

RI - DNMS Licensee Event Report Disposition

Licensee: Lancaster Gen Hospital
 Event Description: Medical Event
 License No: 37 11866-04 Docket No: 03035003 MLER-RI: 2005-053
 Event Date: 8-18-05 Report Date: 8-18-05 HQ Ops Event #: 41928

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input checked="" type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input type="checkbox"/>	Other _____		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	<u>Gabriel/Henderson 8-26-05</u>
<input checked="" type="checkbox"/>	Special Inspection	Inspector/Date	
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log	<input type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To: _____		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input type="checkbox"/>	Levels of RAM Involved <i>N/A</i>	<input type="checkbox"/>	Calculations Adequate <i>N/A</i>
<input checked="" type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	Unique Circumstances or Safeguards Concerns
<input type="checkbox"/>	If any of the above are involved:	<input type="checkbox"/>	Considered Need for AIT
<input type="checkbox"/>	Considered Need for IIT		
	Decision/Made By/Date: _____		

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

<input checked="" type="checkbox"/>	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
<input type="checkbox"/>	Medical Consultant Used-Name of Consultant/Date of Report: _____
<input type="checkbox"/>	Medical Consultant Determined Event Directly Contributed to Fatality
<input type="checkbox"/>	Device Failure with Possible Adverse Generic Implications
<input type="checkbox"/>	HQ or Contractor Support Required to Evaluate Consequences

Licensee submitted Part 21 report. After NRCSS determined this to be unnecessary, licensee retracted it.

See comment at right →

6. SPECIAL INSTRUCTIONS OR COMMENTS

Public SISP Review Inspector Signature: Gabriel Date: 9-9-05
 Non-Public Branch Chief Initials: [Signature] Date: 9/9/05



Lancaster General Hospital

RECEIVED
PERSON 1

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my

August 29, 2005

U.S. Nuclear Regulatory Commission, Region I
U.S. Nuclear Materials Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: License #37-11866-04; **Report of a Medical Event**

To Whom It May Concern:

This letter is submitted as a report of a medical event per the requirements of 10CFR35.3045(d). This incident was phoned in to the U.S. NRC Operations Center on Thursday, August 18, 2005 at 14:08 EDT (Event #41928).

As a means of adhering to 10CFR35.3045(d)(1), the following is in the order of information requested by this aforementioned rule:

- i) **Licensee's name**
Lancaster General Hospital
- ii) **Name of the prescribing physician**
Kenneth Berkenstock, M.D.
- iii) **Brief description of the event**
This incident, which occurred on August 18, 2005, involved the Elekta Gamma Knife unit. The patient had been set up for treatment of a glioblastoma in the normal fashion. The prescribed treatment was to consist of 5 targets, or "shots", of the lesion. The first two shots were completed successfully and without incident. After the third shot was set up, and the treatment initiated at the control, the console indicated an error involving the incomplete opening of the unit's shielded "jaws". This incomplete opening prevented the unit from allowing the patient couch to travel to a treatment position. After this initial "failure", the authorized medical physicist entered the treatment room and examined the patient couch area for sources of obstruction. Noting none, he returned to the console area.

Upon returning to the console, the authorized medical physicist re-initiated the sequence, but again the unit's sensors detected an incomplete opening of the jaws and treatment was prevented.

Kathleen L. Harrison, Vice President - Operations

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iii) Upon this second failure to treat, more members of the Gamma Knife team entered the room. It was then observed by the medical physicist that a **Brief description of the event (continued)**

metal clip that holds a microphone near the patient's head was missing. The physicist speculated that perhaps the clip had been knocked off of its position and had fallen into the treatment area during one of the previous couch movements, and had jammed into the jaw mechanism or shielding. This most likely was preventing proper operation of the shielding jaws.

The Gamma Knife team, at this point, decided to remove the patient from the treatment couch, and did so, relocating her to the waiting area. The authorized user and medical physicist returned to the console and initiated a mock treatment, after first focusing and magnifying the video camera onto the area of the shielding jaws. During this mock treatment, the jaws seemingly opened properly, but again the safety system detected incomplete movement of the jaws and terminated the "treatment". This time, however, as the jaws began to return to the "closed" position, both the physicist and the authorized user noted a small object fall through the back of the shielding area. This further supported their belief that the microphone clip had indeed been separated from its position and had fallen into the shielding area, and was causing this problem.

The authorized medical physicist contacted Elekta, who services the Gamma Knife, and an appointment for service was made for as soon as possible. The current patient, and those scheduled for treatments later that day, were excused and re-scheduled.

Later that day, an Elekta service representative arrived, was able to reproduce the error, and proceeded to correct the problem. As speculated, the service person extracted a small metal clip from the shielding mechanism. This freed up the jaw movement. Two successful tests of this provided adequate assurance that the problem was solved. Prior to correcting this problem, the service representative had contacted a colleague at Elekta to discuss the situation. He later stated to the medical physicist that he had learned from this colleague that this problem had occurred at other sites in the past.

Since the patient had received only about 9 Gy of a prescribed 12 Gy at the time that this interruption of treatment occurred, it was concluded that this constituted a 25% underdose of the target, and thus met the definition of a "medical event".

iv) **Why the event occurred**

A metal clip fell into the shielding of the jaw mechanism and prevented the unit from functioning properly.

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- v) **The effect, if any, on the individual(s) who received the administration**
The patient received an interruption of her treatment, and therefore an underdose of the prescribed treatment on the day of the event. The remainder of the treatment dose was made up in a subsequent visit by the patient. An authorized user familiar with the patient's condition and this situation stated that this treatment interruption would have no deleterious effect on the projected outcome of her treatment.
- vi) **What actions, if any, have been taken or are planned to prevent recurrence**
A service representative from Elekta repaired the unit on 8/18 by removing the metal clip from the unit's shielding device. The unit was then tested for proper operation. The configuration of the microphone has now been changed so that there is no metal clip involved. The microphone is now attached to the couch assembly using a Velcro strip that is attached to the microphone by an adhesive backing. If it is now bumped by a patient, the microphone may still detach, but there is no part of the microphone assembly that can fall into the treatment area of the unit to cause further functional problems.
- vii) **Certification that the licensee notified the individual**
The patient was informed of this incident immediately by the treatment staff. The referring physician, who is also the neurosurgeon and was in attendance at the time of treatment, was also notified immediately. In a subsequent phone call, the patient was also informed that she may have a copy of this report.

If you have need of any further information, please direct them to our Radiation Safety Officer, Mr. Anthony Montagnese, at 717-544-4384.

Sincerely,



Kathleen Harrison
Vice President, Operations

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