

# PETNET Solutions

NMSB 2

March 7, 2007

Licensing Section  
Nuclear Materials Section Branch 1  
Division of Nuclear Materials Safety  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

RECEIVED  
REGION 1  
2007 MAR 12 PM 12:45

03035323

Re: PETNET Solutions North Wales, PA Facility, NRC Materials License # 41-30557-01

Dear Sir/Madam,

The purpose for this letter is to request an amendment for PETNET Solutions North Wales, PA facility (Materials License # 41-30557-01).

Specifically it is requested that the following items be amended to our license:

1. We request that Tigran Sinanian be added to license condition 12 of our license as an authorized user. Mr. Sinanian was previously listed as an authorized nuclear pharmacist (ANP) on New Jersey radioactive materials license number NJSL-10826/01/000.
2. We also request that the Radiation Safety Officer (RSO) be changed from Barbara Missal to Tigran Sinanian, per License Condition 11 of our radioactive materials license (License # 41-30557-01). Mr. Sinanian meets the RSO qualifications per NUREG – 1556 Vol. 13, *NRC's Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses* which states that: Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist (ANP) is also considered qualified to serve as the facility RSO.
3. We also request that Matthew Mauro and Barbara Missal be removed from license condition 12 of our NRC materials license as they are longer employees of PETNET's North Wales, PA facility.

140200

**NMSS/RGN1 MATERIALS-002**

PETNET Solutions, Inc.  
A Siemens Company

810 Innovation Drive  
Knoxville, TN 37932

Tel: (800) 738-0488  
Fax: (865) 218-3018

# PETNET Solutions

We trust that this information is sufficient for you to grant the requested license amendment. If you have any additional questions, please contact me at the number below, or Frank Plastini 518-452-1018.

Sincerely,



Roger Moroney, CHP  
Manager, Radiological Compliance & Corporate RSO  
PETNET Solutions, Inc.  
E-mail: [william.moroney@siemens.com](mailto:william.moroney@siemens.com)  
Voice: 865-218-2595  
Fax: 865-218-3018

Cc: Tigran Sinanian  
RSO  
PETNET Solutions, Inc.  
North Wales, PA

Frank Plastini  
Regional Health Physicist  
PETNET Solutions, Inc  
Northeast Region

**ENCLOSURE**

**Tigran Sinanian**

**New Jersey Radioactive Materials License NJSL-10826/01/000**



Pennsylvania Department of  
State Bureau of Professional and  
Occupational Affairs



License Verification

**Person Information**

**Name:** TIGRAN SINANIAN

**Address(city,state zipcode):** Palisades Park NJ 07650

**Employer Information**

No Information Found

**License Information**

**Type:** Pharmacist    **Secondary Type:** N/A

**Number:** RP437208

**Profession:** Pharmacy

**Status:** Active

**Obtained By:** Reciprocity

**Issue Date:** 10/5/2001

**Expires:** 9/30/2008

**Last Renewed:** N/A

**Standing:** This license is in good standing.

**Disciplinary action history:** No disciplinary actions were found for this license.

[Return to Licensee Search](#) | [Back to Results](#)

# State of New Jersey

Department of Environmental Protection  
 Bureau of Environmental Radiation  
 Radioactive Materials Section  
 PO Box 415, Trenton, NJ 08625-0415  
 Phone (609) 984-5462

## New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

1. License No.: <b>NJSL-10826/01/006</b>	2. Expiration Date: <b>04/30/2010</b>
3. Licensee: <b>PETNET SOLUTIONS, INC.</b>	4. Address: <b>816 Innovation Drive</b>
Radiation Safety Officer: <b>Tigran Sinanian</b>	<b>Knoxville TN 37932</b>
Administrator: <b>Roger Moroney</b>	County: <b>Telephone: (865) 218-2593</b>
	5. Reference No.: <b>4950</b>

### RADIOACTIVE MATERIALS DATA (A)

6. Material	7. Limit (mCi)	8. Form
A. Any radioactive material with atomic number 3-83	2900.0000	Activation Products
B. CO-57	6.0000	Sealed Source
C. F-18	20000.0000	Any Form
D. Ge-68	.015	Sealed Source
E. Na-22	0.200	Sealed Source

### RADIOACTIVE MATERIALS DATA (B)

9. Authorized Use
- A. Contamination, induced activity or activation products resulting from cyclotron operations.
  - B. For installation and calibration.
  - C. For processing, mixing or compounding and distribution/re-distribution to licensed recipients and for in-house calibration.
  - D. For installation and calibration.
  - E. For installation and calibration.

Conditions begin on the following page.

## New Jersey Radioactive Materials License

10. Radioactive material shall only be used at 86-110 Orchard Street, Hackensack, New Jersey 07601.
11. A. Radioactive material listed in Conditions 6, 7 and 8 shall be used by or under the supervision of the following:  
Tigran Sinanian, R.Ph, BCNP, Victor A. Calonico, R.Ph, BCNP and Beth Kraemer, R.Ph..  
  
B. Radioactive material listed in Conditions 6, 7 and 8 may be used by the following for Non-Human Use Only:  
Chris Grosch, Michael Trenbeath, Lucas Fernandez and Larry Beagle.
12. This license authorizes commercial distribution of material listed in Condition 6C only to nuclear pharmacies and distributors that have been specifically licensed to receive the materials.
13. Compliance with other U.S. Agencies having jurisdiction and regulations for radioactive materials must be maintained.
14. In addition to the reporting requirements stated elsewhere in NJAC 7:28, the licensee shall notify the Department as follows:  
  
The licensee shall notify the Department of any identified defects in any products containing naturally occurring and accelerator produced radioactive materials which present a substantial safety hazard. Notification of the Department shall include an initial notification by telephone within 2 days following receipt of the information of the product defect and a written notification within 30 days following receipt of the information of the product defect. The written report is to include the following:  
  
Name and address of individual informing the Department.  
Identification of the product experiencing defect.  
Name of company which supplied the defective product.  
Nature of the defect or failure,  
Date on which licensee was informed of the defective product,  
Number and location of all such products distributed,  
Corrective actions which have been or will be taken, and  
Any advice related to the defect that has been, is being, or will be given to purchasers of the product.
15. The licensee shall not open sealed sources containing radioactive materials.
16. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.
  - A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
  - B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.
  - C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.
17. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.
18. The licensee shall make the following items available to their staff:
  - A. Copy of the New Jersey Radiation Protection Code.
  - B. Copy of the New Jersey State Radioactive Material License.

## New Jersey Radioactive Materials License

19. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
- Notice to Employees -- RPP-14.
  - Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.
  - Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.
20. The following records shall be maintained:
- Radioactive materials received including but not necessarily limited to: date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
  - Survey instrument calibration performed annually and after instrument repair.
  - Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
  - Personnel dosimetry records including but not necessarily limited to name, social security number, and prior employment exposure history.
  - Daily personnel monitoring results including but not necessarily limited to instrument used, date performed and initials.
  - Copies of records and reports required by the US Food and Drug Administration (FDA) as per 21 CFR 211.198 and 310.305 regarding products containing naturally occurring and accelerator produced radioactive materials.
21. While utilizing radioactive material, personnel shall use protective equipment and clothing including but not necessarily limited to: remote handling equipment, adequate shielding, laboratory coats and disposable gloves.
22. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.
23. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license only in accordance with statements, representations and procedures contained in New Jersey Radioactive Materials License Application dated May 24, 2004 signed by Tom Welch.
- Letter dated August 23, 2004
  - Letter dated October 6, 2004
  - Letter dated November 8, 2004
  - Letter dated January 12, 2005
  - Letter dated May 23, 2005
  - Letter dated October 24, 2005
  - Letter dated January 4, 2006
  - Letter dated July 5, 2006
  - Letter dated November 16, 2006

New Jersey Department of Environmental Protection Signature

Date: 1/8/07

By: Auction P. Casazza

For the NJ Department of Environmental Protection

This is to acknowledge the receipt of your letter/application dated

3/7/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 41-30557-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 140200.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.