



FAX COVER

TO: Penny Lanzisera, Senior Health Physicist, U.S. NRC Region I

FAX #: 610-337-5269

SUBJECT: Gamma Knife Questions - Response

DATE: January 19, 2005

PAGES, INCLUDING COVER SHEET: 4

COMMENTS:

From the desk of...

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January 19, 2005

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

RE: License #37-11866-04

Dear Ms. Lanzisera:

This letter is sent in response to the additional questions posed to us in your email dated 01/10/05, regarding the Gamma Knife incident of 09/30/03. The responses will be in the order that they were addressed to us in your email, with your questions re-stated in bold.

- 1) **Re-confirm the date of the event as September 30, 2003.**
We confirm that the event occurred on September 30, 2003.

- 2) **Describe the process for verifying correct coordinate settings and why you believe that this patient set-up was correct (e.g., the correct coordinates were determined during the treatment planning and properly transferred to the headframe, etc.).**

The treatment coordinates are determined from the planning system using MRI images, or occasionally, CT images. The neurosurgeon runs the computer while the Radiation Oncologist and Physicist assist. Once the Neurosurgeon produces a plan that is acceptable to the three, the Physicist sits at the computer, reviews the plan and the MRI images with the isodose lines superimposed on them and then prints the plan. The plan includes the treatment coordinates, gamma angle, time and helmet size for each shot. The Physicist, Radiation Oncologist and Neurosurgeon review and sign the treatment plan. When all the treatment planning quality assurance has been performed, the patient is brought in to the treatment room. The patient treatment coordinates are set by one member of the treatment team, i.e. Radiation Oncologist, Neurosurgeon, Physicist or Nurse, using the coordinates from the treatment plan. The coordinates are then read by another member of the treatment team and checked directly against the treatment plan. Once the patient is locked into the helmet trunnions, the x coordinate and gamma angle are given a final check and the treatment team leaves the room. Once outside the treatment room, at the Gamma Knife Console, treatment time is set and reviewed by two team members. The Physicist and Neurosurgeon or Radiation Oncologist review and initial a check list, verifying that the treatment coordinates, gamma angle, time and helmet size are correct for the shot. At this point the "treatment start" button is pushed on the

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console by either the Radiation Oncologist or the Neurosurgeon. And the treatment commences. This process, beginning with the setting of the coordinates, is repeated for each shot. The patient treated on September 30, 2003 had a single shot in his treatment plan.

- 3) **Describe any secondary checks to confirm that all screws are tightened and why you believe that all the screws were tightened correctly for this case.**
There are no established secondary checks to verify that all screws are tightened. For this case, we believe that they were tightened correctly because the team members who performed the tightening stated that they did so.
- 4) **Confirm that there were no observed malfunctions of the headframe as it was attached to the patient and/or the trunnions or to the trunnion/Z-bar connection itself.**
We confirm that there were no observed malfunctions of the headframe as it was attached to the patient and/or the trunnions or to the trunnion/Z-bar connection itself.
- 5) **Confirm that there was no observable reorientation of the patient after the "vigorous" movement.**
As stated by the physicist, we confirm that there was no observable reorientation of the patient after the "vigorous" movement.
- 6) **Indicate whether the coordinates were re-checked directly after the patient moved "vigorously".**
The coordinates were not re-checked directly after the patient moved "vigorously". The coordinates were re-checked directly after completion of the treatment.
- 7) **Confirm that the X and Y coordinates stayed in place during patient movement and only the Z coordinate changed.**
We confirm that the X and Y coordinates stayed in place during patient movement and only the Z coordinate changed.
- 8) **Indicate the physical location of the Z-bars in question (i.e., were they shipped back to the manufacturer for examination or are they still on-site). If still on-site, is there any observable damage (e.g., scrapes) and do you plan to send them to the manufacturer for damage analysis?**
The Z-bars in question are still on-site. As indicated in past correspondence, we noted no observable damage. At this time, we had not planned on sending them to the manufacturer for damage analysis.

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- 9) **Indicate whether the physicist who conducted the demonstration of the Z-bar slippage was able to recreate 7 cm of movement or did the demonstration result in less movement, and if so, how much.**

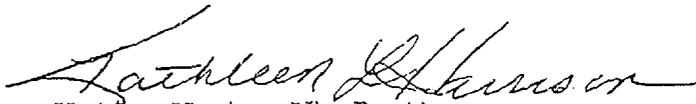
The physicist who conducted the demonstration of the Z-bar slippage did so in an entirely un-scientific way. That is, he conducted an impromptu demonstration to the RSO, who was conducting further investigation into this incident. No actual measurements of pressure, torque, or movement distance were made. However, the degree of slippage demonstrated was sufficient to be visually observed by the RSO.

- 10) **Provide a statement from the physician indicating that the patient did not incur permanent functional damage to other parts of the brain. The physician's statement appears to focus on the trigeminal nerve only and not specifically on the wrong treatment site.**

The following statement is from John A. Gastaldo, MD, attending neurosurgeon for this Gamma Knife case: "As of the last patient visit with the neurosurgeon, on November 30, 2004, the patient has had no adverse consequences as a result of the treatment given on 09/30/03."

I hope that this additional information provides the answers you were seeking. 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