RI - DNMS Licensee Event Report
Disposition

Licensee: ST LUKE'S HOSPITAL

Event Description: Medical event

License No: 37-12915-01 | Docket No: 03 003175 | MLER-RI: 2005-056

Event Date: 7-26-05 | Report Date: 7-27 to Region 7-29 to Ops when licensee concluded that medical event | HQ Ops Event #: 41880

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: Lanzisera/8-9-05
- [ ] 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
- [X] Corrective Actions
- [X] Calculations Adequate
- [Y] Additional Information Requested from Licensee – received 11-8-05

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION – N/A

- [ ] 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)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report: N/A
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality ↓
- [ ] Device Failure with Possible Adverse Generic Implications – N
- [ ] HQ or Contractor Support Required to Evaluate Consequences – N

6. SPECIAL INSTRUCTIONS OR COMMENTS

[X] Non-Public

[ ] Public-SISP REVIEW COMPLETE

Inspector Signature: [signature] Date: 1-30-06

Branch Chief Initials: [signature] Date: 2/2/06

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

Rev. 02/25/05

St Luke's
HOSPITAL
& Health Network

801 Ostrum Street
Bethlehem, PA 18015
610-954-4000

August 23, 2005

Penny Lanzisera
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission – Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Ms. Lanzisera,

The following is a discussion of the in-depth event analysis and intensive review of the medical event that occurred on 7-26-05, was reported to you on 7-27-05, and was later reported to the NRC Operations Center. As a result, you and Dr. Howe of the NRC inspected our facility on 8-09-05 to learn more of the medical event. At the conclusion of your inspection, you requested a synopsis presenting our review and findings within 15 days. The following is per your request.

We would like to present the information as follows:

A. The event description
B. The contributing factors that we have discovered
C. The corrective actions and commitment to these actions
D. The lessons learned from each principal role-player in the procedure
E. The date(s) for full compliance.

A. Event Description

A written directive was prepared for a single treatment of the patient for 12.4 mCi of Sirspheres. It was known by the oncologist and the authorized user radiation oncologist that the overall treatment plan for this patient would probably entail two separate treatments. The 12.4 mCi dose was to be the first. The dose was ordered from Sirtex. The dose delivered was 80-90 mCi, which is the nominal delivered dose provided from Sirtex, regardless of the written directive. To get a dose of 12.4 mCi on the day of the therapy, the authorized medical physicist accepted the drawing of 15.9 mCi. The rationale for this was directed from the preceptor based upon previous experience with low dose, low volume therapies. Through fluoroscopic guidance, the treatment dose was introduced into an in-dwelling catheter into the right lobe only of the patient's liver. This limited treatment location was decided (prior to the initiation of the treatment by verbal communication, i.e. directive) due to the patient's biological conditions at time of treatment (i.e. lung shunting and liver chemistry results, etc.). The dose was presented for administration, and administration began into the catheter. Full vessel stasis was not achieved, and the authorized user chose not to continue with dose administration since there was a risk of administering too much dose. The treatment was stopped. Following the treatment, the vial containing the Sirspheres, called a V-vial, due to its shape, was assayed along with the contaminated tubing. It was then determined that the patient must have been under dosed by approximately 40%. The

manufacturer-approved method of assay is with an ion chamber radiation survey meter in a fixed-walled box geometry. Absolute assay of this product is difficult, if not impossible in the clinical environment. Technical pitfalls of absolute assay include self-absorption of the beta-emitting Yt-90 microspheres, non-uniform distribution of the source, and inconsistent geometry of follow-up source geometry, i.e. vial, tubing, connectors, etc. The product does not lend itself to reliable assay in a conventional dose calibrator-even one specifically designed for beta emitters. Upon discussion of the event with the RSO, the event was reported to the NRC, Region I and the NRC Operations Center as a courtesy notification, in case the event was discovered to be a medical event. Upon review, over the next week, and subsequent NRC inspection, we had understood that it was, indeed to be considered a medical event. Plans were made to inform the patient and/or the referring physicians. This has been completed.

On 8-17-05 an intense interdisciplinary analysis was performed to discuss what occurred, why, how to prevent its recurrence, and to determine what everyone learned from their experiences. The following is a list of attendees at this analysis:

Hal Folander, M.D., Chairman, Department of Radiology
Robert Fournier, M.D., Section Chief, Nuclear Medicine
Ellen Redstone, M.D., Interventional Radiologist
Lee Riley, M.D., Medical Director, Oncology Services
Namisha Deb, M.D., Chairperson, Radiation Oncology, Authorized User
Tian Xue, Ph.D., Chief Medical Physicist, Authorized Medical Physicist
Helene Oplinger, Radiology Administrator
Rod Heckman, R.N., Interventional Clinical Specialist
Kathy Sanders, CNMT, Manager Nuclear Medicine Dept.
Jim Goetz, Network Administrator, Oncology Services
Lisa Dutterer, Associate V.P.
Lynne Mohr, Sirtex representative
Charles Rowland, President, Sirtex, North America
Renee Martino, Director, Clinical Management and Research, Radiology Dept.
Walter L. Robinson, M.S., Radiation Safety Officer
Sue Neyenhouse, Clinical Risk Management
Donna Sabol, Assistant V.P.

B. Contributing Factors

One contributing factor discussed was the difficulty in assessing dose volumetrically with sufficient accuracy in a 5 cc. syringe, especially when doses may need to be drawn in the less than 1 cc range. 1 cc. volume shielded tuberculin syringes will be researched by Sirtex. The small volume required in this administration caused an imprecise estimation of the dose being administered. There was a desire to estimate on the side of caution and dispense only a restricted volumetric amount. In hindsight, this estimate turned out to be too low a dose.

Another factor brought to light was the lack of full understanding of the NRC-allowed written directives for this 10 CFR 35.1000 procedure. The authorized user was unaware of the obligation to make a verbal directive prior to a modified (from the original written directive) dose, to be then followed by a modified written directive upon completion of the procedure.

An additional learning opportunity identified related to the inclusion of all future potential treatment plans in the original written directive. For example, the text could state "one of a possible two treatments". In this way it will be clearly known (to an outside reviewer) whether the patient's plan included a "fractionated" plan from the very beginning or not.

Another opportunity for improvement that was discussed during the course of the intense analysis concerns the most effective method of distribution of the Sirspheres evenly in the solution prior to drawing the dose into the syringe. The manufacture verbally recommends discontinuation of the current procedure, "jetting", and recommends pursuing options utilized by other clinical testing sites such as an electric vibrating toothbrush to agitate the shipping vial prior to drawing the dose.

The final opportunity for improvement reviewed was the need for consensus from all principals involved of an acceptable prescribed dosage range. It is the range of this procedure's clinical acceptability (-5% to +15%) based upon the calculated dose.

C. Corrective actions

1) Low dose (requiring a volume under 1 cc) treatments will be placed on hold until Sirtex can assure us of smaller shielded calibrated syringes.
2) All principals now understand the new dosage range (-5% to +15%), and will not deviate from it.
3) The authorized user better understands the mechanism of verbal modifications to a written directive, and to follow the verbal modification with a modified written directive upon completion of the procedure.
4) The original written directive will include the complete proposed treatment regimen involving Sirspheres, so there can be no misunderstanding that a second treatment, or more, may be required, or if "fractionated" doses are planned.
5) Consideration given to agitating with a vibrating electric toothbrush versus the "jetting" procedure. The use of this method will allow the agitation to be made to the microspheres immediately before drawing the dose.
6) The radiation safety officer will be in attendance at the next Sirspheres treatment to monitor and correct any deviation from good health physics and assure proper regulatory protocol.

D. Lessons learned

The following are the results learned by each principle from their respective experiences of the event, NRC inspection, and intense analysis.

1) The radiation oncologist/authorized user: "the dose leaving the nuclear medicine department must be between (-5% and +15%), so estimations at administration are not required; precise accuracy of the administered dose is not as achievable as other radioactive material therapies; a better system of drawing up small doses is needed; I have learned that a residual portion of the dose is remaining in the tubing when the full amount of the dose in the V-vial is not used; we will not start any procedure if the dose in the V-vial is greater than the maximum dose I feel the patient can clinically tolerate."
2) The manager of the nuclear medicine department: "dose must be drawn to within (-5%-+15%); a time out should occur so the dose range can be communicated to the technologist before the dose drawing preparation occurs; small dose volumes are very difficult to draw up; smaller dose therapies (< 1 cc) will be postponed until Sirtex can provide adequate syringes or a different diluent."
3) The interventionalist: "I will serve as a checkpoint, and not connect the V-vial, containing the Sirspheres, to the patient unless the dose in the vial is within the acceptable range. I am certain that with the planned improvements in the process, we will not have this problem in the future."
4) Authorized Medical Physicist: "1) Always make sure that the dose in the V-vial is within the acceptable limit, and never try a less accurate method. 2) For future treatments, using new techniques, always use methods that have better dosimetry precision, and make sure the

patient dose is within the acceptable limit of the prescribed dose, and also make sure the procedures are safe to the patients and staff."

E. Dates for compliance

The patient's follow-up treatment with Sirspheres has been put on hold until Sirspheres can improve the delivery of low dose quantities. Following our intensive analysis on 8-17-05, all parties knew what the corrective actions were and the importance of their role. We believe we are now in full understanding and therefore compliant with all of the applicable (10 CFR 35.1000, 10 CFR 35, and 10 CFR 20) NRC regulations as they pertain to this issue.

In conclusion, we feel that since the nature of this medical event was an under dosage, the causes of which included deficiencies in the available products that were not within our control, and resulted in no untoward medical or clinical sequeala to the patient, that the consideration of escalated enforcement on this issue should be dismissed as unnecessary. We offer an excellent radiation safety program acknowledged in previous NRC inspections. Furthermore, the "lessons learned" from this cutting-edge technology procedure as described in section D above, substantiates the validity of our request that escalated enforcement consideration be dismissed. Escalated enforcement action would be unnecessarily punitive, and unfairly cause erroneous public perception and misinformation about the quality of the treatments at our hospital. The parties involved collectively and individually have the professional integrity and desire to improve their skills through this experience, and that this experience without an escalated enforcement action has provided the necessary enlightenment about the unfolding clinical and radiation safety issues in this dynamic treatment procedure.

Sincerely,

Elaine C. Thompson

Elaine C. Thompson, Ph.D.
Executive Vice President,
Chief Operating Officer