



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

September 28, 2005

Docket No. 03035003  
EA No. 05-124  
NMED No. 050194

License No. 37-11866-04

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

SUBJECT: PREDECISIONAL ENFORCEMENT CONFERENCE, LANCASTER GENERAL  
HOSPITAL, REPORT NO. 03035003/2005001

Dear Ms. Harrison:

This letter refers to the Predecisional Enforcement Conference held with you and other members of your staff on September 16, 2005 at the NRC Region I office, King of Prussia, Pennsylvania. This meeting enabled us to gain a better understanding of your position and your completed and planned actions to correct the apparent violations identified at your facility. A report summarizing the meeting is enclosed.

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

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosure(s) will be placed in the Public Document Room.

Your cooperation with us is appreciated.

Sincerely,

***Original signed by Francis Costello***

Francis Costello, Acting Director  
Division of Nuclear Materials Safety

Enclosure:  
NRC Report No. 03035003/2005001

cc:  
Anthony Montagnese, Radiation Safety Officer  
Commonwealth of Pennsylvania

K. Harrison  
Lancaster General Hospital

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		
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DATE	9/22/05		9/28/05				

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U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

ENFORCEMENT CONFERENCE SUMMARY

Report No. 03035003/2005001

Docket No. 03035003

License No. 37-11866-04

Licensee: Lancaster General Hospital

Facility Name: Lancaster Health Campus  
2100 Harrisburg Pike  
Lancaster, Pennsylvania

Conference Date and Time: September 16, 2005, at 10:00 a.m.

Conference Location: NRC Region I, King of Prussia, Pennsylvania

Inspectors:	Original signed by Phenderson	9/22/05
	<hr/> Héctor Bermúdez Senior Health Physicist	<hr/> date
	Original signed by Phenderson	9/22/05
	<hr/> Penny Lanzisera Senior Health Physicist	<hr/> date
Approved By:	Original signed by Phenderson	9/22/05
	<hr/> Pamela J. Henderson, Chief Medical Branch Division of Nuclear Materials Safety	<hr/> date

## **CONFERENCE SUMMARY**

### **NRC Enforcement Conference Report No. 03035003/2005001**

On September 16, 2005, representatives of Lancaster General Hospital met with NRC management in the Region I office located in King of Prussia, Pennsylvania. The meeting, open to the public, was held to discuss the findings described in NRC Inspection Report No. 03035003/2004001, and the apparent violations for failure to verify that a gamma stereotactic radiosurgery treatment was in accordance with the treatment plan and written directive; failure to report a medical event; and failure to report an equipment failure.

Mr. Francis Costello made the opening remarks and briefly described the purpose of the conference. Mr. John Wray described the NRC Enforcement Policy and process. Ms. Pamela Henderson reviewed the apparent violations described in the inspection report.

Ms. Kathleen Harrison stated that the licensee is dedicated to compliance with regulatory requirements and noted that the event was openly discussed with the inspectors during the inspection. She indicated that an internal review process based on root cause analysis was conducted promptly after the event in question, and the review revealed that there were no willful aspects associated with the event and that procedures were revised to prevent recurrence of this type of event. As additional corrective actions she indicated that: (i) the z-bars were promptly replaced; (ii) a policy was instituted that required treatment be stopped if the patient indicated discomfort; (iii) an upgrade of the software has been scheduled that should further prevent recurrence of this type of event; (iv) licensee personnel were trained on the revised policies and event reportability; and (v) the z-bars involved in the event were still in the licensee's possession, but was agreeable to sending them back to the manufacturer for inspection.

Ms. Margaret Costella re-affirmed that the z-bars would be returned to the manufacturer for analysis and any findings would be forwarded to the NRC. Regarding completeness and accuracy of the inspection report content, Ms. Costella responded that the only comment she had on the report was that it should have clearly stated that the licensee informed the inspectors of the event.

Mr. Anthony Montagnese described an experiment that he and the physicist performed involving applying extreme force to the z-bars and noting slippage. He stated that discussions he had with the manufacturer indicated that z-bars could not move, however, he noted that a recent article in the Journal of Neurosurgery discussed z-bar slippage in cases of movement of large patients during treatment. He further stated he was aware of the 10 CFR Part 21 requirement, to report equipment failure, but that he concluded at the time this requirement was not applicable to this event.

Mr. Wray provided closing comments on the enforcement policy and enforcement options available to the staff.

Mr. Costello thanked the licensee representatives for their attendance and adjourned the meeting.

## **LIST OF PERSONS ATTENDING**

### Licensee

Kathleen L. Harrison, Vice President for Operations

Margaret F. Costella, General Counsel

Anthony Montagnese, Radiation Safety Officer

### NRC

Francis Costello, Acting Director, Division of Nuclear Materials Safety

Pamela Henderson, Chief, Medical Branch

John Wray, Enforcement Specialist

Audrey Hayes, Enforcement Specialist

Karl Farrar, Regional Counsel

Héctor Bermúdez, Senior Health Physicist

Penny Lanzisera, Senior Health Physicist

Donna-Beth Howe, Medical Radiation Safety Team, Office of Nuclear Material Safety (NMSS)

Sally Merchant, Senior Enforcement Specialist, Office of Enforcement

Cynthia Flannery, Medical Radiation Safety Team Leader, NMSS

Greg Morell, Regional Coordinator, NMSS

Angela McIntosh, Medical Radiation Safety Team, NMSS