NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 7

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.

Licensee	In accordance with letter dated November 17, 2016,	4. Expiration Date: July 31, 2017
1. Triad Isotopes, Inc. 2. 4205 Vineland Road Suite L1 Orlando, FL 32811	3. License number: 09-32781-01MD is amended in its entirety to read as follows:	5. Docket No.: 030-38276 Reference No.:

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material between atomic numbers 3 and 83 with exceptions	A. Any	A. 700 millicuries per radionuclide and total possession not to exceed 1 curie, except for molybdenum-99, iodine-131, technetium-99m, yttrium-90 and xenon-133	A. Any form initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations. Preparation and distribution of radioactive drugs, including compounding of iodine-131 and redistribution of 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 unused molybdenum-99/technetium-99m generators to authorized recipients for non-medical use.

MATERIALS LICENSE SUPPLEMENTARY SHEET

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
B. Molybdenum-99	B. Any	B. 200 curies total	B. Any molybdenum-99/technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations. Preparation and distribution of radioactive drugs, including compounding of iodine-131 and redistribution of 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 unused molybdenum-99/technetium-99m generators to authorized recipients for non-medical use.

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C. Technetium-99m	C. Any	C. 200 curies total	C. Preparation and distribution of radioactive drugs, including compounding of iodlne-131 and redistribution of 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 unused molybdenum-99/technetium-99m generators to authorized recipients for non-medical use.
D. Xenon-133	D. Any	D. 6 curies total	D. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.
E. Iodine-131	E. Any	E. 5 curies total	E. Preparation and distribution of radioactive drugs, including compounding of iodine-131, to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals, including iodine-131, to authorized recipients for non-medical use.

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F. Any byproduct material permitted by 10 CFR 31.11	F. Prepackaged In Vitro diagnostic test kits (P)	F. 20 millicuries total	F. Prepackaged units for in vitro diagnostic tests. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11, provided the packaging and labeling remain unchanged.
G. Any byproduct material authorized under 10 CFR 35.65	G. Sealed Sources	G. 300 millicuries total	G. Any sealed source listed in 10 CFR 35.65 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.65 or under equivalent licenses of Agreement States.
H. Uranium- depleted in Uranium-235	H. Metal	H. 400 kilograms total	H. Metal encased in stainless steel. Shielding for molybdenum-99/technetium-99m generators.
I. Yttrium-90	I. Any	I. 1 curie total	I. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.

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J. Thallium-201	J. Any	J. 2 curies total	J. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.
K. Indium-111	K. Any	K. 500 millicuries total	K. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.
L. Fluorine-18	L. Any	L. 4 curies total	L. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.
M. Gallium-67	M. Any	M. 1 curie total	M. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.

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N. Iodine-123	N. Any	N. 500 millicuries total	N. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1827 Belt Way Drive, Overland, Missouri 63114-5815.

11. The Radiation Safety Officer (RSO) for this license is Carey Untbank, PharmD.

12. 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) and (4), or

    B. Authorized Nuclear Pharmacists:
    Quent Besing, R.Ph.
    Jerrod Brown
    James Coder, PharmD
    Fred Gattas
    Joseph M. Huber
    Todd Kliche

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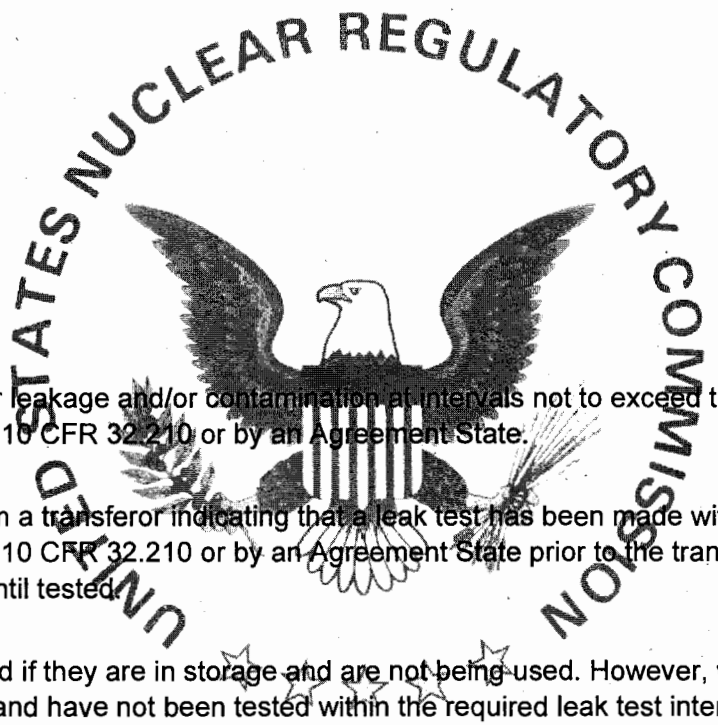
David Mcleland
Salvatore Marascalco, PharmD
David Wright Persinger
Adam Rahman, R.Ph.
Jonathan Vaught
Chad Westbay, R. Ph.
Carey Unthank, PharmD.
Randy Dauzat, R.Ph.
Ryan O'Connor, PharmD.



13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.

B. 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 NRC 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.

C. 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.

D. 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.

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E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the 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.

F. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.

14. Sealed sources containing licensed material shall not be opened.

15. The licensee shall conduct a physical inventory every 6 months 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.

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:

A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

B. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal. the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in the application dated February 15, 2007.

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18. 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 February 15, 2007 (ML070510083)

B. Letter dated June 21, 2007 (ML072110181)

C. Letter dated July 19, 2007 (ML072000314)

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D. Letter dated June 17, 2008 (ML081700443)
E. Letter dated July 3, 2008 (ML081890260)
F. Letter dated February 10, 2009 (ML090420487)
G. Letter dated March 31, 2009 (ML090920441)
H. Letter dated May 28, 2009 (ML091490418)
I. Letter dated June 11, 2009 (ML091770647)
J. Letter dated January 7, 2010 (ML100120620)
K. Letter dated March 29, 2010 (ML100900097)
L. Letter dated April 22, 2010 (ML101130469)
M. Letter dated January 6, 2012 (ML120120324)
N. Letter dated July 28, 2015 (ML15215A687)
O. Letter dated September 14, 2015 (ML15274A111)
P. Letter dated April 20, 2016 (ML16113A478)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: February 21, 2017

By: Colleen Carol Casey
Colleen Carol Casey
Region 3