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December 15, 2004

Penny Lanzisera, Health Physicist  
U.S. Nuclear Materials Safety Branch I  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406

RE: License #37-11866-04

03035003

Dear Ms. Lanzisera:

This letter serves to provide more information, per your request of 11/18/04, regarding the Gamma Knife incident of 09/30/03. In addition, we wish to clarify a couple of points that were in error in our letter to you dated 10/29/04.

First, the letter of 10/29/04 was in error in reporting that the event took place on October 29, 2004. The event, in fact, took place on **September 30, 2003**. We regret not catching this error.

Secondly, the letter states that "...the event occurred due to the actions of the patient (i.e., movement, contrary to the instruction of the physician and technicians),...". This is on page 2 of the letter, in the first paragraph. We wish to clarify what we meant to convey in this regard. All Gamma Knife patients are instructed, prior to treatment, that they will be required to hold still during the treatment. With their head secured into a frame, and the frame tightly secured to the helmet during treatment, movement is extremely limited *mechanically*, as well. In this case, the patient was given these routine instructions to remain still during treatment; however, during treatment, he asked to move his legs due to discomfort in his back. He was instructed by the attending physicist, via intercom, that he could move his legs "a little bit, but not too vigorously". The movement that the patient made, which *was* contrary to the physicist's instructions, could easily be viewed as being "vigorous", contrary to instructions.

We have, by this time, provided hundreds of Gamma Knife treatments. This is the only case in which a displacement of the z-bars has occurred. Numerous other patients have made limited movements during treatment, including the movement of legs and arms, in order to improve their comfort level on the couch. According to the Gamma Knife staff, none of these movements could be classified as "vigorous", and none have displaced the position of the z-bars. In the case in question, two unique factors led us to conclude that this patient's actions caused the resulting change in z-bar position: 1) the patient was of a large stature; and 2) he made a "vigorous" movement of his legs and torso.

These two factors - patient mass and force-of-movement - are crucial points in this situation. As a precautionary measure, we replaced the z-bars soon after this incident, even though

Kathleen L. Harrison, Vice President - Operations

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there was no physical sign of defect or damage which could be concluded to have allowed slippage. With these new z-bars, Dr. Charles Fuller, our Gamma Knife physicist, conducted the "experiment" of tightening these new z-bars to the degree recommended by the manufacturer, and then exerting extreme manual pressure on them. He demonstrated to Anthony Montagnese, our Radiation Safety Officer that, even with proper tightening, the z-bars *could* be moved if enough force was applied to them. Without actual measurements of torque, it was easy to conclude that small movements of a patient's arms, legs, or even torso, would not be able to apply enough force to move these z-bars. However, it was equally clear that a significant amount of force, such as applied by a large man with a strong movement, could cause a slippage of these z-bars.

We remain resolute in our conclusion that this event did not warrant notice to your office, per rules 35.3045(a) and (b). This, once again, is based upon our broad investigation into the incident that showed that: 1) the event was caused by patient action alone, and not either through error on our part nor manufacturer's defect; and 2) that the resulting misplaced radiation dose did not cause any "unintended permanent functional damage to an organ or a physiological system" {35.3045 (b)} in the patient. This latter conclusion is documented in a note from our Gamma Knife physicist (see Attachment A), in which both the authorized user and neurosurgeon concluded that the area of concern for inadvertent exposure - the brain stem - was spared significant dose. (IMPORTANT NOTE: This memo, Attachment A, is dated by the physicist's signature as 10/16/03. This is the date on which the memo was typed and signed. The events that are described within the memo took place on the same day as the treatment of this patient - 09/30/03. After reviewing this memo, it occurred to us that this fact might not be inherently clear).

This 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 (see Attachment B) and by the resolution of the patient's treatment diagnosis, trigeminal neuralgia.

I hope that this additional information is useful. We apologize for not having the attached supporting documents (Attachments A & B) available during your inspection visit. We are interested in resolving this issue in as timely a manner as possible. 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

attachments

COPY

ATTACHMENT A

Physics Note

Addendum to note dated 9/30/2003

Patient: [REDACTED]

MedRec: [REDACTED]

112060657

After realizing that the z-bars had slipped to a coordinate of 55 from 124.5mm, I went to the planning computer with Dr. Berkenstock and Dr. Gastaldo and examined the resulting area of the brain that could have been inadvertently irradiated as a result of the z-bars slipping. Because the x and y coordinates had stayed in proper set position, the radiation would have been limited to a line determined by the moving z coordinate. From this information the physicians were able to determine, by examining the images of the patient's brain on the planning system, that the brain stem would have been spared accidental irradiation.

Charles J. Fuhr, Ph.D.

10/16/2003

ATTACHMENT B

COPY



Paul A. Leslie, M. D.  
Medical Director

NAME: [REDACTED]  
DOB: [REDACTED]

DATE OF STUDY: 11/25/2003  
MRN: [REDACTED]

REFERRING PHYSICIAN: JOHN GASTALDO, M.D.

MRI BRAIN WITH GADOLINIUM

LOCATION: MRI GROUP - HEALTH CAMPUS

CLINICAL INFORMATION: Gamma knife therapy for left trigeminal neuralgia. Followup study.

TECHNIQUE: Thin section T1 and T2weighted axial as well as FLAIR axial imaging of the portions of the brain were obtained. The patient was given intravenous gadolinium and thin section T1weighted axial imaging through the posterior fossa was utilized.

FINDINGS: Comparison is made with prior MR of the brain dated 09/30/03. The ventricles are normal in size. The midline structures are not shifted. The sylvian fissures are symmetric. The trigeminal nerves appear fairly symmetric. No abnormal enhancement is seen in the area of the trigeminal nerve following gadolinium administration.

IMPRESSION:

1. Trigeminal nerves appear fairly symmetric and unchanged in appearance in comparison with 09/30/03. No abnormal enhancement within them with gadolinium administration.

ALEX FEINSTEIN, M.D.

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Scheduling: 717-291-1016	or toll free 888.MRI.1377	Fax: 717-291-4683	Web: www.MRIGroup.com
Campus MRI	Lime Street - MRI	Crooked Oak - Open MRI	Kissel Hill - Open MRI
2100 Harrisburg Pike	560 North Lime Street	1671 Crooked Oak Drive	51 Peters Road
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(Interpretation by Lancaster Radiology Associates)