

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

PETNET Solutions, Inc.  
810 Innovation Drive  
Knoxville, TN 37932  
Royal Oak, MI facility

REPORT NUMBER(S) 2014-001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38346

4. LICENSE NUMBER(S)

41-32720-05MD

5. DATE(S) OF INSPECTION

December 18, 2014

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:


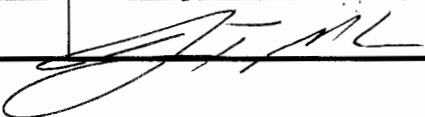
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura, Health Physicist		12/18/14
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		12/24/14

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87127	7. INSPECTION FOCUS AREAS  03.01-03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03210	2. PRIORITY  2	3. LICENSEE CONTACT  Wayne Melchior, PharmD., RSO	4. TELEPHONE NUMBER  (248) 849-8622
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Main Office Inspection                      Next Inspection Date:                      Dec. 2016  
 Field Office Inspection    3601 West 13 Mile Rd, Royal Oak, MI  
 Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a routine inspection of PETNET's Royal Oak pharmacy. The licensee employed one cyclotron engineer, two ANPs, a radiochemist, two technicians, and six contract drivers/couriers. The pharmacy served customers located in the Detroit Metropolitan and surrounding areas and distributed approximately 70 doses daily. The majority of the licensee's activities involved F-18 FDG. The licensee utilized its cyclotron for the production of F-18, C-11, N-13 and O-15 (authorized under License No. 41-32720-06). The corporate office conducted annual audits of the pharmacy (last August 18-21, 2014, with minor findings).

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the radiopharmacy, and independent measurements. During this inspection, the inspector observed early and mid-morning runs. These observations included dose calibrator QC/QA tests, drawing doses, packaging doses for shipment, and conducting surveys for compliance with NRC and DOT requirements. The inspector noted that the pharmacy personnel followed the following radiation safety practices during this inspection:

- All pharmacy personnel wore their assigned dosimetry
- Staff performed personal surveys prior to leaving the restricted area
- Staff wore gloves/protective clothing & used tongs/remote handling tools & remote manipulators while handling RAM
- No evidence of eating or drinking in the restricted areas

The maximum whole body and extremity exposures were reported (in millirem) as follows:

	YTD 2014	2013	2012
TEDE	577	1,120	1,442
SDE	5,970	6,590	11,200

No violations of NRC requirements were identified.