



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 7, 2005

Docket No. 03034217
Control No. 136072

License No. 37-28520-02MD

Donald Ashton
Executive Director
Lakeshore Isotopes, LLC
2727 West 21st Street
Erie, PA 16505

SUBJECT: LAKESHORE ISOTOPES, LLC, ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 136072

Dear Mr. Ashton:

This refers to your license amendment request. Enclosed with this letter is the amended license which includes the addition of a new pharmacist as well as the organizational and administrative changes requested.

In accordance with NRC Regulatory Issue Summary (RIS) 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material (<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417.pdf>), your license has been modified. Your license now contains a revised decay-in-storage (DIS) condition. This revised condition permits greater flexibility for DIS of waste by eliminating a specific holding period prior to disposal. Please review the RIS 2004-17, and the revised condition carefully to ensure that you understand its requirements.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

D. Ashton
Lakeshore Isotopes, LLC

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Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 19

cc:
Peter Pekelnicky, R.Ph., Radiation Safety Officer

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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, 39, 40, and 70, 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 style="text-align: center;">Licensee</p> <p>1. Lakeshore Isotopes, LLC</p> <p>2. 2727 West 21st Street Erie, Pennsylvania 16505</p>	<p>In accordance with the letter dated November 17, 2004,</p> <p>3. License number 37-28520-02MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2012</p> <hr/> <p>5. Docket No. 030-34217 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83, with half-lives less than 120 days, except molybdenum 99, technetium 99m and xenon 133</p> <p>B. Molybdenum 99</p> <p>C. Technetium 99m</p> <p>D. Xenon 133</p> <p>E. Iodine 131</p> <p>F. Any byproduct material listed in 10 CFR 31.11(a)</p> <p>G. Any byproduct material authorized under 10 CFR 35.57(a)</p> <p>H. Depleted Uranium</p>	<p>7. Chemical and/or physical form</p> <p>A. Any, except sealed sources</p> <p>B. Any, except sealed sources</p> <p>C. Any, except sealed sources</p> <p>D. Any, except sealed sources</p> <p>E. Any, except sealed sources</p> <p>F. Prepackaged units for <u>in vitro</u> diagnostic tests</p> <p>G. Sealed sources</p> <p>H. Metal</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 800 millicuries per nuclide and 320 curies total</p> <p>B. 140 curies</p> <p>C. 140 curies</p> <p>D. 1 curie</p> <p>E. 1.8 curies</p> <p>F. 100 millicuries</p> <p>G. 40 millicuries</p> <p>H. 400 kilograms</p>
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
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9. Authorized use:

- A. through E. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate and distribution of unused molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.
- F. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- G. Calibration and checking of the licensee's instruments. Distribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.
- H. Shielding for molybdenum 99/technetium 99m generators.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 2727 West 21st Street, Erie, Pennsylvania, and Northwest Diagnostics, 110 Merchant Lane, Pittsburgh, Pennsylvania .
11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of the following individuals for the materials and uses indicated:
- A. In accordance with 10 CFR 32.72(b)(2)(i) or (4), pharmacists working as authorized nuclear pharmacists.
- B. Authorized Nuclear Pharmacists: G. Kennedy Cawthorne, R. Ph., R. Don Courtney, R.Ph., John P. Devenney, Jr., R. Ph., David L. Gilliland, R.Ph., Clayton Hollingsworth III, R.Ph, Kristen L. Krahulik, R.Ph., David McLeland R. Ph., Peter Pekelnicky, R.Ph., Vince Politi, R.Ph., Gregory L. Sosnowski, R.Ph., Helen Totty, R.Ph., or Jon Woodward, R.Ph..
12. The Radiation Safety Officer for this license is Peter Pekelnicky, R.Ph.
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.**



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- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. 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.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
18. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
 - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
21. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures described in the letter dated October 10, 2001, received by facsimile on April 3, 2002.

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22. 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. The 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 October 12, 2001 [ML012890289]
- B. Letter dated October 10, 2001, received by facsimile on April 3, 2002 [ML020950031]
- C. Letter dated April 22, 2002 [ML021270089]
- D. Letter received May 16, 2002 [ML021370259]
- E. Letter dated October 9, 2002 [ML023010577]
- F. Letter dated April 28, 2004 (except DOT exceptions requested) [ML041210977]



For the U.S. Nuclear Regulatory Commission

Date **January 7, 2005**
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By Original signed by Elizabeth Ullrich
Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406