ELEKTA

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July 12, 2013

Kathy Modes
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region 1
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

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License No. 19-28772-01
Docket No. 03032842
Control No. 580167

Dear Ms. Modes,

In reference to your letter dated May 30 requesting addition information for our license renewal, we offer the following:

1. In box 2 of your application dated March 18, 2013, you requested a new mailing address. Please confirm that you no longer need the Maryland address and wish to use the Georgia address effective immediately.

   Old address:
   Elekta Inc.
   d/b/a Nucletron Corporation
   c/o CSC-Lawyers Incorporating Service Company
   7 St Paul Street
   Suite 1660
   Baltimore, MD 21202

   New Address:
   Elekta Inc.
   d/b/a Nucletron Corporation
   400 Perimeter Center Terrace, Suite 50
   Atlanta, GA 30346

   In addition, your new mailing address has not been updated on the procedures you provided in your application. Please make sure you provide your client's with the correct mailing address and you update these procedures accordingly. Please note that your Sealed Source and Device Registrations (listed in Item 5A – devices and sources in your application) still list the Maryland address, please confirm that you initiated the process to amend these registrations.

The Manufacturer's procedures are still undergoing the revision to reflect the new Georgia address. As noted above, all Sealed Source and Device Registrations are still listed with the

Elekta, Inc., d/b/a Nucletron Corporation, 400 Perimeter Center Terrace, Suite 50, Atlanta, GA 30346
Tel: 770-300-9725 Toll: 800-535-7355 Fax: 770-448-6338 www.elekta.com

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Maryland address and Elekta hereby confirms that the process to amend these registrations was submitted to the Georgia Department of Natural Resources on May 22, 2012. These have not been received as of this date. Once the Georgia Radioactive Materials license and all SS&D's have been received, however, the d/b/a Nucletron Corporation will be omitted.

2. In Item 5A of your application, you list I-125. Cs-137 and Ir-192 sealed sources. Please confirm that you do not need depleted uranium listed on your license for shielding purposes. Some of your customer's high dose rate afterloaders (HDRs) may use a depleted uranium safe and if your field service engineers will package that safe for transport, you may want that listed on your NRC license. If you need depleted uranium listed, please provide the kilogram amount for the possession limit.

We confirm that we do not need depleted uranium added to our list in 5A of our application. No remaining afterloaders contain a depleted uranium safe.

3. In Item 5A of your application, you provided only one model number for the Cs-137 sealed source (Amersham Model CDC.SP1) but your current NRC license lists two model numbers (Amersham Model CDC.SP1 and CDC,K series). Please confirm the model number(s) for the Cs-137 sealed sources.

Upon further review, we would like to remove all reference to Cs-137 in Item 5A of our application as there are no units remaining that contain sources for removal. In addition, any manufacturer's procedures that relate to the LDR that contained the Cs-137 shall also be removed from this application.

4. In Item 5A devices and sources section of your application, you listed a variety of devices, but did not list the Nucletron microSelectron Remote Afterloading Unit Model SEL-400, the microSelectron-LDR, or the OncoSelect PDR Model 106.999. Please confirm that you wish to remove these devices from Item 9.B and 9.C of your NRC license.

We confirm that we wish to remove the microSelectron remote Afterloading Unit Model SEL-400, microSelectron-LDR, and the OncoSelect PDR Model 106.999 as these units are no longer sold, the SSDR's have been made inactive and there are no remaining units.

5. In Item 5A devices and sources section of your application, you provided your Sealed Source and Device Registrations (SSDRs). For SSDR MD-0497-D-104-S, you listed only the Nucletron Source Model No. 096-001, but this SSDR also lists a Model CSN0010-192. Please confirm if Model CNS-0010-92 should be listed on your license.

Upon further review, we would like to remove the SSDR MD-0497-D-104-S for the microSelectron Classic which includes the Nucletron Source Model No. 096.001 from Item 5A of our application as there are no Classic units remaining in any NRC states that will require source exchanges. In addition, any manufacturer's procedures that relate to the Classic microSelectron HDR shall also be removed from this application.

6. Item 6 of your application is a table of the services you will provide. There are two asterisks in the table but these asterisks are not defined. Please provide an explanation for these asterisks.

The asterisks are defined below the table which indicate that the Ir-192* source is a **Custom source (device and corresponding source described on same registry)*

7. Item 6 of your application list source retrievals as a service you will provide. However, source retrievals are not listed in Item 8 for training of your field service engineers. Please confirm that your training will be commensurate with the service you wish to perform at your customer's facilities.

Source retrieval is part of the emergency procedures on which the FSE are trained. The training provided is commensurate with the services performed at our customer's facilities.

8. Item 9 of your application indicates that there will be no Ir-192, C-137, or I-125 source received by Elekta at your Georgia address. In addition Item 10.3 of your application indicates license material is possessed at customer's facilities and is under the control of the medical license. This may be read to indicate that you will take possession at customer's facilities. Please confirm that you will NOT take possession of licensed material (radioactive material and/or sealed sources) while at a client's facility and therefore do not need possession limits listed on your NRC license. In addition, please confirm that your service engineers have been instructed to not take possession of licensed material.

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 your NRC license. 10.3 of our application should have been written ***"Licensed material is possessed at customer's facilities and is under the control of the facility's medical license."*** In addition, Elekta confirms that our service engineers have been instructed to not take possession of licensed material at customer facilities and is also boldly reiterated in the work instruction NADoc0049, Radiation Safety Policy – Brachytherapy, Section 4.15.

9. 9. Items 10.5 and 10.7 of your application state: "Elekta Inc. does not contain any licensed material; therefore, there is no need to evaluate public dose at our facility." Please not that you do not need to submit responses on public dose or surveys.

Noted.

10. 10. Item 10.8 of your application indicates that your field service engineers will conduct and analyze leak test samples and that you have developed general procedures for leak and wipe testing and reporting requirements for leak tests results in excess of 0.005microcuries. Please note that License Condition 14.G. of your NRC license requires you to file a report with the NRC if the test reveals the presence of 0.005 microcuries or more for removable contamination. Please revise your procedure to state that a source is considered leaking if the test result is equal to or greater than 0.005 microcuries.

Document amended to reflect that a source is considered leaking if the test result is equal to or greater than 0.005 microcuries.

11. Attachment 4 of your application addresses customer training. Please confirm that this training will include 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." You may want to include the relevant topics in the training certificate you provide to your clients. Remember that it is important to train on emergency procedures. Please note that you can review the Nuclear Materials Events Database at http://www.nmed.inl.gov and include lessons learned from past events.

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;
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources;
- 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 Brachytherapy device, 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" (using dummy sources) 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.

Elekta's training procedure is being revised to include the relevant topics on the training certificate that is provided to our clients. 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

12. The following list of attachments contain the markings of "proprietary/confidential, confidential, Nucletron Proprietary Information, or Copyright."

a) ALARA ~~and Environmental Hazards~~ Policy (Attachment 6) – **Document edited to remove Environmental Hazards; this was placed in separate document.**

b) Radiation Safety Policy – Brachytherapy (Attachment 6)

c) Emergency Source Unload Procedure for Selectron – LDR (Attachment 7) – **REMOVE**

d) Emergency Tool Kit for the use with the seed Selectron (Attachment 8)

e) Selectron-DLR Cs-137 Source Return Shipments (Attachment 8) - **REMOVE**

f) Performing a mHDR Classic Radiation Survey/Source Exchange Checklist (Attachment 8) - **REMOVE**
g) mHDR v2 Source Exchange Checklist (Attachment 8)
h) Flexisource Handling Procedure (Attachment 8)
i) Flexitron Installation Acceptance & Preventive Maintenance Protocol and Checklists (Attachment 8)
j) selectSeed I-125 Instructions for Use (Attachment 8)
k) selectSeed I-125 Return Agreement and Instructions (Attachment 8)

Please comply with 10 CFR 2.390(b) to request withholding of these documents from release to the public.

In compliance with 10 CFR 2.390 (b), Elekta hereby requests withholding the above stated documents from release to the public. In addition, documents c, e and f should be removed from the license application. Please also withhold Complaint Handling from release to the public; this document is attached to this letter.

13. Section 4.1 in your ALARA and Environmental Hazards Policy (Attachment 5) indicates that a formal annual review will be performed but does not go into detail about the topics covered in this review. You may indicate that you will follow the same audit program in Appendix I of NUREG-1556 Volume 18 titled: Consolidated Guidance for Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Section 4.1 in our ALARA Policy document has been amended to include reference to NADoc0042, Radiation Safety Program which details the topics covered during the audit. I had inadvertently forgotten to include this document in the original submission. In addition, the RSC will evaluate the institutions overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users and workers as well as those of management.

14. Section 4.2.6.3 in your ALARA and Environmental Hazards Policy (Attachment 5) indicates that if an individual's dosimeter records a dose equal to or exceeding Investigation Level II, you will notify the respective regulatory agency. Please not that your Investigational Level II is below the NRC's regulatory dose limit and you should only report if you exceed the dose limit(s) in Subpart C of 10 CFR Part 20. Please review 10 CFR 20.2203 for NRC's reporting criteria and revise this section accordingly.

Section 4.2.6.3 in our ALARA Policy document has been amended to reflect the NRC reporting requirements for exceeding regulatory dose.

15. Section 4.6 in your Radiation Safety Policy – Brachytherapy and Section 4.5 in your Radiation Monitoring Program (Attachment 6) discusses dosimetry. You currently use a monthly exchange badge system. The warning in Section 6 of your emergency Source Unload Procedure for the Selectron-LDR references TLD badges. If you intend to use TLDs or OSL or other types of NVLAP dosimetry, you would need to amend your license or you may state the following and this will provide you with the more flexibility for your dosimetry program:

a. "We will have a prospective evaluation and determine that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will monitor individuals in accordance with the criteria in the section entitled 'Occupational Dose' in NUREG-1556, Volume 18."

All reference to documents concerning the Selectron-LDR should be removed from this license application as per the removal of the device from Item 5A. Additionally, the corrections have been made to Section 4.6 in our Radiation Safety Policy – Brachytherapy and Sections 4.1 & 4.5 and in our Radiation Monitoring Program.

16. Section 4.14.6 in your Radiation Safety Policy – Brachytherapy discusses x-ray services. The NRC does not have jurisdiction in this area. You can remove it from your renewal application.

Section 4.14.6 in your Radiation Safety Policy – Brachytherapy has been removed from our renewal application however; this has been added to our Radiation Safety Program under Elekta licensing as it is a requirement of our program. Elekta understands that the NRC does not have jurisdiction in this area.

17. Section 4.16 in your Radiation Safety Policy – Brachytherapy (Attachment 6) states that sources are shipped from the Netherlands to a license holding facility and then shipped via a commercial carrier to clinical facilities. Then it goes on to state that clinical facilities return depleted sources to a license holding facility and then these sources are returned to the Netherlands. Please name the licensed holding facility and provide the license number so that we can verify they are authorized to perform this activity. Also please indicate who is responsible for obtaining the import and export licenses in accordance with the 10CFR Part 110. This applies to your Source Return Procedure, the Flexisoure Handling Procedure, and the selectSeed I-125 Return Agreement and Instruction in Attachment 8.

The licensed holding facility is RSO, Inc., Radioactive Materials License number MD-33-021-02. Sources are imported and exported under general licensure of RSO Inc.'s RAM license. BWI Corporation provides Customs Clearance for the incoming and outgoing sources. Both Isotron and Mallinckrodt also have an import and export license for sources going into and out of their respective countries.

18. Please remove the padlock code from Section 4.17 in your Radiation Safety Policy – Brachytherapy (Attachment 6). This is not needed for your renewal application.

Padlock code removed from our Radiation Safety Policy – Brachytherapy.

19. Section 4.19.2 in your Radiation Safety Policy – Brachytherapy (Attachment 6) discusses an unshielded source, but it does not provide guidance to lock the room and limit access. It states that one of the Radiation Safety Officers (RSOs) will contact the regulatory agency. If the unshielded source occurs during a service call, then this activity is being done under your NRC license and then Elekta's RSO should make the call. In the past where a procedure indicates two entities perform a job task, it may be

inferred that the other one took care of the action, when in fact, the job task was not done at all. Please revise your procedure to clearly indicate when Elekta's RSO will contact the regulatory agency.

Radiation Safety Policy – Brachytherapy procedure has been revised.

20. Section 4.19.3.1 and 4.19.3.2 and Appendix A in your Radiation Safety Policy – Brachytherapy (Attachment 6) discusses what to do when a source does not retract. It goes on to say to enter the treatment room. It does not clearly state that the field service engineer should only enter the room with an operable survey meter. Please revise your procedure to clearly indicate the use of a survey meter when entering the treatment room.

Radiation Safety Policy – Brachytherapy procedure has been revised

21. Section 4.4 in your Radiation Monitoring Program (Attachment 6) is titled "Contracted Non-Elekta Personnel." Please elaborate when and under what circumstances you will employ contractors, what tasks they will be involved in performing, and what training these contractors will be given etc.

Section 4.4 in your Radiation Monitoring Program titled "Contracted Non-Elekta Personnel is only for Leksell Gamma Knife work in Canada and has now been clearly specified in the procedure.

22. Section 4.7 in your Radiation Monitoring Program (Attachment 6) is titled "Removal of False Exposures." Your process is to remove the exposure from the individual's record, but there is no mention that a review was performed, documented and approved by Elekta's RSO. A change in a person's exposure history should be document and available for inspection. Please revise this process to include documentation.

Section 4.7 in your Radiation Monitoring Program titled "Removal of False Exposures" has been removed from this procedure. A revised "Removal of False Exposures" has been added to ALARA Policy, Section 4.4.

23. Section 5.20.1 in your Calibration Procedure discusses gamma knife activities in the State of California. Your application dated March 18, 2013 to continue service provider activities did not identify the gamma knife as one of those activities. Please also note that the NRC cannot authorize any of the activities in the state of California because California is an Agreement State. Please remove this and any other activities where the NRC does NOT maintain regulatory jurisdiction from your renewal application.

Elekta duly notes that the NRC cannot authorize any of the activities in California as California is an agreement state; however, Elekta respectfully wishes to retain this reference in the documentation as it is part of the Calibration Procedure for the company. Any other reference to agreement state requirements must remain in the documentation but Elekta does realize that the NRC does not maintain regulatory jurisdiction in these areas and is not licensing any activities in these states. In addition, Elekta also wishes to retain references to the Leksell

Gamma Knife in the documentation but understands that the NRC is not licensing any gamma knife activities.

24. Sections 4.2 and 9.1 of your Radiation Safety Manual (Attachment 6) use C-14 and P-32 as examples. You may want to use I-125 and Cs-137 or Ir-192 as examples because these are the nuclides your field service engineers will be using.

Elekta understands and appreciates the NRC's input on this topic; however, in this instance C-14 and P-32 are used as a teaching tool for examples of an extremely long and short half life, respectively. Although Cs-137 has a fairly long half life and I-125 has a fairly short half life, the previous examples are better examples of extremes for this instance. The Field Service Engineers receive training on the half life of other more applicable radioactive isotopes outside the teachings of the Radiation Safety Manual.

25. Section 15.0 of your Radiation Safety Manual states that persons under 18 years of age are not permitted to enter a radiation area. The NRC's regulations do not prohibit minors (see 10 CFR 20.1207). You may want to emphasize this is a company policy.

Section 15.0 of our Radiation Safety Manual has been amended to state that it is company policy that persons under 18 years of age are not permitted to enter a radiation area.

26. Section 15.4.2 of your Radiation Safety Manual discusses selecting a survey meter, but it does not guide the field Service engineer to place the detector near a check source to check for operability. Please revise to ensure meters are operable when they are being selected.

Section 15.4.2 of your Radiation Safety Manual now includes that field service engineers should ensure survey meters are operable when they are being selected by placing the detector near a check source to check for operability prior to use.

27. – 35. Procedure removed no longer applicable

36. – 38. Manufacturer's procedures

39. – 46. Procedures removed no longer applicable.

47. – 63. Manufacturer's procedures

64. On page Appendix C-21 in Section 10 of NUREG-1556, Volume 18, we asked for you to submit a procedure for identifying and reporting to the NRC defects and noncompliance as required by 10 CFR 21.21 (a) of this chapter. Based on our review of your renewal application, we could not find this procedure.

To identify and evaluate deviations and failures to comply associated with substantial safety hazards, the complaint handling procedure NB00323 is followed. In addition, the Radiation Safety Program document discusses regulatory agency notifications (section 4.8) in compliance with 10 CFR part 21 as a reference.

65. As described above, there are many issues with the procedures submitted....

Elekta hereby commits to follow the manufacturer's procedures for inspection, maintenance, source exchange, and operations that involve access to the sealed sources(s) and safety systems. I am working with the manufacturer to amend the procedures to incorporate the items as stated in #'s 36 – 38, and 47 – 63. As mentioned above, procedures listed in #'s 27 – 35 and 39 – 46 are no longer applicable and should be removed from the license application.

Please see attached amended procedures as stated in the body of this letter. Should you need further clarification or have more questions, please feel free to contact me at 770-670-2518 or via email at debbie.bensen@elekta.com.

Kind Regards,

Debra Bensen, RSO

Enclosures: NADoc0042 – Radiation Safety Program
NADoc0043 – Radiation Monitoring Program
NADoc0044 – Radiation Safety Manual
NADoc0045 – ALARA Policy
NADoc0049 – Radiation Safety Policy – Brachytherapy
NB0023 – Complaint Handling [Business Area Brachytherapy Systems (BABS) Procedure]