

NRC FORM 241
(7-1993)

U.S. NUCLEAR REGULATORY COMMISSION

**REPORT OF PROPOSED ACTIVITIES IN
NON-AGREEMENT STATES, AREAS OF EXCLUSIVE
FEDERAL JURISDICTION, OR OFFSHORE WATERS**

(Please read the instructions before completing this form)

APPROVED BY OMB: NO. 3150-0013 **EXPIRES: 07/31/2002**
Estimated burden per response to comply with this mandatory collection request: 15 minutes. This notification is required so that NRC may schedule inspections of the activities to ensure that they are conducted in accordance with requirements for protection of the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-8 EB), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to bsr@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0013), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

1. NAME OF LICENSEE (Name of firm proposing to conduct the activities described below)
Elekta Instruments, Inc.

2. TYPE OF REPORT
 INITIAL REVISION CLARIFICATION

3. ADDRESS OF LICENSEE (Mailing address or other location where licensee may be located)
*3155 Northwoods Pkwy.
Norcross, GA 30071*

4. LICENSEE CONTACT AND TITLE
*Marta Knotts
Manager Gamma Knife Service*

5. TELEPHONE NUMBER (Include Area Code) **6. FACSIMILE NUMBER (Include Area Code)**
770 800-9925 *770-448-6338*

7. ACTIVITIES TO BE CONDUCTED UNDER THE GENERAL LICENSE GIVEN IN 10 CFR 150.20

WELL LOGGING LEAK TESTING AND/OR CALIBRATIONS TELETHERAPY/RADIATOR SERVICE

PORTABLE GAUGES OTHER (Specify) ⇒ *Preventative maintenance*

RADIOGRAPHY ⇒ REGISTERED AS USER OF PACKAGING (CERTIFICATES OF COMPLIANCE NUMBERS)

8. CLIENT NAME, ADDRESS, CITY/COUNTY, STATE, ZIP CODE
*Wills Eye Hospital
Neurosensory Inst. Diag. & Treatment
900 Walnut St. Bldg
Philadelphia, PA 19107*

9. ACTUAL PHYSICAL ADDRESS OF WORK LOCATION (Street and Number or other location. Give as complete an address or directions as possible.)
Same

10. CLIENT TELEPHONE NUMBER (Include Area Code) **11. WORK LOCATION TELEPHONE NUMBER (Include Area Code)**

12. DATES SCHEDULED **13. NUMBER OF WORK DAYS** **14. ADD** **15. DELETE** **16. LOCATION REFERENCE NUMBER**

FROM *11-10-99* TO *11-10-99* *1* **NUMBER TO BE ASSIGNED BY NRC**
000191

LIST ADDITIONAL WORK SITES ON SEPARATE SHEET(S) TO INCLUDE ALL INFORMATION CONTAINED IN ITEMS 8-16 ABOVE.

17. LIST RADIOACTIVE MATERIALS, WHICH WILL BE POSSESSED, USED, INSTALLED, RECOVERED, OR TESTED (Include description of type and quantity of radioactive material, sealed sources, or devices to be used.)
Cobalt-60

18. AGREEMENT STATE SPECIFIC LICENSE WHICH AUTHORIZES THE UNDERSIGNED TO CONDUCT ACTIVITIES WHICH ARE THE SAME, EXCEPT FOR LOCATION OF USE, AS SPECIFIED IN ITEM 8 ABOVE. (Four copies of the specific license must accompany the initial NRC Form 241.)

19. CERTIFICATION (MUST BE COMPLETED BY APPLICANT)

I, THE UNDERSIGNED, HEREBY CERTIFY THAT:

- All information in this report is true and complete.
- I have read and understand the provision of the general license 10 CFR 150.20 reprinted on the instructions of this form; and I understand that I am required to comply with these provisions as to all byproduct, source, or special nuclear material which I possess and use in non-agreement states or offshore waters under the general license for which this report is filed with the U.S. Nuclear Regulatory Commission.
- I understand that activities, including storage, conducted in non-agreement states under general license 10 CFR 150.20 are limited to a total of 180 days in calendar year, with the exception of work conducted in off-shore waters, which is authorized for an unlimited period of time in the calendar year.
- I understand that I may be inspected by NRC at the above listed work site locations and at the Licensee home office address for activities performed in non-agreement states or offshore waters.
- I understand that conduct of any activities not described above, including conduct of activities on dates or locations different from those described above or without NRC authorization, may subject me to enforcement action, including civil or criminal penalties.

CERTIFYING OFFICER - RSO or Management Representative (Name and Title) **SIGNATURE** **DATE**
Marta Knotts - mgr. G.K. Service *Marta Knotts* *11-3-99*

WARNING: False statements in this certificate may be subject to civil and/or criminal penalties. NRC regulations require that submissions to the NRC be complete and accurate in all material respects. 18 U.S.C. Section 1001 makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

FOR NRC USE ONLY **SIGNATURE** **DATE** **TOTAL USAGE - DAYS TO DATE**
D.M. Heim, LA/DNMS *Grant M. Nemo* *11/4/99* *68*

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Received in on 11 NE 5
11/4/99 cc [initials]

PDR STPRG

Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354

Lonice C. Barrett, Commissioner

Harold F. Fehs, Director

Environmental Protection Division

404/362-2675

February 12, 1999

Mr. Paul L. Sumner, Director
Regulatory Affairs & Quality Assurance
Elekta Instruments, Inc.
3155 Northwoods Parkway, NW
Norcross, Georgia 30071

Dear Mr. Sumner:

In accordance with your request dated December 11, 1998, your Georgia Radioactive Material License Number **GA 1153-1** has been amended in its entirety. Enclosed is license amendment number .13, which changed the facility address and added personnel to the license. This amendment supersedes all previous license amendments.

You will notice additional changes to your license, in format, arrangement, and license conditions. These come mainly from the incorporation of the standard license conditions for distribution. These conditions are not new requirements; they emphasize information that is contained in the Sealed Source and Device (SS&D) Registration Certificates.

Additionally, your SS&D Registration Certificates **GA 269-D-101-S** and **GA 269-D-102-S** were amended to reflect the change of address. The first page of each certificate is enclosed.

Since the SS&D amendments did not require an actual safety evaluation, there is no charge for those actions. Thus, you are currently overpaid to the Department the sum of \$2400. This amount can be refunded to you, or it can be applied to future invoices (i.e., annual fee, inspection, etc.). For your information, annual fees for the SS&D certificates will be mailed out next week. If you choose, you may deduct \$2400 from the invoiced amount, noting this overpayment with your remittance.

Please be sure to carefully read the entire license. If you have any questions, please contact me via telephone at (404) 362-2675 or via e-mail at ejameson@mail.dnr.state.ga.us.

Sincerely,



Eric T. Jameson
Principal Radiological Health Specialist
Radioactive Materials Program

Enclosures -- 3

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE**

(amended in its entirety)

CORRECTED PAGE -- ADDRESS CHANGE ONLY, February 12, 1999**NO:** GA 269-D-102-S**DATE:** October 9, 1997**PAGE:** 1 of 16**DEVICE TYPE:**

Medical Teletherapy

MODEL:Leksell Gamma System Model 23004 Type B
Leksell Gamma System Model 23004 Type B-2**DISTRIBUTOR:**Elekta Instruments, Inc.
3155 Northwoods Parkway, NW
Norcross, Georgia 30071**MANUFACTURER**ELEKTA INSTRUMENT SA
4, rue de l'Athenee
CH 1205 Geneva
SWITZERLAND**SEALED SOURCE MODEL DESIGNATION:**General Electric Company
AB ELEKTA Model No. 43047**ISOTOPE:**

Cobalt-60

MAXIMUM ACTIVITY:6600 Curies. 201 sources with a mean average not to exceed
32.83 Curies and no single source to exceed 36 Curies.**LEAK TEST FREQUENCY:**

6 months

PRINCIPAL USE:

Code C -- Medical Teletherapy

CUSTOM DEVICE: Yes No

**REGISTRY OF RADIOACTIVE SEALED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICE**

(amended in its entirety)

CORRECTED PAGE -- ADDRESS CHANGE ONLY, February 12, 1999**NO.** GA 269-D-101-S **DATE:** January 2, 1997 **PAGE:** 1 of 12**DEVICE TYPE:** Medical Teletherapy**MODEL:** Leksell Gamma System Model 23016**DISTRIBUTOR:** Elekta Instruments, Inc.
3155 Northwoods Parkway, NW
Norcross, Georgia 30071**MANUFACTURER:** Elekta Instrument SA
P.O. Box 330
1211 Geneva 12
SWITZERLAND**SEALED SOURCE MODEL DESIGNATION:** General Electric Company
AB ELEKTA Model No. 43047
Registry No. CA-312-S-106-S**ISOTOPE:**

Cobalt-60

MAXIMUM ACTIVITY:6600 Curies, 201 sources with a mean average not to exceed 32.8
Curies and no single source to exceed 36 Curies**LEAK TEST FREQUENCY:**

6 months

PRINCIPAL USE:

Medical Teletherapy

CUSTOM DEVICE: Yes No

Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354
 Lonice C. Barrett, Commissioner
 Harold F. Rehels, Director
 Environmental Protection Division
 404/362-2676

RADIOACTIVE MATERIALS PROGRAM GEORGIA RADIOACTIVE MATERIALS LICENSE

Pursuant to the Georgia Radiation Control Act O.C.G.A. 31-13 (H.B. 947) 1990 and the Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Georgia Department of Natural Resources and orders issued by the Department, now or hereafter in effect, and to any condition specified below.

Page 1 of 6 Pages
 License Number GA. 1153-1
 Amendment Number .13

License (1. Name and 2. Address)

Elekta Instruments, Inc.
 3155 Northwoods Parkway, NW
 Norcross, Georgia 30071

- 3. In accordance with amendment request dated December 11, 1998, **License Number GA. 1153-1** is amended in its entirety to read as follows:
- 4. **Expiration Date:** June 30, 1999
- 5. **Telephone Number:** (770) 300-9725
Facsimile Number: (770) 448-6338

6. RADIOACTIVE MATERIAL (ELEMENT AND MASS NUMBER)	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY LICENSEE MAY POSSESS AT ANY ONE TIME
A. Cobalt 60	A. Sealed sources (Models as specified in Condition 10.D)	A. 6600 Curies; 201 sources with a mean average not to exceed 32.8 Curies, and no single source to exceed 36 Curies
B. Cesium 137	B. Sealed source (Victoreen Model Number 844-3-8)	B. 103 microcuries, no single source to exceed 10 microcuries

Georgia Department of Natural Resources
Radioactive Materials License
Supplementary Sheet

Page 2 of 6 Pages
License Number GA. 1153-1
Amendment Number .13

9. AUTHORIZED USE

- A. Pursuant to (8) of Rule 391-3-17-.02, the licensee is authorized to use and/or possess devices listed in Condition 10.D. of this license in accordance with the provisions of the certificate of registration issued for each device pursuant to (11)(l) of Rule 391-3-17-.02. When at existing irradiation facilities, the licensee shall strictly abide by all requirements of the customer's license and applicable requirements of the U.S. Nuclear Regulatory Commission or Agreement State within which the authorized work is performed. The authorized use and/or possession of the sources and devices includes activities incident to the following:
- (1) Source installation into and removal from devices.
 - (2) Installation, relocation, repair and maintenance of devices, including leak testing of sealed sources and radiation surveys of devices.
 - (3) Distribution of devices to persons licensed to receive the material pursuant to the terms and conditions of a specific license issued by the Department, the US Nuclear Regulatory Commission, or an Agreement State.
 - (4) Receipt, storage, and transfer of devices received from customers for disposal.
 - (5) Instruction and training of individuals in use of the devices.
- B. For use in the Victoreen Model 541-205 dosimeter calibrator to calibrate Victoreen Model 541R Pencil Dosimeters.

CONDITIONS

10. A. This license does not authorize the possession of cobalt 60.
- B. Cobalt 60 may be used only at facilities of customers in Georgia who possess a valid Georgia Radioactive Materials License for the cobalt-60 sources. This condition does not prohibit use in other Agreement States and States under the jurisdiction of the U.S. Nuclear Regulatory Commission under reciprocity procedures which may be established by an Agreement State or the U.S. Nuclear Regulatory Commission.
- C. Cesium 137 may be used only at the licensee's address in Item 2, above.

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Condition 10 (continued)

D. The following table lists the devices which Elekta Instruments, Inc. may distribute pursuant to the terms and conditions of this license. The table lists the devices by model number, the sealed source model(s) which may be used in the device, and the isotope and maximum quantity which may be contained in the device.

Device Model (SS&D certificate)	Sealed Source Model (SS&D certificate)	Isotope	Maximum Activity Per Device
Leksell Gamma System Model 23016 (GA 269-D-101-S)	General Electric Company A B Elekta 43047 (CA 312-S-106-S)	Cobalt 60	6600 Curies per device. 201 sources with a average not to exceed 32.8 Curies and no single source to exceed 36 Curies.
Leksell Gamma System Model 23004 Type B/B-2 (GA 269-D-102-S)	General Electric Company A B Elekta 43047 (CA 312-S-106-S)	Cobalt 60	6600 Curies per device. 201 sources with a average not to exceed 32.8 Curies and no single source to exceed 36 Curies.

11. The licensee shall comply with the provisions of Georgia Department of Natural Resources Rule 391-3-17-.03, "Standards for Protection Against Radiation, Amended.", Rule 391-3-17-.06, "Transportation of Radioactive Material, Amended.", and Rule 391-3-17-.07, "Notices, Instructions and Reports to Workers: Inspections, Amended."

12. In accordance with DNR Board Policy adopted May 27, 1992, the fees associated with this license, fee category F., are:

Application fee	\$1400	Renewal fee	\$1100
Amendment fee	\$ 630	Routine Inspection fee	\$ 800
Non-routine Inspection fee	\$ 690	Annual fee	\$1500

Additionally, the fees associated with each device evaluation, fee category J.1, are:

Application fee	\$3300	Renewal fee	\$ 0
Amendment fee	\$1200	Routine Inspection fee	\$ 0
Non-routine Inspection fee	\$ 0	Annual fee	\$2100

Checks for the fees should be made payable to the Department of Natural Resources, Radioactive Materials Program, and mailed to the following address:

Radioactive Materials Fees
 P.O. Box 101161
 Atlanta, GA 30392

Georgia Department of Natural Resources
Radioactive Materials License
Supplementary Sheet

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License Number GA. 1153-1
Amendment Number .13

Condition 12 (continued)

Mail license applications, amendment, and renewal requests the same day as the check to the following address:

Radioactive Materials Program
4244 International Parkway, Suite 114
Atlanta, GA 30354

Inspection fees are payable upon receipt of each invoice from the Department following inspections. Annual fees are billed by the Department at the beginning of each fiscal year.

13. The Radiation Safety Officer in this program shall be Martin Knotts.
14.
 - A. Installation, relocation, removal, maintenance, repair and operation testing of Elekta Instruments, Inc., Leksell Gamma System Gamma Knife shall be done by or under the supervision of Martin Knotts, Ulf Pettersson, Billy Andersson, Jim Mounts, Chris Trax, or Joe Swauger.
 - B. Loading and unloading source capsules of Leksell Gamma units shall be done by Martin Knotts, Ulf Pettersson, or Jim Mounts.
15. Except for maintaining labeling as required by 391-3-17.-03, the licensee shall obtain authorization from the Department before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the Sealed Source and Device (SS&D) Registration Certificate issued by the Department.
16. Sealed sources containing radioactive material shall not be opened by the licensee.
17. Sealed sources shall be loaded into the Leksell Gamma Unit by persons authorized by the Department, the U. S. Nuclear Regulatory Commission, or any Agreement State to perform such services.
18.
 - A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta, purple or black on a yellow background, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.
 - B. Each label required by this condition shall bear the statement, "Removal of this label is prohibited."
19. The licensee shall test each device distributed under this license for leakage or contamination of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at the time of installation of the device. The licensee shall furnish the customer with a written report of each leak test in units of microcuries (μCi) or becquerels (Bq).

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License Number GA. 1153-1
Amendment Number .13

Conditions (continued)

20. After each installation of teletherapy sources (loading or reloading) at a customer site the licensee shall perform radiation surveys with an operable radiation survey instrument, calibrated in accordance with 391-3-17-.05(7)(c), to verify that:
- A. The maximum and average radiation levels at 1 meter from the sources with the source in the "off" position do not exceed 10 mR/hr (100 μ Sv/hr) and 2 mR/hr (20 μ Sv/hr), respectively; and,
 - B. With the teletherapy source in the "on" position with the largest clinically available treatment field, the radiation levels in restricted and unrestricted areas of the facility do not exceed the limits in 391-3-17-.03.
21. A. Relocation of the unit within the treatment rooms that could result in increased radiation levels in areas outside the teletherapy treatment rooms shall be evaluated by a radiation survey made as described in Elekta's Radiation Safety Instructions in letter dated June 14, 1994.
- B. Relocation of the Leksell Gamma Unit to a new treatment room or facility is not permitted except as authorized by the customer's license.
22. The licensee shall maintain a record of the radiation measurements made following installation of sources for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the Leksell Gamma Unit, the isotope, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy unit while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in mR (μ Sv) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the individual performing the survey.
23. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:
- A. By transfer of waste to an authorized recipient;
 - B. By transfer to a specifically licensed recipient; or
 - C. As provided otherwise by a specific condition of this license pursuant to the requirements of (12) of Rule 391-3-17-.03.
24. All records or copies of records pertaining to Radioactive Material License GA. 1153-1 and its associated SS&D Registration Certificates shall be maintained by the Radiation Safety Office at the address listed in Item 2 of this license.

Georgia Department of Natural Resources
Radioactive Materials License
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Amendment Number .13

Conditions (continued)

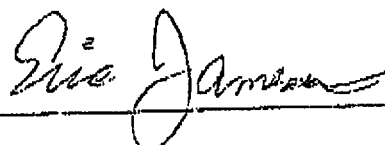
25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the documents, including any enclosures listed below:
- A. Application dated May 31, 1994, signed by Martin Knotts, Project Manager;
 - B. Letter dated June 14, 1994, and facsimile received June 30, 1994, signed by Martin Knotts, Project Manager;
 - C. Letters dated January 5, 1995 and March 9, 1995, signed by Martin Knotts, Project Manager;
 - D. Letter dated June 23, 1995, signed by Martin Knotts, Project Manager;
 - E. Letter dated April 10, 1996, signed by Martin Knotts, Project Manager;
 - F. Letter dated December 30, 1996, signed by Martin Knotts, Director of Technical Service;
 - G. Letter dated July 10, 1997, signed by Martin Knotts, Director of Technical Services; and
 - H. Letter dated December 11, 1998, signed by Paul Sumner, Director of Regulatory Affairs and Quality Assurance.

The Georgia Department of Natural Resources' regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.

FOR THE DEPARTMENT OF NATURAL RESOURCES

Date: February 12, 1999

BY



Eric T. Jameson