Georgia Department of Natural Resources
205 Butler Street, S.E., East Floyd Tower, Atlanta, Georgia 30334
Joe D. Tanner, Commissioner
Harold F. Reheis, Director
Environmental Protection Division

March 11, 1994

Martin Knotts
Elekta Instruments, Inc.
8 Executive Park West
Atlanta, Georgia 30329

This letter is in reference to the application for the device evaluation of the medical teletherapy unit Model 23004-B. The information requested below is necessary in order to further our evaluation.

1. In reference to your response to question number three of our letter dated January 14, 1993, confirm that the label will indicate that the Model 23004 is a Type-B.

2. In reference to your response to question number five of our letter dated January 14, 1993, provide diagrams which depict a Cobalt-60 source, and bushing configuration prior to, and after being loading into the Model 23004-B.

3. In reference to your response to question number seven of our letter dated January 14, 1993, it is stated that Elekta will set the timed relay to automatically initiate the treatment stop sequence at 80 seconds instead of 90 seconds.

   In NCRP Report Number 33 under topic Design Requirements 4.2.2(d)8., it is stated that when the door to the treatment room is opened, the beam control mechanism shall automatically and **rapidly** return to the "OFF' position.

   Does it take the unit 80 seconds to return to the "OFF" position? If so, it does not appear that the unit meets the above criteria of returning **rapidly** to the "OFF" position.

4. In reference to your response to question number eleven of our letter dated January 14, 1993, you state one option is for the facility's standard operating procedure to require an operator to immediately initiate the treatment stop cycle.

   This option will not satisfy the requirement of continuous viewing of the patient.

5. In reference to your response to question number twelve of our letter dated January 14, 1993, you state that an occasional broken microswitch has required replacement.

   Were these microswitches considered components of the safety system? Also, is this possibly a generic problem that may require a different type of microswitch to be used on this system?

6. In reference to your response to question number fifteen of our letter dated January 14, 1993, you submitted new leakage radiation measurements which were performed on the Leksell Gamma Knife, Model B, No.30 located at the University Clinic, Graz, Austria.

   Is the Leksell Gamma Knife, Model B. the same as the Leskell Gamma Unit Model 23004-B?

   What are the specifications on the Scitomat .6134A. survey meter?

   In Exhibit 6, it is stated at a 5cm distance from the door surface a maximum of approximately 400 uSv/h can be expected at the lower part of the lower shielding door, and at 60cm from the same surface the maximum reading will be approximately 40 uSv/hr. Does this 60 cm distance correspond to a distance of one meter from the closest source?

7. In your initial submittal, you indicated on the drawings that the scatter and leakage radiation exposure rates were to be considered confidential information. This information does not meet the criteria of confidential or proprietary information; therefore, will not be withheld from public review upon request.

8. In reference to your response to question number nineteen of our letter dated January 14, 1993, in Exhibit 7 reference is made to using a shipping cask with the name "Croft".

   Submit a current copy of the Certificate of Compliance for this cask.

9. In reference to your response to question number nineteen of our letter dated January 14, 1993, in Exhibit 7 reference is made in Section C.2., Operating Inside the Loading Cell, that sampling can also be performed with the aid of the sampling rod. Also, under the topic, Dosimetry During Loading, it is stated an instrument for measuring wipe tests is used before and during loading.

   Confirm that these procedures shall assure that all sources are leak (wipe) tested when the sources are loaded or unloaded from unit.

10. In reference to your response to question number nineteen of our letter dated January 14, 1993, in Exhibit 7 under the topic, Dosimetry During Loading, reference is made to checklist 28 R00KI that contains a number of radiation checks during the loading procedure.

    Submit a copy of the above referenced checklist.

11. In reference to your response to question number nineteen of our letter dated January 14, 1993, in Exhibit 8, Alpha Omega Services, Inc.'s Radioactive Materials License No. 2641-70 the authorization of use statement 9.H. reads as follows: the cobalt 60 sealed source, General Electric Model #43047, is to be used for installation, maintenance, and loading (source capsules) of Elekta instruments **Leskell Gamma System Model 23016 at existing irradiation equipment installations.** The licensee shall abide by all requirements of the customer's license and applicable requirements of the USNRC or Agreement state within which the authorized work is performed.

    Has Alpha Omega Services amended this license to include the **initial installation** of these sources in Elekta's irradiation equipment? Also, will this license be amended to include the Model 23004-B Unit?

12. In reference to your response to question number twenty-three of our letter dated January 14, 1993, it is stated that the DC motor, and battery system are checked during the **semi-annual** Preventative Maintenance checks; however, in the last paragraph on this page, it is stated the battery systems are checked **annually** during the Preventative Maintenance Checks.

    Which of these frequencies of battery system checks are correct?

13. In reference to your response to question number twenty-five of our letter dated January 14, 1993, it is stated that the Emergency Interrupt Push Button on the side of table has the same function as the Emergency Interrupt button on the console, and is wired in parallel. Also, in your initial submittal in the Description on page 4 under the subtopic, Control Panel, it is stated that pushing the Emergency Interrupt Button halts the movement of the shield doors or the sliding cradle; and releasing the button allows movement to continue.

    In NCRP Report Number 33 under topic Design Requirements 4.2.2(d)7., it is stated that the beam-control mechanism shall be so designed as to return automatically to the "OFF" position in the event of any breakdown or interruption of the activating force and shall stay in the "OFF" position until reactivated from the control panel.

    Due to the ability to interrupt the movement of the shield doors or the sliding cradle without the unit returning automatically to the "OFF" position, it appears that the unit does not meet the Design Requirement of 4.2.2(d)7. Describe what modifications will be made to satisfy this design requirement.

14. In reference to your response to question number twenty-nine of our letter dated January 14, 1993, it is stated that Elekta can not say that various inspections and adjustments to Leskell Gamma Unit will only be performed by Elekta personnel.

    Since the inspection, and maintenance items listed below are considered components of the safety system of the unit, any maintenance to these components **shall** be performed only by personnel that have been trained, and specifically licensed by the NRC or an Agreement States' Program to perform these type of activities.

    G.3-Smooth Grinding the collimator holes or collimator
    G.3.3-The adjustment of Microswitches in Helmets a) thru g) on page G.4
    G.4-Removal of the plastic hood using the special vacuum tools (4 pcs.)
    G.6-Frame of operating table pages G.5 and G.6
    G.6.1-Cable Drag Chain page G.6
    G.6.2-Microswitch Adjustment pages G.6 and G.7
    G.6.3-Cover Belt page G.8

    Confirm that the information listed above will be removed from the Leskell Gamma Unit Manual.

15. In reference to your response to question number thirty of our letter dated January 14, 1993, it is stated that the warning light, A3, is physically located on the outside of the treatment room in the vicinity of the treatment room door.

    In NCRP Report Number 33 under topic Design Requirements 4.2.2(d)5., it is stated that there shall be on the housing and on the control panel a warning device that plainly indicates whether the beam is "ON" or "OFF".

    Confirm that a warning device will be installed on the housing of the radiation unit that plainly indicates whether the beam is "ON" or "OFF".

16. In your initial submittal on page 8 under the topic, Operational Features, it is stated that a stop treatment cycle is not initiated should a power failure occur during a treatment, since the batteries will power the system and continue the treatment until the timer automatically begins the stop treatment cycle. Also, under the subtopic, Control System, Item 17. on page 6, it is stated that the independently programmed timers have battery power backup in the event of power failure and will continue to display times for at least five (5) minutes.
**NOTE: It is our understanding that it is not uncommon for patient treatment times to last much longer than five (5) minutes with the Gamma Knife.**

In NCRP Report Number 33 under topic Design Requirements 4.2.2(d)7., it is stated the beam-control mechanism shall be so designed as to return automatically to the "OFF" position in the event of any breakdown or interruption of the activating force and shall stay in the "OFF" position until reactivated from the control panel.

Since the unit continues to remain in the "ON" position during a power failure, it does not appear to meet the design requirement of automatically returning to the "OFF" position in the event of any interruption of the activating force for the system including the timing device.

* Confirm that modifications will be made to the unit to assure that the stop treatment cycle is initiated in the event of a power failure.

* Does a stop treatment cycle automatically occur when power is lost and a patient's remaining treatment time exceeds the five minute battery backup power limit, if not explain.

17. In reference to your initial submittal, provide a revised version of Section 1 of the Application for the Model 23004 which incorporates any changes that have occurred since the submission of the application(i.e. Time required to reach patient-in position; radiation levels; etc.).

18. Does the unit have an interlock system to assure that the operator has selected the appropriate helmet (collimator size) for a patient's treatment? If not, what prevents an operator from selecting the inappropriate helmet (collimator size) for a particular treatment?

Should you have any questions, please call me at 404-362-2675.

Sincerely,

William L. Slocumb
Radiation Specialist