plan by asking open-ended questions requiring more than a "yes/no" answer. The Time Out will be documented via signatures from each of the aforementioned team members.
2. After the mapping study, the IR will clearly indicate the preferred treatment site(s) in his notes so the AU is clear as to the development of the treatment plan.

These have been incorporated into the Radiation Medicine Sirsphere Policy and each member of the team has been instructed regarding the changes. Additionally, this incident is being tracked through our internal Risk Management system for further review and potential improvements to the program. These actions/reviews have been conducted and implemented prior to the next case, which is scheduled for 30 June 2016.

I may be reached at 202-444-4637 or david.a.smith@gunet.georgetown.edu should you require further information.

David A. Smith, PhD
Radiation Safety Officer

2 Attachments
1. Details of incident
2. AU Narrative

Attachment 1 Details of Incident

1. Original Written Directive for Right Hepatic Lobe (19 May 2016)
    a. Activity prescribed: 25.49 mCi
    b. Dose to Lobe prescribed: 32.13 Gy
    c. Activity delivered: 23.48 mCi
    d. Dose to Lobe delivered: 29.59 Gy

2. Revised Written Directive for Left Hepatic Lobe (16 June 2016)
    a. Activity prescribed: 19.67 mCi
    b. Dose to Lobe prescribed: 43.37 Gy
    c. Activity delivered: 23.48 mCi
    d. Dose to Lobe delivered: 51.77 Gy
    e. Percent variation of administered activity to that prescribed = 19.4%
3. Rationale for determining this incident did not meet Medical Event Reporting in accordance with 10 CFR 35.3045 (local assessment for each criterion bolded).
    a. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin (**YES**); and
        i. The total dose delivered differs from the prescribed dose by 20 percent or more (**NO**);
        ii. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range (**NO**); or
        iii. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more (**NO**).
    b. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
        i. An administration of a wrong radioactive drug containing byproduct material (**NO**);
        ii. An administration of a radioactive drug containing byproduct material by the wrong route of administration (**NO**);
        iii. An administration of a dose or dosage to the wrong individual or human research subject (**NO**);
        iv. An administration of a dose or dosage delivered by the wrong mode of treatment (**NO**); or
        v. A leaking sealed source (**NO**).

    c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue (**YES**) and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site) (**NO**).

Attachment 2 AU Narrative

Department of Radiation Medicine
3800 Reservoir Rd / Washington, D.C. 20007
Phone: 202-444-3320 / Fax: 202-444-9323

PHYSICIAN: Keith Unger, MD

Narrative: My review of the patient's medical record for their second Y-90 treatment on 6/15/16 revealed a discrepancy in the documented treatment site due to a miscommunication.

1. The 1st treatment was planned on 5/19/16 for the right lobe to an activity of 29.10 mCi.
2. The treatment was delivered to the left lobe as intended by the IR to an activity of 26.8 mCi, which is within 20% of the replanned prescribed dose to left lobe.
3. The patient was scheduled for treatment of the right lobe for 6/16/16.
4. The planned activity to the right lobe will be 29.10 mCi.
5. An incident report was filed and the RSO was notified. There was no potential harm to the patient. No dose corrections are indicated.

Authored By: Keith Unger, MD
Electronically signed by: Keith Unger, MD, MD 6/16/2016 7:40:35 AM
KEITH UNGER, MD

RADIATION ONCOLOGIST