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To Duane White <Duane.White@nrc.gov>

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bcc

Subject Additional Information for NMED 080896

On April 7, 2009, you requested additional information on the above NMED event. I can supply additional information from ML090790017 and I made a phone call to the licensee to obtain the serial number of the unit and the curie amount at the time of treatment. Due to potential escalated enforcement action, this report should not be closed. Of note, I am trying to get information as to whether this is being considered an AO and a medical consultant has been hired. A site inspection was performed on December 18, 2009, see above ADAMS document.

(1) What was the cause of the event?

Human error was identified as the cause of the event. A treatment planning sheet was mismarked as to the location of the treatment and review of the document did not identify the error.

(2) What corrective action(s) were taken to prevent a recurrence?

Stricter verification procedures were implemented. The "Physician Order" must accompany the patient during each phase of his/her treatment. The "Order" will be the sole document used for identifying the treatment site and will be referred to at each step of the treatment. Multiple individuals will be called upon to verify that the site referred to in the "Order" matches that with the site being treated. Just prior to the treatment, the clinical team and the patient, or the patient's representative, will confirm the "Order", treatment plan and the site all match.

(3) What are the model number and serial number of the gamma knife?

The model number of the gamma knife is a [REDACTED] and the serial number is 4308.

(4) Who was the manufacturer of the gamma knife?

The manufacturer of the gamma knife was [REDACTED].

(5) What was the activity in the gamma knife?

The Cobalt-60 activity on December 16, 2008, was 3,294 Curies.

(6) Was the patient administered 4,000 rad to the left side of the brain?

Yes, the patient was administered 4,000 rad to the left side of the brain. The error was discovered as the patient was being removed from the room and treatment was thought to have been completed.

Again, pending a decision on enforcement, this item is to be left open.