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The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Environmental Health

Radiation Control Program

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RECEIVED

MAR 15 2019

March 8, 2019

James Coder, R. Ph., Pharm D, BCNP
Radiation Safety Officer
PETNET Solutions, Inc.
810 Innovation Drive
Knoxville, Tennessee 37932

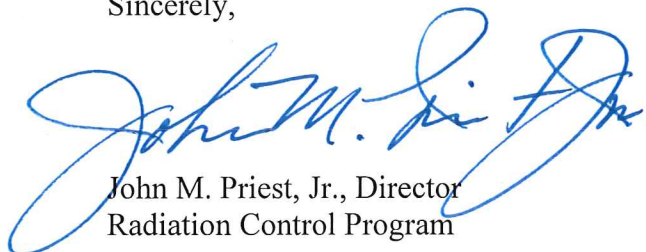
RE: Amendment Number: 06
License Number: 42-0650
Docket Number: 23-3475

Dear Dr. Coder,

Enclosed is the above referenced license amended as requested in your letter dated October 5, 2018.

Please review the enclosed document carefully. If there are any errors or questions, please do not hesitate to contact this office at the number above.

Sincerely,



John M. Priest, Jr., Director
Radiation Control Program

JMP/jg
Enclosure: (1)



THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
MATERIALS LICENSE

Pursuant to Massachusetts General Laws Chapter 111, Sections 3, 5M, 5N, 5O and 5P and Massachusetts Regulations for the Control of Radiation, Section 120.100, Licensing of Radioactive Material, and in reliance on statements and representation heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials 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 105 CMR 120.000. This license shall be deemed to contain the conditions specified in 105 CMR 120.000 and is subjected to all applicable rules, regulations of the Department of Public Health, Commonwealth of Massachusetts, now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. PETNET Solutions, Inc.</p> <p>2. 810 Innovation Drive Knoxville, Tennessee 37932</p>	<p>3. License Number: 42-0650 is amended in its entirety, in accordance with the letter dated October 5, 2018, to read as follows:</p> <p style="text-align: center;">Amendment No: <u>06</u></p> <hr/> <p>4. Expiration Date: May 31, 2023</p> <hr/> <p>5. Docket No: 03-9554</p>
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6. Radioactive Material	7. Chemical/Physical Form	8. Maximum Possession Limit
A. Carbon-11	A. Any	A. 5 curies
B. Nitrogen-13	B. Any	B. 2 curies
C. Fluorine-18	C. Any	C. 40 curies
D. Germanium-68	D. Sealed calibration check source (As listed in SS&D Registry Sheet NR-1235-S-106-S, or NR-1235-S-102-S	D. Not to exceed 1.2 millicurie per source; 25 millicuries total
E. Cesium-137	E. Sealed calibration check source (As listed in SS&D Registry Sheet NR-1235-S-102-S	E. Not to exceed 0.5 millicurie per source; 25 millicuries total

COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM MATERIALS LICENSE SUPPLEMENTARY SHEET	LICENSE NUMBER: 42-0650
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9. Authorized use:

- A. through C. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 105 CMR 120.128 (J) for medical use.
- D. RadQual BM03-68L or RadQual BM06S-68 for instrument calibration and instrument calibration checks.
- E. RadQual BM06E-37 for instrument calibration and instrument calibration checks.

CONDITIONS

- 10. Radioactive material shall be only used or stored at the licensee's facilities located at 268 West Cummings Park, Woburn, Massachusetts.
- 11. This license is subject to an annual fee as determined by the Executive Office for Administration and Finance.
- 12. A. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of Richard Chung, R.Ph., James Coder, R.Ph., Jaehwa Lee, PharmD., R.Ph., Walter Adichie, R.Ph., Daniel H. Kim, R.Ph. David Krydka, R.Ph., Craig Sawyer, R.Ph., Brittany Shulman, R.Ph., and individuals working or designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128 (J)(2)(a) and (b) who hold a valid Massachusetts Board of Pharmacy License.

B. The Radiation Safety Officer for this license is James Coder, R.Ph.
- 13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from the source holder by the licensee.

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14. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the Agency, to account for all sources and/or devices received and possessed under the license. Records of inventories shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of inventory.
15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months or at such other intervals as are specified by the certificate of registration referred to in 105 CMR 120.128(N). In the absence of a certificate from a transferor indicating that a leak test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- B. 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.
- C. The leak test shall be capable of detecting the presence of 185 becquerel (0.005 microcurie) of radioactive material on the test sample. Records of leak test results shall be kept in units of becquerel or microcurie and shall be maintained for inspection by the Agency. If the test reveals the presence of 185 becquerel (0.005 microcurie) or more of removable contamination, a report shall be filed with the Agency and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Agency regulations. The report shall be filed within 5 days of the date the leak test result is known with the Massachusetts Department of Public Health, ATTN: Director, Radiation Control Program. The report shall specify the source involved, the test results, and the corrective action taken.
- D. The licensee is authorized to collect leak test samples for analysis. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or Agreement State to perform such services.

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16. The licensee shall not acquire licensed material in a sealed source or in a device that contains a sealed source unless the source or device has been registered pursuant to 105 CMR 120.128(N), or equivalent regulations of the U.S. Nuclear Regulatory Commission, or Agreement State. The licensee may possess and use sealed sources which were in the licensee's possession as of the date of this license.
17. 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 105 CMR 120.125(C) for establishing financial assurance for decommissioning.
18. 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 105 CMR 120.146 for establishing an emergency plan for responding to a release of licensed material.
19. The licensee is authorized to hold radioactive material with a half-life of less than 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.
 - B. A record of each such disposal permitted under this License Condition shall be retained for three (3) years. The record must include the date of disposal, the date on which the radioactive 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. The licensee shall only transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of 49 CFR Parts 170 through 189, 10 CFR Part 71, and 105 CMR 120.770 "Transportation of Radioactive Material."

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21. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with statements, representations and procedures contained in the documents, including any enclosures, listed below. The Massachusetts Regulations for the Control of Radiation (105 CMR 120.000) shall govern, unless statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

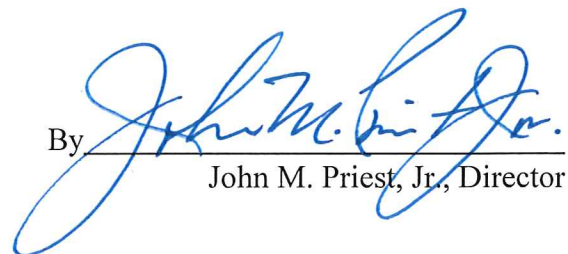
- A. Electronic letter dated May 18, 2017 with attachments
- B. Electronic letter dated July 7, 2017 with attachment
- C. Application dated April 26, 2016
- D. Letter dated March 9, 2016
- E. Electronic letter dated December 29, 2016
- F. Letter dated February 6, 2017
- G. Electronic letter dated February 2 2018 with attachments
- H. Letter dated February 16, 2018 with attachments
- I. Electronic letter dated April 3, 2018 with attachments
- J. Electronic letter dated April 18, 2018 with attachments
- K. Letter dated October 5, 2018
- L. Electronic letter dated December 20, 2018 with attachment

FOR THE COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

Date

3/8/19

By


John M. Priest, Jr., Director

