

U.S. NUCLEAR REGULATORY COMMISSION

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 style="text-align: center;">Licensee</p> <p>1. Advanced Isotopes of Idaho</p> <p>2. 4968 Rainbow Lane Chubbuck, Idaho 83202</p>	<p>In accordance with application dated November 11, 2015</p> <p>3. License number 11-29216-01MD is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2026</p> <p>5. Docket No. 030-37048 Reference No.</p>
--	---

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83, except molybdenum-99, technetium-99m, iodine-131, samarium-153, and xenon-133</p> <p>B. Iodine-131</p> <p>C. Molybdenum-99</p> <p>D. Technetium-99m</p> <p>E. Xenon-133</p> <p>F. Samarium-153</p> <p>G. Yttrium-90</p> <p>H. Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400</p> <p>I. Any byproduct material authorized under 10 CFR 35.65</p> <p>J. Any byproduct material with atomic numbers 2-83, inclusive</p> <p>K. Depleted uranium</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Sealed sources</p> <p>I. Sealed sources</p> <p>J. Analytical samples</p> <p>K. Metal</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 450 millicuries per radionuclide and 1 curie total</p> <p>B. 750 millicuries</p> <p>C. 30 curies</p> <p>D. 30 curies</p> <p>E. 2 curies</p> <p>F. 500 millicuries</p> <p>G. 75 millicuries</p> <p>H. 500 millicuries</p> <p>I. 250 millicuries</p> <p>J. As needed</p> <p>K. 500 kilograms</p>
--	--	--

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
11-29216-01MD

Docket or Reference Number
030-37048

Amendment No. 08

9. Authorized use:

- A. through G. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium-99m generators authorized recipients for non-medical use.
- H. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.
- I. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- J. Possession incident to the performance of wipe testing of customer's sealed sources.
- K. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

- 10. Licensed material shall be used or stored only at the licensee's facility located at 4968 Rainbow Lane, Chubbuck, Idaho.
- 11. Licensed material shall be used by, or under the supervision of:
 - A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) and (4), or
 - B. Authorized Nuclear Pharmacist(s): Nicole Chopski, PharmD; Gloria Gest, R.Ph; and Catherine Heyneman, PharmD.
- 12. The Radiation Safety Officer for this license is Catherine Heyneman, PharmD.
- 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) for establishing decommissioning financial assurance.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

11-29216-01MD

Docket or Reference Number

030-37048

Amendment No. 08

14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be leak 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.
- D. Sealed sources need not be leak 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) 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. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Boulevard, Arlington, Texas 76011-4511, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- F. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the Commission or an Agreement State to perform such services.
15. This license does not authorize distribution to persons exempt from licensing.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
11-29216-01MD

Docket or Reference Number
030-37048

Amendment No. 08

18. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days from decay-in-storage before disposal without regard to its radioactivity if the licensee:
 - 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;
 - 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;
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the 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.
20. The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy-supplied syringes and vials and their contents.
21. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
11-29216-01MD

Docket or Reference Number
030-37048

Amendment No. 08

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 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 November 11, 2015 (ML15356A713)
- B. Letter dated May 11, 2016 (ML16134A216)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: May 13, 2016

By: _____
Michelle M. Hammond, M.Sc., Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4511