

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

PETNET Solutions, Inc.
1345 West 16th Street
Indianapolis, Indiana

REPORT NUMBER(S) 2014001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38158 , 030-38156

4. LICENSE NUMBER(S)

41-32720-02MD , 41-32720-01

5. DATE(S) OF INSPECTION

March 26 , 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. *from 030-38158/12-01*
- ☐ 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	Geoffrey M. Warren / Andrew Brannick	<i>GJ Warren / Andrew Brannick</i>	3/26/14
BRANCH CHIEF	Aaron T. McCraw	<i>Aaron T. McCraw</i>	4/7/14

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 1345 West 16th Street Indianapolis, Indiana REPORT NUMBER(S) 03038156/2014001 and 03038158/2014001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-38156 and 030-38158	4. LICENSE NUMBER(S) 41-32720-01 and 41-32720-02MD	5. DATE(S) OF INSPECTION March 26, 2014
6. INSPECTION PROCEDURES USED 87125, 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07, 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210, 02500	2. PRIORITY 2	3. LICENSEE CONTACT Joel Readinger, R. Ph., RSO	4. TELEPHONE NUMBER (317) 278-9600
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☒ Main Office Inspection Next Inspection Date: Mar. 2016

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. At this facility, PETNET operated a cyclotron for production of fluorine-18 (F-18) and nitrogen-13 (N-13) under the -01 license and a radiopharmacy for production and distribution of F-18 FDG and N-13 ammonia doses under the -02MD license. At this site, the company employed two pharmacists, two pharmacy technologists, one chemist, and one cyclotron engineer, and contracted with another company for eight drivers. The licensee had eleven to twelve regular customers located mostly in central Indiana, and distributed 50 to 60 doses daily. The pharmacy was open weekdays from 2:00 am through noon. The cyclotron engineer typically worked from 6:00 pm through 2:00 am. Three cyclotron runs were scheduled daily, unloading at 3:30, 5:30, and 8:00 am. Shipments for each run left the facility by 6:00, 8:30, and 10:00 am, respectively. The maximum dose received by licensee personnel in 2012 was 2470 mrem whole body and 20.7 rem extremity; for 2013, 1774 mrem whole body and 17.1 rem extremity, and for 2014 to date, 109 mrem whole body and 2.7 rem extremity.

Performance Observations: The inspectors observed F-18 receipt from the cyclotron, QC sample collection and evaluation, dose drawing, dose packaging and surveys, package preparation and survey, package labeling, shipping paper preparation and placement, package blocking and bracing, daily surveys, package return surveys, and placing of materials in decay in storage (DIS). Licensee personnel demonstrated chemistry reagent setup, and dose calibrator constancy, and described waste disposal, cyclotron operation and maintenance, oversight of cyclotron operation, emergency procedures, and control of public dose. The inspectors noted no concerns with these activities. The inspectors observed that the licensee used remote handling systems and a hot cell for dose preparation and long-handled tools and proper shielding for doses outside the hot cell. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

During the previous inspection, the licensee was cited for the failure for drivers to survey themselves or the carts used to transfer packages out of the restricted area as required by License Condition 21 of the -02MD license. During this inspection, the inspectors observed that drivers did not enter the restricted area and that carts were kept either inside or outside the restricted area; instead, packages were transferred between carts at the marked boundary. These actions were in accordance with the corrective actions provided by the licensee. Based on this, the violation is closed.