

ELEKTA

Br. 3
03038675

To who it May Concern,

Elekta, Inc. would like to submit an amendment to the 10-35096-01 license.

The key changes to the license are adding Cobalt-60 the Leksell Gammknife teletherapy device to the license and to appoint Matthew Williams as an RSO to Elekta, Inc.

Attached are the license amendment and supporting documentation.

If any additional information is needed please to not hesitate to contact me.

Regards,

Matthew Williams

REC RG 104 18 16 AM 10:16

590701
NRC/RCN MATERIALS-002

Item 5A – RADIOACTIVE MATERIAL (Sealed Sources and Devices)

Reference	A. Element and Mass Number	B. Chemical and/or Physical Form	Maximum Use Activity	C. Maximum Activity per source
1.	Co-60	Sealed Source—models 43685 and 1000026 <manufactured by Nordion (Canada) Inc. (Formerly MDS Nordion Inc.) and model 43047 <manufactured by General Electric Company	As authorized in customer radioactive materials license	6600 curies (244.2 TBq) installed. 192 sources installed. No single source to exceed 36 curies.
2.	Ir-192	Sealed Source--model 105.002 <manufactured by AOS, Inc. or Mallinckrodt B.V.>	As authorized in customer radioactive materials license	12 curies (444 GBq) installed. 13 curies (481 GBq) replacement source to decay at facility
3.	Ir-192	Sealed Source--model 105.002 002 <manufactured by AOS, Inc. or Mallinckrodt B.V.>	As authorized in customer radioactive materials license	2 curies (74 GBq) installed. 3 curies (111 GBq) replacement source to decay at facility
4.	Ir-192	Sealed Source: model 136147 (formerly Model 09-00-001) <manufactured by Mallinckrodt B.V.>	As authorized in customer radioactive materials license	12 curies (444 GBq) installed. 13 curies (481 GBq) replacement source to decay at facility
5.	I-125	Sealed Source--model 130.002 <manufactured by Eckert & Ziegler BEBIG >	As authorized in customer radioactive materials license	1.1 millicuries (40.7 MGq) per seed, maximum number of seeds per cartridge 100

Inactive Device Registries				
Reference	A. Element and Mass Number	B. Chemical and/or Physical Form	Maximum Use Activity	C. Maximum Activity per source
6.	Co-60	Sealed Source—model 43047 <manufactured by General Electric Company and Elekta models 43047 and 43685 Manufactured by Nordion Inc.	As authorized in customer radioactive materials license	6600 curies (244.2 TBq) installed. 201 sources installed. No single source to exceed 36 curies.
7.	Co-60	Sealed Source— models 43685 and 1000026 <manufactured by Nordion (Canada) Inc. (Formerly MDS Nordion Inc.) and model 43047 <manufactured by General Electric Company	As authorized in customer radioactive materials license	6600 curies (244.2 TBq) installed. 201 sources installed. No single source to exceed 36 curies.
8.	Ir-192	Sealed Source--Nucletron model 096.001 <manufacturer by AEA Technology (QSA Global) or Mallinckrodt B.V.>	As authorized in customer radioactive materials license	10 curies (370 GBq) installed.
9.	Cs-137	Sealed Source--Amersham Model CDC.SP1 < manufactured by Amersham>	As authorized in customer radioactive materials license	40 millicuries per source, 48 sources per channel, maximum 11.52 curies/6 channel device

• **5a - Devices and Sources Con't.**

Reference (Table 1)	Device/Source & MD SDDR	Device/Source Type	Source
1	Leksell Gamma Knife® Perfexion™ • NR-0269-0497-D-104-S	Gamma Stereotactic Radiosurgery Unity	Co-60 (Elekta Models 43047, 43685, 1000029)
2	MicroSelectron HDR model 105.999 • NR-0497-D-108-S	HDR remote afterloading brachytherapy unit	Ir-192 (Nucletron Model 105.002)
2 or 3	MicroSelectron HDR model 106.990 • NR -0497-D-114-S	HDR remote afterloading brachytherapy unit	Ir-192 (Nucletron Model 105.002)
4	Flexitron HDR model 136149A02 • NR -0497-D-115-S	HDR remote afterloading brachytherapy unit	Ir-192* (Nucletron Model 136147)
5	SeedSelectron model 130.001 • NR -0497-D-110-S	Automatic seed loading device for prostate cancer	I-125 (Isotron Model 130.002)
N/A	Co-60 sealed source • NR-0269-S-103-S	Medical Teletherapy Source	Co-60 Models 43047, 43685 and 1000029
N/A	Ir-192 sealed source • NR -0497-S-107-S	HDR, PDR Medical Gamma Afterloading Source	Ir-192 Model 105.002
N/A	selectSeed 1-125 • NR -0497-S-113-S	LDR Sealed Brachytherapy Implant Seed	I-125 Model 130.002
	Inactive Devices		
6	Leksell Gamma System Model 23016 • NR-269-D-801-S	Medical Teletherapy	Co-60 (Elekta Models 43047, 43685)
7	Leksell Gamma System Model 24001 and 23004 • NR-269-D-802-S	Medical Teletherapy	Co-60 (Elekta Models 43047, 43685, 1000029)
8	MicroSelectron-HDR Classic • NR -0497-D-816-S	HDR remote afterloading brachytherapy unit	Ir-192* (Nucletron Model 096.001)

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Reference (Table 1)	Device/Source & MD SDR	Device/Source Type	Source
2	OncoSelect HDR 3 model 105.980 • MD-0497-D-808-S	HDR remote afterloading brachytherapy unit	Ir-192 (Nucletron Model 105.002)
9	Selectron Model SEL 103, SEL 106 • MD-0497-D-801-S	LDR remote afterloading brachytherapy	Cs-137 (Amersham model CDC.SP1)

Please note that no remaining afterloader models contain a depleted uranium safe so we do not need to include depleted uranium in our list in above.

Item 6. – Purposes(s) for which licensed material will be used.

Authorized use incident to performing the Services Listed Below on the following Sealed Source and Devices.

SSDR	Installation	Radiation Surveys	Removal	Relocation	Repair	Maintenance (PMI, routine, emergency)	Source Exchange	Source Retrieval	Packaging (source)	Leak Test	Customer Training
Active											
NR-0269-D-104-S	X	X	X	X	X	X	X**	X**	--	X**	X
MD-0497-D-108-S	--	X	X	X	X	X	X	X	X	X	X
MD-0497-D-114-S	X	X	X	X	X	X	X	X	X	X	X
MD-0497-D-115-S	X	X	X	X	X	X	X	X	X	X	X
MD-0497-D-110-S	X	--	X	X	X	X	--	--	--	--	X
Inactive											
NR-0269-D-801-S	--	X	X	--	--	--	X*	X**	--	X	--
NR-0269-D-802-S	--	X	X	X	X	X	X**	X**	--	X	--
NR-0497-D-816-S	--	X	X	--	--	--	X*	X*	--	X	--
MD-0497-D-808-S	--	X	X	X	X	X	X	X	X	X	X
MD-0497-D-801-S	--	X	X	--	--	--	X*	X*	X	X	--

*Source removal only

**Source Exchange, retrieval and leak testing is contracted to Alpha-Omega Services, Inc

Item 7 – Responsible Individuals

7.1 Individual Responsible for Radiation Safety Program

Radiation Safety Officer: Debra L. Bensen
Radiation Safety Officer: Matthew Williams

Documentation in support of training and experience for Debra L. Bensen is currently on file under this license as well as Georgia radioactive materials license GA-1153-1. Documentation in support of Training and Experience for Matthew Williams is appended as **Attachment 1**.

7.2 Authorized Users

Before using licensed material, authorized users will receive the training described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000.

Item 8- Training for Individuals Working in or Frequenting Restricted Areas

Licensed activities are conducted only by individuals qualified by training and experience. Training may be in the form of lectures, handouts/bulletins, videos, "hands on", and/or self-paced study that emphasize practical subject matter important to the safe handling of licensed materials. Duration and technical level of training received is commensurate with the associated hazards encountered during routine and emergency conditions and the services performed at our customer facilities.

Field Service Engineers work as authorized users and receive training as follows:

- Before assuming duties with, or in the vicinity of, radioactive materials;
 - o On-the Job Training
 - On-the-job training is performed under the supervision of a qualified individual (manufacturer's representative) that includes supervised hands-on experience performing the task authorized on the license that are commensurate with the expected hazards during routine and emergency conditions;
 - o Factory Training
 - Engineers are formally trained (by manufacturer's representative) in the principles of maintenance of each model afterloader or Gammaknife on which they are to be qualified, including the principles of routine and emergency service. Engineer Training Agendas appended as **Attachment2**.
- Whenever there is a significant change in duties, regulations, or the terms and conditions of the license;
- Annually for refresher training

Topics covered during initial and annual refresher training (by RSO or designee) may include:

- Fundamentals of Radiation
 - o Characteristics of radiation;
 - o Units of radiation dose and quantity of radioactivity;
 - o Hazards of exposure to radiation;
 - o Levels of radiation from licensed material;
 - o Methods of controlling radiation dose (time, distance, and shielding);
 - o ALARA concept.
- Radiation Detection Instruments:
 - o Operation;
 - o Calibration;
 - o Limitations of radiation survey instruments;
 - o Radiation survey techniques for measuring radiation field;
 - o Radiation survey techniques for measuring removable/fixed contamination;
 - o Handling and proper use of personnel monitoring equipment.
- Radiation Protection Equipment and Use;
 - o Proper use of protective equipment;
 - o Decontamination of contaminated protection equipment
- NRC regulations (10 CFR 19 and 20) or agreement state equivalent
- NRC regulations (10 CFR 21, 30, 31, 32, 34, 35, 36, 39, 40, 70, and 71) as applicable and/or agreement state equivalent.
- Operating and Emergency Procedures
- Case histories relevant to operations
- Course Examination (Didactic):
 - o Successful completion of an written/oral examination depending on the complexity and hazards of authorized activities;
 - o Review of incorrect answers with student.
- Discussion and/or drill on emergency procedures when indicated.
- Individuals found to be deficient in both practical and didactic areas are re-trained.

Ancillary staff will receive commensurate training on the above topics before assuming duties with or in the vicinity of radioactive material and whenever there is a change in duties, regulations or terms and conditions of the license.

Field service engineers and ancillary staff involved in the shipping and receiving of radioactive material receive commensurate training on security and radioactive material shipping in accordance with DOT requirements and IATA standards.

Customer training includes the relevant topics listed in Appendix J of NUREG-1556, Volume 9 titled: "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses." The Customer Training is provided by our Clinical Applications Support personnel and the Field Service Engineers. Topics include, but are not limited to:

- Emergency procedures (including emergency response drills).
- Operating instructions;
- Computerized treatment planning system;
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources;
- Size and appearance of different types of sources and applicators;
- Previous incidents, events, and/or accidents;
- Design, use, and function of the afterloader and GammaKnife devices, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
- Hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system including "dry runs" (no source loaded) of routine patient setup and treatment and implementation of the licensee's emergency procedures;
- Practical examinations, to determine each trainee's competency to use the device.

It has been noted that Elekta can review the Nuclear Materials Events Database at <http://www.nmed.inl.gov> and include lessons learned from past events

Item 9 – Facilities and Equipment

There will be no Co-60, Ir-192, Cs-137 or I-125 sources received by Elekta Inc. at 400 Perimeter Center Terrace, Suite50, Atlanta, GA 30346.

Engineers perform servicing at customer's clinical facilities (temporary job sites).

- For the Leksell Gamma Knife normal service procedures do not require source manipulation.
- For remote afterloaders, sources are transferred between the shipping container and afterloader by means of a transfer tube connecting the two units. The depleted source is loaded into the shipping container and the new source, into the afterloader. This is performed remotely at the treatment console station. Trained Elekta Inc. field service engineers will prepare the return shipment to be picked up by a shipping agency.
 - On a regular basis Alpha-Omega Services, Inc. (AOS) in Vinton, LA, ships sources to licensed medical facilities and after decay in use, the depleted sources are returned to AOS, Inc.
 - Infrequently, sources are shipped from Mallinckrodt in The Netherlands to Elekta Inc., c/o RSO, Inc. Sources are then shipped via a commercial carrier to clinical facilities. These clinical facilities return depleted sources to Elekta Inc., c/o RSO,

Inc. Elekta Inc., reserves the right to change their contracted radioactive material holding facility if necessary.

- o I-125 sources are shipped direct from Eckert & Ziegler BEBIG to the end user. Unused seeds remain at the client facility for decay and disposal.

Item 10 - Radiation Safety Program

Elekta Inc. has established a radiation safety program commensurate with the scope and extent of activities for the use of the licensed materials in our servicing operations as stated in **Items 5 and 6** above. The RSO is responsible for managing the radiation safety program thereby ensuring that radiation safety activities are being performed according to approved policies and procedures and that regulatory compliance to U.S government laws and requirements have been met. The radiation safety program is outlined in Elekta controlled documents which are maintained and available for inspection.

10.1 Audit Program

A Radiation Safety Program Audit is conducted annually to ensure regulatory compliance and is available for inspection. The audit program follows Appendix I of NUREG-1556 Volume 18 titled: Consolidated Guidance for Materials Licenses: Program-Specific Guidance About Service Provider Licenses.” The Program areas covered in this audit include:

- Licensing Review
- Training, Retraining and Instructions to Workers
- Internal Reviews, Audits, and Inspections
- Facilities
- Leak Tests
- Inventories
- Receipt and Transfer of Radioactive Material
- Transportation
- Personnel Radiation Protection - ALARA
- Notifications/Incidents and Reports
- Posting and Labeling
- Bulletins and Information Notices/Regulation Changes
- Evaluation of Other Factors.
- Open Action Items, Problems or Deficiencies Noted and Recommendations

10.2 Radiation Monitoring Instruments

Field service engineers are equipped with survey meters, count rate meters and self-reading dosimeters. The following table indicates the current make, model, indicated use, and number available of the issued equipment.

Type of Instruments	Number Available	Radiation Detected	Sensitivity Range	Type	Use
Radiation Alert Inspector	46	Beta, Gamma	0-300,000 cps, 0.001-100 mr/hr	Detector	Leak Test Analysis

Ludlum 2401-ECX	45	Gamma	0-20 r/hr	Detector	Exposure Surveys
Canary III	51	Gamma	1 mrem – 1024 mrem	Detector	Personnel Monitoring
Rados, RDS-110	3	Gamma	.001/h to 10 R/h	Detector	Survey
Rados, RDS-120	4	Gamma	.001/h to 10 R/h	Detector	Survey
Rados, RDS-200	7	Gamma	.001/h to 10 R/h	Detector	Survey
Victoreen, 450	1	Gamma	.01 to 5000mR/hr	Detector	Survey
Rados, 60R	16	Gamma	1mR to 999R	Detector	Monitoring

We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000.' We reserve the right to upgrade our survey instruments as necessary.

10.3 Material Receipt and Accountability

Licensed material is possessed at customer's facilities and is under the control of the facility's medical facility license. These facilities should already have written procedures to insure the security and accountability of the licensed material. Elekta Inc. field service engineers are instructed to comply with the security and accountability procedures of the licensed facility. Elekta hereby confirms that we will NOT take possession of the licensed material (radioactive material and/or sealed sources) while at a client's facility and therefore do not need possession limits listed on our NRC license.

In addition, Elekta Inc Afterloader field service engineers are trained to comply with the requirements of the International Air Transport Associates (IATA's) Dangerous Goods Regulations and requirements of the U.S. Department of Transportation for the return shipment of licensed material to a manufacturer licensed to receive the depleted sources. Shipping records are maintained for a minimum of three years.

10.4 Occupational Dose

We will monitor individuals in accordance with the criteria in the section entitled 'Occupational Dose' in NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,'" dated November 2000. NVLAP-accredited dosimetry (film badge, TLD, OSL, etc.) will be processed by a NVLAP-accredited entity. NVLAP-accredited dosimetry will be exchanged at the frequency specified in Section 8.10.4 of NUREG-1556, Vol. 18.

10.5 Public Dose

N/A

10.6 Operating and Emergency Procedures

ALARA

The RSO will implement and maintain ALARA program that includes: management commitment, establishment of investigational dose limits for occupational workers, and review of occupational exposure.

- The management of Elekta Inc. is committed to the ALARA Policy for keeping individual and collective radiation doses As Low As is Reasonably Achievable (ALARA). In accordance with this commitment, will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within the organization.
- Elekta has established Investigation Levels for occupational external radiation exposure which, when exceeded with initiate review or investigation by the Radiation Safety Officer and/or Radiation Safety Committee. Agency reporting is required if the dose limit(s) in Subpart C of 10 CFR Part 20 are exceeded.
- An annual ALARA review is conducted for all badged employees and brought before the committee for evaluation of Elekta's overall efforts for maintaining exposures ALARA. This review will include the efforts of the RSO, authorized users and workers as well as those of management.
- The ALARA program is outlined in Elekta controlled documents and is maintained and available for inspection.

Training

Licensed activities are conducted only by individuals who have received radiation safety and HAZMAT trainings commensurate with the associated hazard and technical level of the employee as detailed in **Item 8**.

Personal Dosimetry

Occupationally exposed employees who are likely to exceed 10% of the regulated limits shall be supplied with personal dosimetry devices. Occupational Dosimetry is addressed in **Item 10.4** above.

Survey Meters

One or more dose-rate survey meters, which are capable of monitoring dose rates in the range of 0.1 mR/hr in graduated ranges, will be supplied. Survey meters are issued to all afterloader Field Service Engineers. Radiation Monitoring Instruments is addressed in **Item 10.2** above.

Customer Facility License

In compliance with NRC and Agreement State regulations, each facility in which a remote afterloading device and/or teletherapy unit and its radioactive source is installed or possessed, must maintain a current Radioactive Materials License listing the isotope, chemical or physical form, possession limit, designated Radiation Safety Officer and other required information. This license must authorize the facility to possess, use, ship, and maintain in storage licensed quantities of byproduct material. This license has a finite expiration date, and if a Notice of Timely Renewal has not been received by the facility before the specified expiration date, the license is considered to be expired.

All facility licenses submitted to Elekta are checked for completeness and accuracy of those items relating to the device and sources. No source order will be processed until a hard copy of the facility license is available to Elekta Inc. Upon expiration of a facility license, Elekta will refuse to process further source orders until the license is current, or upon written confirmation that a Notice of Timely Renewal has been issued by the appropriate regulatory agency.

Customer Agreements

The procedure for obtaining an agreement with the customers is outlined in NUC-S006, Service Process Section 4.2 Warranty and 4.5 Field Change Order.

Afterloaders are sold with a warranty that includes service and source exchanges. At the end of the warranty period, a service contract is extended to the customer by sales and/or by service and an agreement is reached. The scope of the service coverage includes:

Quarterly preventive maintenance; source exchange and installation; annual in-service training on emergency procedures; replacement of check cable, batteries, circuit boards and reference optopairs at manufacturer's recommended frequency; examination of applicators, check ruler and transfer tubes; emergency service; and full 24 hour phone support.

Upgrades to existing devices, the roll out of service patches and yearly service releases as well as how service bulletins and customer information bulletins are distributed is described in the Field Change Order procedure.

Source Handling and Servicing

Afterloader

Servicing, source handling and shipping procedures are specified in Service Information Bulletins and Manuals specific for the applicable afterloader models which are serviced by the Elekta field service engineers. The field service engineers will follow established protocols issued through manufacturer's procedures, manuals and/or bulletins. Procedures supporting the servicing and source exchange and handling procedures are addressed in **Section 10.9 Maintenance**.

Manufacturer's procedures provided to the Field Service Engineers emphasize Time, Distance and Shielding when working with radioactive sources. In addition, when Field Service Engineers are on site, they are instructed to use an operable survey meter before entering the room. Radiation surveys will be performed on all afterloaders after maintenance and/or source handling work. If measured readings are abnormal for the machine being surveyed, the machine shall not be released to the user for clinical use. The hospital and Elekta RSO will be notified and the machine posted with appropriate labels.

At the time of source exchanges and/or maintenance (routine and emergency), the engineer is given access to the afterloader, teletherapy devices and source(s) by the facility representative (such as the RSO or medical physicist). At the completion of the source exchange or maintenance, the Elekta, Inc. engineer informs the facility representative who then secures the source and/or afterloader. During source exchange and/or maintenance, the presence of the engineer serves to secure the source(s) and afterloader. During radiation safety training given by Elekta, Inc., engineers are instructed not to leave source(s) unattended. If the engineer is called away temporarily during a source exchange or service, the engineer has been instructed to secure the source before leaving the area.

The source remains the possession of the customer facility and although the FSE will insure the source is secured at all times, the FSE does not, at any time, take possession of the radioactive material.

GammaKnife

Service procedures are specified in Service Information Bulletins and Manuals specific for the applicable teletherapy models which are serviced by the Elekta field service engineers. The field service engineers will follow established protocols issued through manufacturer's procedures, manuals and/or bulletins. Procedures supporting the servicing procedures are addressed in **Section 10.9**

Manufacturer's procedures provided to the Field Service Engineers emphasize Time, distance and Shielding when working with radioactive sources. In addition, when Field Service Engineers are on site, they are instructed to use an operable survey meter before entering the room.

At the time of maintenance (routine and emergency), the engineer is given access to the teletherapy devices by the facility representative (such as the RSO or medical physicist). At the completion of the maintenance/service, the Elekta, Inc. engineer informs the facility representative who then secures the teletherapy device.

For any engineer to service the teletherapy device unescorted at the facility a background investigation will be completed prior to the unescorted service in accordance with 10 CFR part 37

Agency Reporting

The RSO is responsible for NRC incident notifications and should consult the appropriate regulations for reporting requirements. Reporting time frames vary depending on the severity of the incident. Typical incidents in NRC states requiring reporting include: theft or loss of radioactive material, excess personnel exposure, unauthorized radioactive material releases, over exposures, etc. For non-conforming products and/or defects; the Technical Assistance Group (TAG) and Field Service Engineers document and evaluate the customers complaints and requests and are instructed to be on the lookout for any defects or non-compliances that require 10 CFR Part 21 reporting. These are then escalated to the Elekta RSO for reporting and the Complaint Handling Department for further investigation.

Emergency

Prompt and proper action is a prime consideration in limiting eventual damage. An emergency may involve exposure or contamination. Specific device emergency procedures have been developed, implemented and maintained in the appropriate Service Information Bulletins and User Manuals. The emergency procedures developed are for all likely situations for all units, for example: stuck shielded source, stuck unshielded source, leaking source, toppled/damaged HDR, alarming rate meter, I-125 seed jam, etc. Facility-related emergencies such as fire, tornadoes, earthquakes, etc. are the facility's responsibility.

Elekta hereby confirms the following manufacturer's procedures for handling emergency source situations have been developed and are maintained on file.

1. Emergency Unload Procedure for ¹⁹²Ir Sources, mHDR, mHDR Classic, mPDR, SIB-ARD 190.609
2. Emergency Source Unload Procedures, Flexitron, 666.00073 SIB

3. Emergency Tool Kit for use with the seedSelectron, 190.027ENG
4. Leksell Gammaknife Perfexion, Emergency Procedures
5. Leksell Gammaknife Icon, Emergency Procedures

Records Retention

All documents and records generated as a result of licensed activity made under the license must be maintained for a minimum retention period as required by the respective regulatory agency. The minimum retention period is the length of time equivalent to the design and expected life of the product, but in no case less than six (6) years from the date of initial distribution of any directly related products to customers, or for a period ending at least six (6) years after the last product has been manufactured (made available for release to customer sites in relation to a specific version, as applicable), whichever is greater. Quality System documentation shall be maintained for at least six (6) years past the date of ineffectiveness, obsolescence, or supersession.

Radiation Safety Program Records Retention (Minimum Required)

(Parts of 21 CFR Part 20 & 35)

<u>Record</u>	<u>US Retention</u>
Occupational exposure & Rad Safety Program Provisions	License Termination
Leak Test	Until source is transferred or Disposed
Audits of Rad Safety Program	3 years
Instrument Calibration	3 years
Dangerous Goods Shipping Documents	3 years

10.7 Surveys

N/A

10.8 Leak Tests

Leak test, when required, will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Sheet. Leak tests will be performed by trained Elekta Inc. or AOS field service engineers. Prior to obtaining contamination test samples, field service engineers are trained to wear disposable gloves as a protective measure in the event that radioactive contamination is present. The Leak Test/Wipe Test Procedure is detailed below:

Leak Testing Procedure

- Leak Testing of depleted and replacement sources: Use moderate pressure; wipe the entire accessible length of the source cable above the top of the shielded container (pig), towards the top of the pig. Wiping toward the pig reduces the chance of pulling the source out of the pig should the source lock fail.
- Initial and removal leak testing for sources loaded into the Leksell Gamma Knife product will be performed by trained AOS field service engineers. Routine leak test will be conducted in accordance with the unit's corresponding sealed source and device registry.

Wipe Testing Procedure for Afterloader

Check Cable:

- Wipe testing the outer shipping container (barrel, drum) of gamma-emitting sealed sources:
- Pack the shielded shipping container into the outer shipping container, include all packing materials and replace the top.
- Use moderate pressure, wipe twice (2x) around the side of the outer container with a standard wipe.
- Then, using moderate pressure, make two (2x) diagonal swipes across the lid of the outer shipping container with the same wipe. This will provide a wipe test of approximately 300 cm² from the exterior of the outer shipping container.

Test Evaluation for Afterloader

- Use the "inspector®" GM Survey Instrument or equivalent to evaluate the sample.
- To make measurements place the wipe on the sample tray so that the side of the wipe that was in contact with the source cable faces the detector.
- Center the sample in the depression on the sample tray. A leaking source is defined by the detection of a wipe having 0.005 µCi (11,100 dpm) of activity. Similarly, a contaminated container is defined by the detection of a wipe having 0.003 µCi (6,600 dpm) of activity.

In a low background radiation area, determine the background counts (B) with the Inspector for 1 minute. This is the background count rate (BR). Note: The maximum BR is 80 cpm. This is based on what is known as the Lower Limit of Detection (LLD) which is calculated using the following equation:

$$\text{LLD} = (4.66) (\sqrt{B}) + 3 + B$$

A desirable LLD ensures that 10% of a limit can be statistically discerned by the instrument. The limit for contamination on the outside of a shipping container (6,600 dpm) is the most restrictive limit. Ten percent of this limit is 660 dpm which is equivalent to 132 cpm (assuming a nominal instrument efficiency of 0.2). Therefore, the LLD must not exceed 132 cpm to ensure the instrument can detect low radioactivity levels. Using a one minute count time, a background

count of 80 counts (80 cpm) corresponds to an LLD of 125 counts (125 cpm), which is less than the restrictive limit of 132 cpm. Therefore, BR is conservatively limited to 80 cpm to ensure the LLD is appropriate. Should the LLD exceed this value, repeat steps 1 and 2 in a low background area.

(Step 1)

An LLD must be calculated based on the actual background reading obtained. This is done using the equation above.

(Step 2)

In the same area used to determine background, count the wipe for 1 minute to determine the gross sample count rate (SWR for source and DWR for drum). If the total counts on the wipe are less than or equal to the calculated LLD, there is no radioactivity on the smear.

Calculate the amount of radioactivity on the wipe as follows:

- **Source Activity (dpm) = (SWR-BR) / (E); or**
- **Drum Activity (dpm) = (DWR-BR) / (E)**

Where: **SWR** = source wipe count rate, **DWR** = drum wipe count rate and **E** = instrument efficiency, found on the instrument's calibration sticker.

Contact the RSO should any result exceed **1000 dpm (16.6 Bq)** as this is indicative of a potential problem.

10.9 Maintenance

Elekta, Inc. will implement and maintain procedures for routine maintenance of our device according to each manufacturer's written recommendations and instructions.

11. Waste Disposal

No Waste is generated by Elekta Inc. in service and source exchange activities. Depleted sources are returned to the manufacturer (Nordion Inc., AOS, Inc., Mallinckrodt B.V., or Eckert and Ziegler, BEBIG).

ATTACHMENT 1

Matthew Williams Supporting Documents

EDUCATION

Masters of Science, Medical Physics

Georgia Institute of Technology & Emory University, Atlanta, Georgia

Bachelors of Science, Nuclear and Radiological Engineering

Georgia Institute of Technology, Atlanta, Georgia

PROFESSIONAL EXPERIENCE

Radiation Safety Officer – Elekta Inc. 4/2015- Present

- Manage Region North America (United States, Canada, and Mexico) Radiation Detection, Instrument Calibration, Reciprocity Management, Dose Monitoring Program
- Monitor Licensee Radioactive Materials License validity. Assist Licensees on an ongoing basis so the Licensee's operations, equipment, and facilities comply with regulatory requirements
- Design, implement and manage, in accordance with regulatory requirements, appropriate personnel monitoring to measure "external" and "internal" exposures to ionizing radiation
- Ensure after-loading or reloading survey programs that measure or control radiation fields and radioactive contamination during licensed activities, such as source transfers during initial loading or reloading of the Leksell Gamma Knife are conducted, recorded and records filed
- Develop Radiation Safety Training Program and guidance documents to ensure regulatory compliance

Diagnostic Medical Physicist – Alliance Medical Physics 7/2014 – 12/2014

- Perform diagnostic medical physics equipment evaluations on radiographic and fluoroscopic equipment using film, DR or CR, film/screen mammography, FFDM, PACS, stereotactic breast biopsy units, CT, MRI, ultrasound, and industrial x-ray units.
- Assist facilities with ACR modality accreditation.
- Prepare shielding designs, perform shielding integrities, and radiation scatter surveys for diagnostic imaging facilities.
- Personnel, patient, and fetal dose evaluations and calculations

Health Physicist - Georgia Institute of Technology 8/2013- 7/2014

- Managing a team of 4 Graduate/Post-Docs Conduct comprehensive radiological surveys on Radioactive Material Labs and X-ray units
- Provided calibration services for radiation detection devices Held training courses for Radioactive Material, X-ray, and Clinical Accelerator safety
- Inspection of x-ray units, radioactive waste handling, shipment of RAM packages (Type A and Type B) and radioactive waste, sealed source leak tests, prepare safety reports, and laser safety

CLINICAL EXPERIENCE

January 2013 – August 2014

Emory University

- Completed QC/QA for PET Scanners, Portal Imager, Ultrasound, Film Processor Mammography, Fluoroscopy, Dose Calibrator, Gamma Camera
- Perform Weekly, Monthly and Annual Clinac QA
- Assist in conventional treatment planning for lung, breast, prostate, total body, and brain Malignancies
- Assist in Tandem & Ovoid Procedure, Prostate Implant Procedure, Eye Plaque Procedure Lung HDR Procedure, and GYN HDR Procedure
- VMAT and IMRT plan verification

ACADEMIC RESEARCH

Georgia Institute of Technology: *Compton Spectroscopy for Varian LINAC*

January 2013 –December 2013

- Use CZT and NaI(Tl) scintillator detectors to acquire Compton scattering data
- Design, modified, and constructed detector mount to allow 3D rotation of system
- Quantified beam current along central axis to ensure appropriate fluency at detector face
- Calculated energy spectrum for 8Ci Cs source, as well as 6 MV photon beam

Winship Cancer Institute at Emory University:

January 2013 –December 2013

Quantization, Resolution, and Contrast Recovery in PET Scanner

- Quantified the limits of gamma camera resolution
- Calibration of PET scanners using CRC

- Calculate recovery coefficients and contrast recovery
- Use ACR phantom to acquire CRC data to ensure accurate calibration across PET machines

SKILLS

Programming: Assembly, JAVA, Python, FORTRAN, SCALE6.1, MCNP5, C++

Software: MATLAB, Mathematica, Microsoft Office, Adobe Acrobat, Simulink, SolidWorks, EES, RELAP5, GEANT4

Varian Eclipse, RadCal

Publications

- Nolan Hertel E, Bojan Petrovic, **Matthew Williams**, Daniel Christ, James Cook, Corey Ginetz, Spenser Lewis, Kalen Terry, "Georgia Tech Neutron Generator Room Shielding Analysis" (2012)

ATTACHMENT 2

Engineer Training Agendas



Agenda mHDR V2/V3 Technical Training Course

105.999/106.990/Oncentra TPS

AGENDA WEEK 1

Monday

08:30 – 09:00 Introductions

09:00 – 10:00 Introduction to Brachytherapy and Demos

10:00 – 10:15 Break

10:15 – 12:00 Mechanics

12:00 – 13:00 Lunch

13:00 – 14:15 Mechanics (Continued)

14:15 – 14:30 Break

14:30 – 16:30 Electronics and Calibrations

Tuesday

08:30 – 10:30 V2 Set-up and Programming

10:30 – 10:45 Break

10:45 – 12:00 V2 Programming

12:00 – 13:00 Lunch

13:00 – 14:00 Introduction to V3

14:00 – 15:00 V3 TCS Set-up and Programming

15:00 – 15:15 Break

15:15 – 16:30 V3 Programming

Wednesday

08:30 – 09:30 V2/V3 PM Procedures

09:30 – 10:30 V2/V3 PM Procedures and Calibrations

10:30 – 10:45 Break

10:45 – 12:00 V2/V3 PM Procedures and Calibrations

12:00 – 13:00 Lunch

13:00 – 15:00 V2/V3 Source Exchange Procedures

15:00 – 15:15 Break

15:15 – 16:30 V2/V3 Source Exchanges & Documentation

Thursday

08:30 – 10:30 Installations, Networking & Customer Acceptance

10:30 – 10:45 Break

10:45 – 12:00 Paperwork and Reciprocity

12:00 – 13:00 Lunch

13:00 – 15:00 CLM Requirements for paperwork and FCO's

15:00 – 15:15 Break

15:15 – 15:30 Emergency Procedures & Customer Training

15:30 – 16:30 Emergency Unload Procedures Training

Friday

08:30 – 09:00 Source Exchange Tools and OJT Requirements

09:00 – 10:15 Source Exchange Practice

10:15 – 10:30 Break

10:30 – 12:00 PM Procedures Practice

12:00 – 13:00 Lunch

13:00 – 15:15 PM Procedures Practice

15:15 – 15:30 Break

15:30 – 16:30 PM Procedures Practice

AGENDA WEEK 2

Monday

08:30 – 17:00 Oncentra TPS Training

Tuesday

08:30 – 17:00 Oncentra TPS Training

Wednesday

08:30 – 12:00 Oncentra TPS Training with Jerry Ragusa

12:00 – 13:00 Lunch

13:00 – 17:00 HAZMAT/Radiation Safety

Thursday

08:30 – 10:30 AM/Source Exchange Practice

10:30 – 10:45 Break

10:45 – 12:00 PM/Source Exchange Practice

12:00 – 13:00 Lunch

13:00 – 15:00 Corrective Maintenance and Troubleshooting

15:00 – 15:15 Break

15:15 – 16:30 PM/Source Exchange Practice

Friday

08:30 – 10:00 Written Test

10:00 – 10:15 Break

10:15 – 12:00 Written Test and Grading

12:00 – 13:00 Lunch

13:00 – 15:00 Troubleshooting (Practical Exam)

15:00 Class Ends

Training Agenda

HDR Flexitron

Training Lab

Monday

Time	Topic
8:30 – 9:00	Introductions
9:00 – 10:30	Introduction to Flexitron and Demos
10:30 – 10:45	Break
10:45 – 12:00	Components/TCC Software
12:00 – 1:00	Lunch
1:00 – 3:00	TCC Programming
3:00 – 3:15	Break
3:15 – 4:30	Source Exchange

Tuesday

Time	Topic
8:30 – 10:30	Flexitron Mechanical Components
10:30 – 10:45	Break
10:45 – 12:00	Procedures
12:00 – 1:00	Lunch
1:00 – 3:00	Procedures
3:00 – 3:15	Break
3:15 – 4:30	Procedures and Calibrations

Wednesday

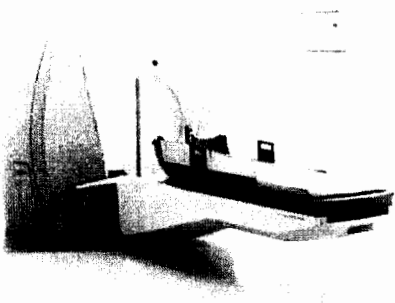
Time	Topic
8:30 – 9:00	System Installation and Configuration
9:00 – 10:30	Software Installation
10:30 – 10:45	Break
10:45 – 12:00	Upgrades and Software Installation
12:00 – 1:00	Lunch
1:00 – 3:00	Troubleshooting
3:00 – 3:15	Break
3:15 – 4:30	Corrective Maintenance and Calibrations

Thursday

Time	Topic
8:30 – 10:30	Installations, Networking & Customer Acceptance
10:30 – 10:45	Break
10:45 – 12:00	Emergency Procedures & Customer Training
12:00 – 1:00	Lunch
1:00 – 13:00	Procedures Practice
3:00 – 3:15	Break
3:15 – 4:00	Emergency Unload Procedures Training
4:00 – 5:00	Written Test Begins

Friday

Time	Topic
8:30 – 10:00	Written Test
10:00 – 10:15	Break
10:15 – 12:00	Practice
12:00 – 1:00	Lunch
1:00	Class Ends



Leksell Gamma Knife® Perfexion™ 2nd Line Service Training,

Atlanta

Program

Monday

08:30-08:45 am	Welcome and introduction <ul style="list-style-type: none"> • Course contents • General presentation of Service and Field Support • Course material 	
08:45-09:30 am	Gamma Knife information <ul style="list-style-type: none"> • History • Perfexion™ features and benefits 	
09:30-10:00 am	System introduction <ul style="list-style-type: none"> • Film – Perfexion™ use and capabilities 	
10:00-10:15 am	<i>Coffee break</i>	
10:15-10:45 am	Customer visit preparations <ul style="list-style-type: none"> • Regulatory issues • NRC • RSO • Service with radiation exposure (doors open, sectors not at home position) • Elekta.biz 	
10:45-12:00 pm	Operation of the system <ul style="list-style-type: none"> • Performing test treatments 	
12:00-12:45 pm	<i>Lunch</i>	
12:45-02:45 pm	System geography <ul style="list-style-type: none"> • Removal of covers • Closer look at the sub systems 	
02:45-03:00 pm	<i>Coffee break</i>	
03:00-04:15 pm	Safety procedures <ul style="list-style-type: none"> • Emergency procedures • QA procedures 	
04:15-05:00	Service Tool <ul style="list-style-type: none"> • Service Tool theory 	
05:00-05:30 pm	Service Tool <ul style="list-style-type: none"> • Service Tool practice • Log files 	

Tuesday

	•	
08:30-09:00 am	Examination	
09:00-10:00 am	System electronics	
10:00-10:15 am	<i>Coffee break</i>	
10:15-10:45 am	Physics <ul style="list-style-type: none"> • Physics applicable to LGK • Dosimetry – Film and Ionization Chamber 	
10:45-12:00 am	Corrective Maintenance <ul style="list-style-type: none"> • Replacing parts 	
12:00-12:45 pm	<i>Lunch</i>	
12:45-02:45 pm	Trouble shooting	
02:45-03:00 pm	<i>Coffee break</i>	
03:00-05:00 pm	Corrective Maintenance <ul style="list-style-type: none"> • MCU replacement • ECU replacement 	
05:00-05:30 pm	Current FCO's	

Wednesday

08:30-09:00 am	Examination	
09:00-10:00 am	Trouble shooting	
10:00-10:15 am	<i>Coffee break</i>	
10:15-10:45 am	Leksell® Stereotactic Neurosurgery (LSN) <ul style="list-style-type: none"> • Leksell® Stereotactic System • Basic trouble shooting LSN • Planned Maintenance 	
10:45-11:15 am	Planned Maintenance <ul style="list-style-type: none"> • Customer relations • Safe working • Manuals • Preparations at home • Tools • Preparations on site • Connecting a laptop 	
11:15-12:00 pm	Planned Maintenance <ul style="list-style-type: none"> • Inspections • Restore covers • Operational tests 	
12:00-12:45 pm	<i>Lunch</i>	
12:45-03:00 pm	Planned Maintenance <ul style="list-style-type: none"> • Radiophysical tests • Leksell Stereotactic System • Leksell GammaPlan® • Cleaning • Final tests • Reporting • Questions 	
03:00-03:15 pm	<i>Coffee break</i>	
03:15-05:00 pm	Trouble shooting	

Thursday

09:00-10:00 am	Leksell GammaPlan® <ul style="list-style-type: none">• Overview	
10:00-10:15 am	<i>Coffee break</i>	
10:15-12:00 am	Leksell GammaPlan® <ul style="list-style-type: none">• Create a treatment	
12:00-01:00 pm	<i>Lunch</i>	
01:00-03:00 pm	Leksell GammaPlan® <ul style="list-style-type: none">• Setup and installation	
03:00-03:15 pm	<i>Coffee break</i>	
03:15-05:00 pm	Leksell GammaPlan® <ul style="list-style-type: none">• Setup and installation	

Friday

08:30-09:00 am	Intellimax Connect	
09:00-10:00 am	Leksell GammaPlan® <ul style="list-style-type: none">• Service Tool SW + Rescue + Legacy Data Conversion tool	
10:00-10:15 am	<i>Coffee break</i>	
10:15-11:00 am	Leksell GammaPlan® <ul style="list-style-type: none">• Service Tool SW + Rescue + Legacy Data Conversion tool	
12:00-01:00 pm	<i>Lunch</i>	
01:00-02:00 pm	Examination	
02:00-04:00 pm	Leksell GammaPlan® <ul style="list-style-type: none">• General practice• Questions	
04:00-04:30 pm	<ul style="list-style-type: none">• Summary & evaluation	

This is to acknowledge the receipt of your letter application dated 04/18/2016 *rec'd in RI*

04/18/2016, and to inform you that the initial processing which includes an administrative review has been performed.

10-35096-01 (Amendment)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 590701.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.