

# Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354

Lonice C. Barrett, Commissioner  
Harold F. Reheis, Director  
Environmental Protection Division  
(404) 362-2675

November 27, 1995

Richard S. Grome  
Attorney-In-Fact  
ELEKTA RADIOSURGERY, INC.  
8 Executive Park West, Suite 809  
Atlanta, Georgia 30329

Dear Mr. Grome:

As per our discussion this morning, I need ELEKTA RADIOSURGERY, INC. to review the attached draft of the device registry document for the Leskell Gamma System Model 23004, Type-B. If you do not have any problems with this draft, I will need a letter from a chief executive officer within ELEKTA RADIOSURGERY, INC. acknowledging that the information relative to the unit is accurate, and ELEKTA concurs with all the requirements and recommendations in the document.

ELEKTA RADIOSURGERY, INC. must provide our agency with a final version of all manuals (safety, maintenance, etc.), unit specifications (timer settings, etc.) and installation and operational procedures. These documents must include all the revisions, and commitments which have been made by ELEKTA RADIOSURGERY, INC. during this device review process.

**NOTE: Our agency will not issue the device registration or amend ELEKTA's distribution license for this device until the above information is submitted for review in final form.**

ELEKTA RADIOSURGERY, INC. needs to request an amendment to have the Model 23004, Type-B added to the distribution license. This request must include all services including the time intervals at which ELEKTA or ELEKTA's agent (i.e. source installation and removal) will provide these services to a licensee. The names of individuals, and their training/experience that must be added to the license in order to perform such services. Also, reference all previously submitted manuals and procedures which will be followed by these individuals. Additionally, the request must either reference or include all manuals, documents, procedures, radiation surveys, leak test results, and training which will be provided to a licensee at the time of installation. Also, include the make, model, activity and total number of the Cobalt-60 sources for this unit.

If you have any questions concerning this subject, please give me a call at (404) 362-2675.

Sincerely,



William L. Slocumb  
Environmental Radiation Specialist, Prin.