

From: Penny Lanzisera
To: admontag@lancastergeneral.org
Date: Mon, Jan 10, 2005 4:40 PM
Subject: Additional questions on gamma knife treatment
Place: LAT@nrc.gov

Mr. Anthony Montagnese
L.N. 37-11866-04
D.N. 030-35003
Inspection: 2004-001

Please address the following questions with regards to the treatment that occurred on September 30, 2003. Thanks in advance for your cooperation.

- 1) Re-confirm the date of the event as September 30, 2003.
- 2) Describe your 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.).
- 3) Describe any secondary checks to confirm that all screws are tightened and describe why you believe that all the screws were tightened correctly for this case.
- 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.
- 5) 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."
- 7) 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?
- 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.
- 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.

Sincerely, Penny Lanzisera
Senior HP, US NRC
610-337-5169

CC: Hector Bermudez; LAT@nrc.gov; Pamela Henderson

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