Georgia Department of Natural Resources
4244 International Parkway, Suite 4, Atlanta, Georgia 30354
Joe D. Tanner, Commissioner
Environmental Protection Division
Harold F. Reheis, Director
(404) 362-2675

January 13, 1995

Mr. Martin Knotts
Project Manager Radiation Systems
Elekta Radiosurgery, Inc.
8 Executive Park West, Suite 809
Atlanta, Georgia 30329

Dear Mr. Knotts:

We have received the DRAFT conclusions and recommendations of the INEL team that investigated the incident with the gamma knife at the University of Southern California (USC). The report concludes that the failure to the couch to retract from the unit was the presence of contaminants in the hydraulic fluid.

The report recommends the following actions:

1. Analysis of the oil and filter in the gamma knife at the USC to determine the composition of the contaminants; the particle size of the contaminants; and the amount of contaminants. The analysis should be performed in accordance with The International Organization of Standardization (ISO) code for the sample and filter oil, the types of contaminants and their approximate shapes (if possible) should be requested from the laboratory.

2. Oil Analysis: Oil samples from at least five other gamma knives installed in the U.S. be analyzed and results be reviewed.

3. Oil Analysis: Oil samples from all new units installed in the U.S. in the future be analyzed after the device testing is completed and before certification.

4. Filter Configuration: Installation of 20μm filters to filter out contaminants in the bed positioning portion of the hydraulic system and in the door closing portion of the hydraulic system with installation of check valves to prevent back flow through the filters.

5. Emergency Tool: A second emergency tool, a long handled pry bar for disengaging the head frame from the trunnion be obtained for all users of the gamma knife.

6. Emergency Procedures: All gamma knife facilities should review their emergency procedures to ensure they cover the following points in the event a bed fails to retract: if the power is on, the hydraulic pressure is within range, but the treatment bed fails to retract after the timer reaches 0.00, .move on to the emergency procedures for releasing the patient from fixation in the helmet.

7. Training: All gamma knife facilities should hold a staff review and walk through of their emergency procedures. Operating staff should dismount the head cage from the trunnions using the long handled wrench and lever provided for emergencies.

8. Video Tape: A VCR or similar recorder be connected to the CCTV and the treatments be recorded. Once a treatment is completed without incident the tape may be reused for the next treatment.

Additionally, we recommend that all gamma knife facilities be sent an update of LGU MEMO #003. The update should clearly indicates that the valve failure at USC was the result of contaminants in the hydraulic fluid.

Please provide us with your response to the recommendations within 15 days, including your schedule for implementing the recommendations. A copy of the draft conclusions and recommendations are enclosed for your information.

Sincerely,

Thomas E. Hill

Thomas E. Hill, Manager
Radioactive Materials Program

TEH:klc
enclosure