## **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.

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- 1. Jubilant DraxImage Radiopharmacies, Inc. d/b/a Triad Isotopes
- 2. 790 Township Line Rd. Suite 175 Yardley, PA 19067

July 12, 2019, EAR REGU In accordance with letter dated

- 3. License No.: 09-32781-01MD is amended in its entirety to rea as follows:
- 4. Expiration Date: December 31, 2032
- 5. Docket No.: 030-38276 Reference No.: 030-18456/24-04206-08MD

For preparation and distribution of

compounding of iodine-131 and

radioactive drugs, including

- 6. Byproduct, source, and/or special nuclear material
- A. Any byproduct material between Atomic Nos. 3 and 83 with exceptions
- 7. Chemical and/or physical form
- Maximum amount that licensee may possess at any one time under this license
- 700 millicuries per
- 9. Authorized use
- radionuclide and 1 curie
- radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients. For redistribution of unused molybdenum-99/technetium-99 generators to authorized recipients for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

- B. Molybdenum-99
- B. Any

A. Anv

200 curies total

B. Same as Item 9.A.

- C. Technetium-99m
- C. Any

200 curies total

Same as Item 9.A.

D. Xenon-133

D. Any

D. 6 curies total

D. Same as Item 9.A.

NRC	FORM 374A			U.S. NUCLEA	R REGU	LATORY COMMISS	SION		PAGE 2 OF 6 PAGES
MATERIALS LICENSE		License No. 09-32781-01MD		1	Docket or Reference No. 030-38276 030-18456/24-04206-08MD				
	SUPPLEMENTAR			Amendment No. 14		-			
6.	Byproduct, source, and/or special nuclear material	7.	Chemical and	or physical form	8.	Maximum amou may possess at under this licens	any one time	9.	Authorized use
E.	lodine-131	E.	Any	CLEAF	E.	5 curies total		Ε.	Same as Item 9.A.
F.	Any byproduct material permitted by 10 CFR 31.11	F.	Prepackaged	A 36	F.	20 millicuries to	otal	F.	For redistribution to specific licensees or general licensees in accordance with 10 CFR 31.11, provided the packaging and labeling remain unchanged.
G.	Any byproduct material permitted by 10 CFR 35.65	G.	Sealed source	es	G.	300 millicuries	total O	G.	For redistribution of sealed sources initially distributed by a manufacturer licensed in accordance to 10 CFR 32.74 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	. Н.	Metal	No		400 kilograms	total	H.	For use as shielding in molybdenum-99/technetium-99m generators.
ł.	Yttrium-90	l.	Any	W 7	ी ही	1 curie total		١.	Same as Item 9.A.
J.	Thallium-201	J.	Any		J.	2 curies total		J.	Same as Item 9.A.
K.	Indium-111	K.	Any		K.	500 millicuries	total	K.	Same as Item 9.A.
L.	Fluorine-18	L.	Any		L.	4 curies total		L.	Same as Item 9.A.
M.	Gallium-67	M.	Any		M.	1 curie total		M.	Same as Item 9.A.
N.	Iodine-123	N.	Any		N.	500 millicuries	total	N.	Same as Item 9.A.

RC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION			PAGE 3 OF 6 PAGES
MATERIALS LICENSE	License No. 09-32781-01MD	Docket or Reference 030-38276	No. 030-18456/24-04206-08MD
SUPPLEMENTARY SHEET	Amendment No. 14		

CONDITIONS

- 10. Licensed material may be used or stored at the licensee's facilities located at 1827 Belt Way Dr., Overland, Missouri, 63114.
- 11. The Radiation Safety Officer (RSO) for this license is Jessica L. Glass, Pharm.D.
- 12. Licensed material shall only be used by, of under the supervision of:
  - A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2) or (4), or
  - B. Authorized Nuclear Pharmacists:

Steven H. Alvey, R.Ph.
James Coder, Pharm.D.
Jessica L. Glass, Pharm.D.
Kelly Lutkewitte, Pharm.D.
David Wright Persinger, R.Ph.
John Vardsveen, Pharm.D.

Quent Besing, R.Ph.
Randy Dauzat, R.Ph.
Janene Hamner, R.Ph.
Salyatore Marascalco, Pharm.D.
Adam Rahman, R.Ph.
Jonathan Vaught, Pharm.D.

Jerrod Brown, Pharm.D. Fred Gattas, Pharm.D. Joseph M. Huber, R.Ph. David McLeland, R.Ph. Carey Unthank, Pharm.D. Chad Westbay, R.Ph.

13. 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.

NRC FORM 374A	U.S. NUCLEAR REGULATORY COMM	IISSION PAGE 4 OF 6 PAGES	
MATERIALS LICENSE SUPPLEMENTARY SHEET	1	Docket or Reference No. 030-38276 030-18456/24-04206-08MD	
	Amendment No. 14		

- 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 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.
- C. 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.
- D. 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.
- E. 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 GFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- F. Tests for leakage and/or contamination 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. In addition, the licensee is authorized to collect leak test samples for analysis by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- G. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for three years.

NRC FORM 374A	U.S. NUCLEAR REGULATORY COMM	SSION	PAGE 5 OF 6 PAGES
MATERIALS LICENSE	License No. 09-32781-01MD	Docket or Reference No. 030-38276 030-18456/24-0	04206-08MD
SUPPLEMENTARY SHEET	Amendment No. 14	·	

- 14. Sealed sources containing licensed material shall not be opened by the licensee, except as specifically authorized.
- 15. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for three 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 or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:
  - A. Before disposal as ordinary trash, the waste 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, 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.
  - B. A record of each such 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 fadionuclides 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. 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.
- 18. This license does not authorize distribution to persons exempt from licensing.

ense No. -32781-01MD			
-32701-011VID	Docket or Reference No. 030-38276 030-18456/24	PAGE 6 OF 6 PAGES 4-04206-08MD	
nendment No. 14			
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Date: October 4, 2019

Ву: \_\_\_\_

Bryan A. Parker Region III