

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Elekta, Inc.</p> <p>2. 400 Perimeter Center Terrace Suite 50 Atlanta, GA 30346</p>		<p>In accordance with the application dated February 17, 2023,</p>	<p>4. Expiration Date: August 31, 2023</p>
		<p>3. License No.: 10-35096-01 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-38675 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cobalt-60</p> <p>B. Iodine-125</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed Sources (Elekta, Inc., Model 43047, 43685, and 1000029; General Electric Company, Model 43047; Studsvik Nuclear AB, Model 43685)</p> <p>B. Sealed Sources (Isotron selectSeed, Model 130.002)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not applicable (See Condition 10)</p> <p>B. Not applicable (See Condition 10)</p>	<p>9. Authorized use</p> <p>A. For use and/or possession incident to device installation, relocation, dismantling, alignment, replacement, repair, servicing of Elekta, Inc. Leksell Gamma System Model 24001 Series, 23004 Series, and Leksell Gamma Knife Models Perfexion, Icon, and Elekta Esprit; including customer training.</p> <p>B. For use and/or possession incident to device installation, relocation, dismantling, alignment, replacement, repair, servicing of Elekta, Inc. Model seedSelect 130.001 remote afterloading devices; including customer training.</p>

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SUPPLEMENTARY SHEET**

License No.: 10-35096-01

Docket or Reference No.:
030-38675

Amendment No. 4

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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>C. Iridium-192</p> <p>D. Iridium-192</p> | <p>7. Chemical and/or physical form</p> <p>C. Sealed Sources (Elekta, Inc., Model 105.002)</p> <p>D. Sealed Sources (Nucletron B.V., Model 136147)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>C. Not applicable (See Condition 10)</p> <p>D. Not applicable (See Condition 10)</p> | <p>9. Authorized use</p> <p>C. For use and/or possession incident to device installation, relocation, dismantling, alignment, replacement, repair, servicing of Elekta, Inc. Model 105.999 and 105.990 remote afterloading devices; including customer training.</p> <p>D. For use and/or possession incident to device installation, relocation, dismantling, alignment, replacement, repair, servicing of Elekta, Inc. Model 136149A02 Flexitron remote afterloading device; including customer training.</p> |
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CONDITIONS

10. The licensee does not take possession of the radioactive material(s) and/or source(s) while at the client's facility.
11. Licensed material may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.
- If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.
12. Licensed material shall only be used by, or under the supervision of, individuals who have received the training described in the application dated August 20, 2013, and have been designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
13. The Radiation Safety Officer (RSO) for this license is Debra L. Bensen.
14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

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- C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- E. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. The licensee is authorized to conduct source retrieval activities in accordance with the application dated August 20, 2013.

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17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated August 20, 2013 (ML13234A425)
- B. Letter dated June 10, 2014 (ML14170B163)
- C. Letter dated September 13, 2018 (ML18262A339)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: April 6, 2023By: _____
Elizabeth Ullrich
Region 1