UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

August 23, 2005

Docket No. 03035003 License No. 37-11866-04
EA No. 05-124
NMED No. 050194

Kathleen Harrison
Vice President for Operations
Lancaster General Hospital
555 North Duke Street
P.O. Box 3555
Lancaster, PA 17604-3555

SUBJECT: INSPECTION 03035003/2004001, LANCASTER GENERAL HOSPITAL, LANCASTER, PENNSYLVANIA SITE

Dear Ms. Harrison:

On October 21, 2004, Héctor Bermúdez and Penny Lanzisera of this office conducted a safety inspection at the Lancaster General Hospital's Cancer Center of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selected examination of representative records. During the inspection, the inspectors also reviewed the circumstances associated with a medical event which occurred at the facility in September 2003, and which was not reported to the NRC as required. The medical event involved the administration of a gamma stereotactic radiosurgery (GSR) treatment to a patient at a location other than the intended treatment site for a portion of the treatment.

The inspection was continued in the Region I office until August 2, 2005, in part to review: (1) additional information provided by your staff regarding the medical event; and (2) a report by a medical consultant retained by the NRC to review this medical event. The findings of the inspection were discussed with you, your Radiation Safety Officer, Mr. Montagnese, and other members of your organization on October 21, 2004, April 4 and 5, 2005, and July 13, 2005. The enclosed report presents the results of this inspection and also provides a synopsis of the medical consultant's report received by the NRC on July 8 and August 2, 2005.

The inspection revealed that on September 30, 2003, during the aforementioned GSR treatment, the placement of the stereotactic frame changed. Specifically, at the conclusion of the treatment, the z-bar coordinate of the GSR's frame was 7 centimeters different from that initially set. This resulted in an estimated dose of 35-40 Gray to the wrong treatment site. As discussed in the enclosed inspection report, you concluded that the event was caused by patient intervention when the patient moved vigorously during the treatment. However, the treatment was not suspended to verify the setting coordinates after viewing this vigorous movement. Additionally, your staff demonstrated to your Radiation Safety Officer, after the medical event, that the z-bar coordinate could be shifted by placing pressure on the frame,

implying failure of the z-bars or z-bar screws used to set the z coordinate for GSR treatments. You immediately replaced the z-bars, but to date have not returned the replaced z-bars or screws to the manufacturer for further analysis of equipment failure.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action. The apparent violations involved: (1) failure to implement adequate procedures to verify that the administration of the gamma stereotactic dose was in accordance with the treatment plan and written directive, as required by 10 CFR 35.41; (2) failure to report the medical event involving a dose administered to the wrong treatment site in accordance with 10 CFR 35.3045; and (3) failure to report an equipment malfunction of the gamma stereotactic radiosurgery device's z-bars in accordance with 10 CFR 21.21. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. Accordingly, no Notice of Violation is presently being issued for these inspection findings.

A predecisional enforcement conference, open to the public, to discuss these apparent violations has been scheduled for September 16, 2005, at 10:00 a.m. The NRC announces enforcement conferences to the public by issuing a press release. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the apparent violations sooner, corrective actions, significance of the issues, and the need for lasting and effective corrective action. In particular, you should be prepared to discuss: (1) additional information regarding your procedures to ensure that administrations are conducted in accordance with the written directive; (2) quantitative data to support your conclusion that equipment failure may have contributed to the medical event (e.g., experimental data collected by the physicist); and (3) the rationale for not returning the malfunctioning z-bars and screws back to the manufacturer for analysis. In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on 1) the severity of the apparent violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding the apparent violations is required at this time.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then licensee **toolkits.** The Current General Policy and Procedure for NRC Enforcement Actions are included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then

Enforcement Policy. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Original signed by Francis Costello

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosure:
1. Inspection Report No. 03035003/2004001
2. NUREG 1600 (Enforcement Policy)
3. NRC Information Notice 96-28

cc:
Anthony Montagnese, Radiation Safety Officer
Commonwealth of Pennsylvania

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03035003/2004001
Docket No.	03035003
License No.	37-11866-04
Licensee:	Lancaster General Hospital
Address:	555 N. Duke Street Lancaster, Pennsylvania
Locations Inspected:	Lancaster Health Campus 2100 Harrisburg Pike
Inspection Dates:	October 21, 2004, April 4 and 5 and July 13, 2005
Date Followup Information Received:	October 29 and December 15, 2004, January 19, July 8 and August 2, 2005

Inspectors:

/RA by Pamela Henderson Acting For/ **8/5/05**

_____ _____
Hector Bermudez date
Senior Health Physicist

/RA/ **8/5/05**

_____ _____
Penny Lanzisera date
Senior Health Physicist

/RA/ **8/5/05**

Approved By:

_____ _____
Pamela J. Henderson, Chief date
Medical Branch
Division of Nuclear Materials Safety

Document Name: E:\Filenet\ML052360015.wpd

EXECUTIVE SUMMARY

Lancaster General Hospital
NRC Inspection Report No. 03035003/2004001

A routine unannounced onsite inspection was performed on October 21, 2004, to review the licensee's gamma stereotactic radiosurgery (GSR) program. The inspection revealed that on September 30, 2003, during a GSR treatment, the placement of the stereotactic frame changed. Specifically, at the conclusion of the treatment the z-bar coordinate of the frame was 7 centimeters different from that initially set. Upon review, the licensee concluded that the patient moved vigorously during the treatment, resulting in misalignment of the frame and delivery of approximately of 35-40 Gray to the wrong treatment site. The licensee also concluded that the event was caused by patient intervention, did not result in permanent functional damage to an organ or physiological system, and therefore, was not reportable to the NRC.

Within the scope of this inspection, three apparent violations of NRC regulations were identified:

- failure to verify that the administration is in accordance with the treatment plan and written directive, as required by 10 CFR 35.41(b)(2).

- failure to report a medical event, as required by 10 CFR 35.3045.

- failure to report an equipment failure, as required by 10 CFR 21.21(d).

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspectors toured the licensee's GSR facility, interviewed several clinical and administrative personnel, and reviewed applicable records to establish the current scope of the licensee's program.

b. Observations and Findings

The licensee operates a community hospital and, at a separate location, a health center that conducts specialized activities, such as cancer treatment. The inspection under this license was limited to the review of the GSR activities. The GSR device is located at the health center and was found attended during the inspection. The licensee treats approximately 4-5 patients per week with the device. Two authorized medical physicists (AMP) and two authorized users (AU) are involved with the program. The Radiation Safety Officer (RSO) is on site at either the hospital or the health center daily.

c. Conclusions

No safety concerns were identified.

II. Management Oversight of the Program

a. Inspection Scope

The inspectors reviewed minutes of the Radiation Safety Committee (RSC) meetings, reviewed audits conducted of the radiation safety program, and interviewed licensee personnel.

b. Observations and Findings

The inspectors noted that the licensee had an active RSC that was overseeing the implementation of the program as evidenced by the discussions held during the meetings and the results of personnel interviews. Audits of the program were being conducted and the results reviewed during RSC meetings. Additionally, the RSC reviewed the GSR treatment that was conducted on September 30, 2003 and referred the case to an internal review group, who performed a thorough investigation. The licensee concluded that a medical event occurred due to patient intervention and thus was not reportable to the NRC.

c. Conclusions

No safety concerns were identified.

III. Facilities and Equipment

a. Inspection Scope

The inspectors toured the licensee's facilities and evaluated the adequacy of the facilities and equipment to assure that radioactive material could be used safely and that radiation exposures to workers and members of the public could be maintained ALARA.

b. Observations and Findings

The facilities and equipment, including emergency response equipment, were as described in the license and adequate to ensure safety. Posting and labeling were also found to be adequate.

c. Conclusions

No safety concerns were identified.

IV. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspectors observed the conduct of periodic checks performed on the therapy device. The inspectors also interviewed clinical personnel, made independent radiation surveys of areas of use, and reviewed a sampling of representative records to evaluate the adequacy of the licensee's program for device calibration, spot-checks, and sources exchange.

b. Observations and Findings

An AMP conducts all full calibrations and spot checks of the GSR device. Per discussions with the AMP conducting these activities and a review of representative records the inspectors confirmed that these were being performed in accordance with the licensee's procedures and the regulatory requirements.

The sources had been recently replaced. Required surveys and device calibrations were conducted and documented.

c. Conclusions

No safety concerns were identified.

V. Medical Administration on September 30, 2003

a. Inspection Scope

The inspectors reviewed records and interviewed licensee staff concerning a GSR treatment on September 30, 2003, where the frame shifted during the treatment.

b. Observations and Findings

Description of the Event

Approximately 30 minutes into a 51 minute GSR treatment to deliver 85 Gray - 100 percent isodose - to the prescribed treatment site the patient became uncomfortable and asked if he could move to be more comfortable. The AMP instructed the patient that he could move his legs "a little bit, but not too vigorously." The licensee reported that "the movement that the patient made, which was contrary to the physicist's instructions, could easily be viewed as being vigorous." At the completion of the procedure, the licensee noted that the z-bars used to set the z coordinate had changed position by approximately 7 centimeters. The x and y coordinates remained unchanged. The licensee's AMP stated that the z-bars were tightened at the beginning of the treatment and the location of the z-bars at the start of the treatment was set by the AMP and verified by the physician as correct. The licensee concluded that the z-bar slippage occurred when the patient moved and was caused by patient intervention.

The licensee's authorized user and neurosurgeon concluded on September 30, 2003, and the licensee reiterated in letters dated October 29 and December 15, 2004, that:

- the patient received "some dose some place around the ventricle (in a safe place);"
- the area of concern for inadvertent exposure (the brain stem) was spared significant dose;
- the patient moved "vigorously," contrary to initial instructions provided by the physician, and the patient's movement caused the event. In addition, the patient's large stature contributed to the amount of force applied to the z-bars upon patient movement;
- the event did not result in harm to the patient, in that, the patient has had no recurrence of pain and the treatment to the unintended area did not appear to impair or harm the patient;
- the patient received approximately 35-40 Gray to the skin and tissue of an unintended site.

10 CFR 35.41(b)(2) requires, in part, that procedures for administrations requiring a written directive include verifying that the administration is in accordance with the written directive. The inspectors concluded that the licensee's procedures to ensure compliance with 10 CFR 35.41(b)(2) were inadequate in that they did not provide for the immediate re-checking of treatment parameters after vigorous patient movement during treatment. This was identified as an apparent violation of 10 CFR 35.41(b)(2).

Notification of the Event

10 CFR 35.3045(a)(3) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the administration of radiation from byproduct material results in a dose to tissue other than the treatment site that exceeds by 50 rems to the tissue and 50 per cent or more of the dose expected from the administration defined in the written directive. 10 CFR 35.3045(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after the discovery of the medical event.

The licensee notified the patient on September 30, 2003, that perhaps not enough dose have been given to the treatment area and scheduled a repeat MRI scan to assess the treatment. The licensee stated that "the conclusion of 'no harm' was subsequently supported by a follow-up MRI of this patient's head, which showed 'no abnormal enhancement' as might be expected from a radiation-induced lesion and by the resolution of the patient's treatment diagnosis, trigeminal neuralgia."

In reviewing 10 CFR 35.3045(a)(3) and 35.2, the licensee determined that the event constituted a "medical event", however, the regulations also indicate that "a report of an event is not necessary if it is the result of a patient intervention, unless the event results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician (see Section 35.3045(b)." The licensee stated in their October 29, 2004, report that "based upon all the information available, the patient's treating physicians believed that the patient would not have any permanent functional damage to an organ or physiological system. Therefore, the licensee concluded, based on their investigation, that a report pursuant to 10 CFR 35.3045 was not required. This conclusion was discussed with the inspectors on October 21, 2004, and restated in the licensee's letters dated October 29 and December 15, 2004.

The licensee stated in their letter dated December 15, 2004, that the patient's movement could "easily be viewed as being vigorous." However, the licensee did not suspend the treatment to verify the setting coordinates after viewing this "vigorous" movement. In addition, the licensee did not provide sufficient evidence to exclude equipment setup as the cause of the change to the z-axis coordinates rather than patient movement. As a result, the NRC concluded that the event was reportable under 10 CFR 35.3045. The licensee's failure to report a medical event that occurred on September 30, 2003, was identified as an apparent violation of 10 CFR 35.3045. On April 4, 2005, the licensee was informed of the NRC's determination that the event was reportable in accordance with 10 CFR 35.3045. On April 5, 2005, the licensee made the required verbal NRC notification and on April 11, 2005, the licensee made the required written NRC notification. In addition, the licensee informed the patient and the referring physician as required in 10 CFR 35.3045.

Historical evidence from the manufacturer of the GSR device has shown that z-bar movement has only been observed when the screws are not properly tightened or when there was a lubricant on the z-bar. The AMP asserts that the screws were properly tightened for this treatment and performed a demonstration for the RSO of z-bar movement with properly tightened screws. The licensee described this experiment in their letter dated December 15, 2004, however, quantitative data from this demonstration indicating that the z-bar could be moved 7 centimeters was not provided. Further, the licensee did not return

the z-bars to the manufacturer for detailed inspection and testing to determine whether the event was in fact caused by an equipment failure.

10 CFR 21.21(d)(1) requires, in part, that the licensee notify the Commission when it obtains information reasonably indicating a failure to comply affecting a basic component supplied for an activity that is subject to the licensing requirements under 10 CFR Part 30. 10 CFR 21.21(d)(3) requires, in part, that initial notification be made by facsimile or telephone within two days following receipt of the information, and in writing within 30 days of receipt of the information providing the information specified in 10 CFR 21.21(d)(4). Licensee representatives indicated that their procedures to ensure compliance with 10 CFR 21.21 provided for vendor notification but did not provide for NRC notification of an equipment failure to comply as required. The licensee's failure to report an equipment failure was identified as an apparent violation of 10 CFR 21.21. On April 5, 2005, the licensee was informed of the NRC's determination that the equipment failure was reportable in accordance with 10 CFR 21.21(d). On April 6, 2005, the licensee made the required notification to the NRC' Operations Center and on April 22, 2005, the licensee provided the written report with the information required by 10 CFR 21.21(d)(3).

Licensee's Corrective and Preventive Actions

The licensee implemented the following corrective actions:

- inspection of z-bars, which indicated no observable damage;
- immediate replacement of z-bars;
- plan to upgrade to a Model C GSR device with an Automatic Positioning System (APS). This system does not require z-bars when used in the APS mode;
- implemented a Policy for Stopping Gamma Knife Treatment that includes additional checks of patients treated for greater than 30 minutes and provides for stopping treatments for patient re-positioning with rechecking of coordinate settings;
- AMP conducted an experiment of tightening the new z-bars and exerting extreme manual pressure on the z-bars. The AMP demonstrated that while mild pressure could not move the z-bars, extreme pressure could.

c. Conclusions

The licensee's procedures to ensure that each administration is in accordance with the written directives, in accordance with 10 CFR 35.41(b)(2), were inadequate in that they did not provide for the re-checking of treatment coordinates immediately after vigorous patient movement.

The NRC reviewed the licensee's rationale for concluding that the medical event was not reportable, and was a result of patient intervention, and concluded that the event required reporting under 10 CFR 35.3045(a)(3). In addition, the NRC concluded that the equipment failure was also reportable under 10 CFR 21.21.

The NRC concluded that the manufacturer, Elekta Instruments, Inc. should be notified of the frame slippage for an evaluation of potential generic issues. In addition, the NRC will share the information concerning the medical event with the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH).

Three apparent violations of NRC requirements were identified.

VI. Medical Consultant's Report

The NRC contracted a medical consultant to review the incident, its effect on the patient, and licensee's corrective actions taken to prevent recurrence of similar incidents. The medical consultant's report was received on July 8, 2005. The consultant concluded that the dose delivered to the wrong treatment site is of no physiologic consequence and that, to rule out any clinically meaningful late brain injury, an MRI of the brain at this time would be appropriate. The consultant further stated that specialized medical follow-up would not be warranted, if the MRI were negative with respect to late radiation injury and the patient remained free of signs and symptoms during routine follow-up.

On August 2, 2005, after reviewing a follow-up MRI of the patient's brain that was done on January 4, 2005, the consultant stated that he did not think that additional follow-up was required with respect to the event, unless the patient develops new neurologic signs or symptoms referable to the left brain.

VII. Exit Meeting

An exit meeting was conducted on October 21, 2004, to discuss the preliminary findings with the licensee's staff identified at the end of this report. On April 4, 2005, the inspectors informed the licensee that the medical administration on September 30, 2003, was a reportable medical event. On April 5, 2005, the inspectors informed the licensee that the equipment failure to comply as intended was also reportable per 10 CFR 21.21. On July 13, 2005, the inspector informed the licensee of the results of the medical consultant report and that further NRC review identified an apparent violation of 10 CFR 35.41(b)(2).

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*+#Anthony Montagnese, Radiation Safety Officer
*Charles Fuller, Ph.D., Authorized Medical Physicist
*+Kathleen Harrison, Vice President of Operations
Dr. John Gastaldo, Neurosurgeon
Christine Burfete, Nurse
+Maggie Constello, Legal counsel

*Present at exit conducted on October 21, 2004
+Present at discussion conducted on April 4, 2005
+Present at discussion conducted on April 5, 2005
#Present at discussion conducted on July 13, 2005