

**MID-AMERICA ISOTOPES, INC.
706 EAST LIBERTY LANE
ASHLAND, MO 65010**

September 27, 2007

U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Rd.
Lisle, IL 60532-4351
Attention: Materials Licensing Branch

FAX (630) 515-1259

Dear Sir:

Please amend our license number 24-26241-01 MD to allow for the following changes.

- (1) In addition to the authorized nuclear pharmacist(s) listed under condition 11 of our license we would like to add the following Authorized Nuclear Pharmacist.

Jon W. Woodward R.Ph.

Jon is currently licensed under the State of Kansas, Radioactive Materials License number 10-C842, Condition 12. Attached is a copy of License No. 10-C842 for your review.

Jon has over seven years experience as a nuclear pharmacist .

In addition, Jon W. Woodward R.Ph., was the Nuclear Pharmacy Manager for Geodax Inc. in Pittsburgh, PA from September 2000 to April 2002. I currently do not have a copy of the NRC license listing Jon as an ANP.

If you need any additional information please give me a call at (573) 657-1776. Thank you.

Sincerely,



Scott C. Brower R.Ph., B.C.N.P.
Radiation Safety Officer

enclosures

State of Kansas

Radioactive Materials License

Pursuant to the Nuclear Development and Radiation Control Act (L. 1963, Ch. 290) and Kansas Annotated Regulations numbers 28-35-133 et. seq., and in reliance on statements and representations made to this agency by the licensee designated below, a license is hereby issued authorizing the licensee to transfer, receive, possess, and use the radioactive material or materials listed below; and to use such materials at the place or places listed below; and to use the material for the purpose or purposes listed below. This license is subject to all applicable rules, regulations, and orders now in effect or placed in effect by the Department of Health and Environment and any conditions specified below.

Amendment No. 5

Licensee			3. License Number
1. Name PFI LLC 2. Address 825 N WACO WICHITA, KS 67203			10-C842
			4. Expiration Date
			October 31, 2010
			5. Reference Number
6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at One Time	
A. Fluorine-18	A. Activation product of 97% Oxygen-18 water; Fluorodeoxyglucose	A. 20 curies	
B. Nitrogen-13	B. Activation product of Oxygen- 16 water; Ammonia Nitrogen- 13	B. 5 curies	
C. Carbon-11	C. Activation product of Nitrogen gas	C. 5 curies	
D. Oxygen-15	D. Activation product of Nitrogen gas	D. 5 curies	
E. Any radioactive material with atomic number 1-83 inclusive	E. Any form as activated components and targets	E. As necessary	
F. Cobalt-57	F. Sealed sources (Isotope Products RV-057)	F. 11 millicuries	
G. Cesium-137	G. Sealed sources (Isotope Products RV-137)	G. 500 microcuries	
H. Technetium-99m	H. pertechnctate	H. 250 millicuries	

CONDITIONS

Authorized use.

- A. Manufacturing and distribution of PET radiopharmaceuticals to persons specifically licensed for its use pursuant to K.A.R. 28-35-181a, K.A.R. 28-35-181b or equivalent license; and

State of Kansas

Page 2 of 5

Radioactive Materials License

Supplementary Sheet

License Number: 10-C842 Amendment No. 5

activities pursuant to cyclotron startup, testing and operation.

- B. Manufacturing and distribution of PET radiopharmaceuticals to persons specifically licensed for its use pursuant to K.A.R. 28-35-181a, K.A.R. 28-35-181b or equivalent license; and activities pursuant to cyclotron startup, testing and operation.
- C. Manufacturing and distribution of PET radiopharmaceuticals to persons specifically licensed for its use pursuant to K.A.R. 28-35-181a, K.A.R. 28-35-181b or equivalent license; and activities pursuant to cyclotron startup, testing and operation.
- D. Manufacturing and distribution of PET radiopharmaceuticals to persons specifically licensed for its use pursuant to K.A.R. 28-35-181a, K.A.R. 28-35-181b or equivalent license; and activities pursuant to cyclotron startup, testing and operation.
- E. For use and storage as induced radioactivity in portions of the cyclotron; related equipment; facility; and for handling of irradiated target bodies and/or target windows.
- F. To be used for instrument calibration and quality control.
- G. To be used for instrument calibration and quality control.
- H. To be used for instrument calibration and quality control.

Radioactive materials shall only be used at the following location(s):

PFI LLC, 536 N St. Francis
WICHITA, KS 67203

- 11. The following shall be responsible for the licensee's radiation protection program
David Saidian Radiation Safety Officer
- 12. Radioactive material listed in Item 6 above is authorized for use by individuals for the materials and uses described as follows:

Cyclotron operation, synthesis of radiopharmaceuticals and use of radioactive material shall be by, or under the supervision and in the physical presence of an individual listed below:

Jon W. Woodward R.Ph. Subitem(s) A, B, C, D, E, F, G, H

Synthesis of radiopharmaceuticals and use of radioactive material shall be by, or under the supervision and in the physical presence of an individual listed below:

Eric Bosley R.Ph. Subitem(s) A, B, C, D, E, F, G, H

The cyclotron shall be operated by or under the supervision and in the physical presence of an individual listed below:

William Harris Subitem(s) A, B, C, D, E, F, G, H

Brian Phipps Subitem(s) A, B, C, D, E, F, G, H

David Saidian Subitem(s) A, B, C, D, E, F, G, H

State of Kansas

Page 3 of 5

Radioactive Materials License

Supplementary Sheet

License Number: 10-C842 Amendment No. 5

13. The licensee shall perform testing for leakage or contamination of sealed sources in accordance with K.A.R. 28-35-216a.
14. Sealed sources containing radioactive material shall not be opened.
15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, and shall include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.
16. The Radiation Safety Committee shall meet at least quarterly.
17. Positron Emission Tomography (PET) radiopharmaceuticals manufactured and/or prepared for human use are subject to approval by the U.S. Food and Drug Administration (FDA). The licensee shall adhere to additional requirements and policies developed by the FDA governing the manufacturing/preparation of PET radiopharmaceuticals.
18. The licensee shall maintain, for inspection by the Department, logs showing the manufacture, receipt, transfer and disposition of all radioactive material.
19. Maintenance, modification and repair of the cyclotron and its accessories are to be carried out by the manufacturer or personnel qualified to perform such activities. This includes the handling of parts of the cyclotron, beam lines, and related components which become radioactive due to direct proton irradiation or due to secondary neutron activation. The licensee shall maintain documentation of the qualification of maintenance personnel for inspection by the Department.
20.
 - A. Access to the cyclotron beam and target area shall be equipped with an electrical interlock system that will turn the cyclotron off immediately upon opening any shield.
 - B. All safety and warning devices, including interlocks, shall be checked for proper operation upon initial installation, at intervals not to exceed three (3) months and after maintenance which might affect their operability. Results of such tests shall be maintained for inspection at the cyclotron facility.
 - C. In the event of malfunction of any interlock, the cyclotron shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
21. Upon initial operation, and subsequent to any maintenance of the cyclotron, radiation surveys shall be performed with the proton beam "on" and shall clearly establish:
 - A. The radiation levels in controlled areas are not likely to cause personnel exposure in excess of the limits specified in Regulation 28-35-212a of the Kansas Radiation Protection Regulations, Part 4, "Standards for Protection Against Radiation."

State of Kansas

Page 4 of 5

Radioactive Materials License

Supplementary Sheet

License Number: 10-C842 Amendment No. 5

B. That quantities of radiation in uncontrolled areas do not exceed the limits specified in Section 28-35-214(a).

A report of the results of the above surveys and tests shall be maintained for inspection by the Department.

22. Notwithstanding the possession limits in Item 8 of this license, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in K.A.R. 28-35-180b for establishing financial assurance for decommissioning.
23. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of K.A.R. 28-35-196a, "Preparation of Radioactive Material for Transport".
24. The licensee shall comply with the provisions of Kansas Radiation Protection Regulations, Part 4, "Standards for Protection Against Radiation" and Part 10, "Notices, Instructions and Reports to Workers; Inspections."
25. The licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license according to the most restrictive of; the Kansas Radiation Protection Regulations, this license or statements, representations, and procedures contained in the following documents.
 - a. The letter dated April 18, 2003, signed by David Saidian, with attachment.
 - b. The letter dated June 11, 2003, signed by David Saidian, with attachment.
 - c. The letter dated August 27, 2003, signed by David Saidian, with attachment.
 - d. The electronic mail dated October 6, 2003 from David Saidian, with attachment.
 - e. The electronic mail dated October 9, 2003, from David Saidian, with attachment.
 - f. The facsimile dated January 26, 2004, from David Saidian, with attachment.
 - g. The facsimiles dated January 29, 2004, February 2, 2004 and February 4, 2004, from Shannon, with attachments.
 - h. The electronic mail dated February 5, 2004, from David Saidian.
 - i. The letter dated February 12, 2005, signed by David Saidian, with attachment.
 - j. The letter dated March 21, 2005, signed by William F. Harris.
 - k. The electronic mail dated August 15, 2005, from David Saidian.
 - l. The letter dated August 16, 2006, signed by David Saidian, with attachments.
 - m. The electronic mail dated October 17, 2006, from David Saidian.
 - n. The electronic mail dated February 6, 2007, from David Saidian.

State of Kansas

Page 5 of 5

Radioactive Materials License

Supplementary Sheet

License Number: 10-C842 Amendment No. 5

FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT

Date March 2, 2007

By: _____



**Thomas A. Conley, CHP
Radiation Control Program**