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 application dated September 30, 2020,	4. Expiration Date: March 31, 2036
1. NukeMed Inc., dba SpectronRx		5. Docket No.: 030-38044 Reference No.:
2. 17490 Dugdale Dr. South Bend, IN 46635	3. License No.: 13-32726-01MD is renewed in its entirety to read as follows:	

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 with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days, with exceptions	A. Any	A. 200 millicuries per source and 2 curies total	A. For preparation and distribution of radioactive drugs and radiochemicals for medical use to authorized recipients in accordance with 10 CFR 32.72, including chemical synthesis, radiodination using iodine-123, iodine-124, and iodine-131, and redistribution of used and unused generators as described in letter dated March 11, 2020. For preparation and distribution of radioactive drugs and radiochemicals for non-medical use to authorized recipients, including chemical synthesis, radiodination using iodine-123, iodine-124, and iodine-131, and redistribution of used and unused generators as described in letter dated March 11, 2020. Also for research and development as defined in 10 CFR 30.4.

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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. Generators	B. 20 curies total	B. Same as Subitem No. 9.A.
C. Technetium-99m	C. Any	C. 20 curies total	C. Same as Subitem No. 9.A.
D. Iodine-131	D. Any	D. 8.5 curies total	D. Same as Subitem No. 9.A.
E. Iodine-123	E. Any	E. 6 curies total	E. Same as Subitem No. 9.A.
F. Iodine-124	F. Any	F. 6 curies total	F. Same as Subitem No. 9.A.
G. Actinium-225	G. Any	G. 125 millicuries total	G. Same as Subitem No. 9.A.
H. Fluorine-18	H. Any	H. 20 curies total	H. Same as Subitem No. 9.A.
I. Lutetium-177	I. Any	I. 15 curies total	I. Same as Subitem No. 9.A.
J. Carbon-11	J. Any	J. 10 curies total	J. Same as Subitem No. 9.A.
K. Copper-62	K. Any	K. 300 millicuries total	K. Same as Subitem No. 9.A.
L. Copper-64	L. Any	L. 3 curies total	L. Same as Subitem No. 9.A.
M. Gallium-68	M. Any	M. 5 curies total	M. Same as Subitem No. 9.A.
N. Indium-113m	N. Any	N. 1 curie total	N. Same as Subitem No. 9.A.
O. Nitrogen-13	O. Any	O. 1 curie total	O. Same as Subitem No. 9.A.
P. Oxygen-15	P. Any	P. 1 curie total	P. Same as Subitem No. 9.A.
Q. Rhenium-188	Q. Any	Q. 1 curie total	Q. Same as Subitem No. 9.A.
R. Rubidium-82	R. Any	R. 3 curies total	R. Same as Subitem No. 9.A.

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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
S. Strontium-82	S. Any	S. 3 curies total	S. Same as Subitem No. 9.A.
T. Tin-113	T. Any	T. 1 curie total	T. Same as Subitem No. 9.A.
U. Tantalum-178	U. Any	U. 300 millicuries total	U. Same as Subitem No. 9.A.
V. Tungsten-178	V. Any	V. 300 millicuries total	V. Same as Subitem No. 9.A.
W. Tungsten-188	W. Any	W. 1 curie total	W. Same as Subitem No. 9.A.
X. Zinc-62	X. Any	X. 300 millicuries total	X. Same as Subitem No. 9.A.
Y. Zirconium-89	Y. Any	Y. 2 curies total	Y. Same as Subitem No. 9.A.
Z. Indium-111	Z. Any	Z. 1 curie total	Z. Same as Subitem No. 9.A.
AA. Any byproduct material permitted by 10 CFR 35.65	AA. Sealed Sources	AA. 30 millicuries per source and 50 millicuries total	AA. For use in calibration and checking of the licensee's instruments.
AB. Uranium- depleted in Uranium-235	AB. Metal	AB. 100 kilograms total	AB. For shielding for generators and shipping containers.

CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at:
    A. 9550 Zionsville Rd., Indianapolis, Indiana, 46268
    B. 17490 Dugdale Dr., South Bend, Indiana, 46635
    .

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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).

B. Authorized Nuclear Pharmacists:

Scott D. Chance, R.Ph.	Bettina Hickman, R.Ph.	Beth M. Kraemer, R.Ph.
John H. Malola, Pharm.D.	Stanley Miller, R.Ph.	Mark Peters, R.Ph.
John A. Zehner, R.Ph.		

C. Authorized Users: Pulak Chakraborty, Ph.D., Crag Hill, Ph.D., Christopher Ritter, David Trump, Ph.D., and A. Lake Wooten, Ph.D. for licensed material listed in Items 6.A. through 6.Z. for research and development.

12. The Radiation Safety Officer (RSO) for this license is John A. Zehner, R.Ph.

13. In addition to the possession limits in Item 8, the licensee shall further restrict 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. This license does not authorize distribution to persons exempt from licensing.

15. 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.

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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 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.

F. 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.

G. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

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 sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 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.

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18. Except for maintaining labeling as required by 10 CFR Part 20, or Part 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission 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 certificate of registration issued either by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State.

19. 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 3 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.

20. Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human or animal consumption.

21. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

22. 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.

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23. In accordance with letter dated April 14, 2020 (ML20105A439), the licensee may make changes to procedures submitted via letter dated March 24, 2020 (ML20085J260).

24. 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 statements, representations, and 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 impose on the licensee requirements that are more restrictive than or in addition to the regulations.

A. Application dated April 29, 2009 (ML13256A308)
B. Letter dated September 30, 2009 (ML092750334)
C. Letter dated December 14, 2009 (ML093491139)
D. Letter dated January 19, 2010 (ML100200911)
E. Letter dated March 11, 2010 (ML100710734)
F. Letter dated December 12, 2013 (ML13351A266)
G. Letter dated January 29, 2014 (ML14038A221)
H. Letter dated August 12, 2019 (ML19228A267)
I. Letter dated August 12, 2019 (ML19228A245)
J. Letter dated February 10, 2020 (ML20049A059)
K. Letter dated March 24, 2020 (ML20085J260)
L. Letter dated April 14, 2020 (ML20105A439)
M. Letter dated April 24, 2020 (ML20118C132)
N. Letter dated October 26, 2020 (ML20315A318)
O. Application dated September 30, 2020 (ML20274A212)

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N. Letter dated October 26, 2020 (ML20315A318)
O. Application dated September 30, 2020 (ML20274A212)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: March 29, 2021

By: Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2021.03.29 23:29:52 -05'00'

Sara A. Forster
Region III