

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

PETNET Solutions, Inc.
810 Innovation Drive
Knoxville, TN 37932

REPORT NUMBER(S) 2012-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38228

4. LICENSE NUMBER(S)

41-32720-04MD

5. DATE(S) OF INSPECTION

July 31, 2012

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 violations(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	<i>Deborah A. Piskura</i>	7/31/2012
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB	<i>T. Bloomer</i>	8/14/12

Docket File Information

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3. DOCKET NUMBER(S) 030-38228	4. LICENSE NUMBER(S) 41-32720-04MD	5. DATE(S) OF INSPECTION July 31, 2012	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.08		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Rita Gentilcore, R.Ph., RSO	4. TELEPHONE NUMBER (314) 577-8800
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☐ Main Office Inspection Next Inspection Date: July 2014

☒ Field Office Inspection 3635 Vista Ave., St. Louis, MO

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This initial inspection was conducted in accordance with Manual Chapter 2800; the initial license for medical distribution of PET material was issued November 2011. The licensee formerly operated under a State of Missouri registration. The St. Louis pharmacy employed two ANPs, two pharmacy technicians, and 6 contract drivers/couriers. The pharmacy served approximately 15-20 customers located in the St. Louis Metropolitan and surrounding areas and distributed approximately 30-40 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. 41-32720-03). The corporate office conducted annual audits of the pharmacy (last September 2011 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 and used tongs/remote 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 2012	2011
Whole body	1,087	1,392
Extremity	19,350	13,700