

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

PETNET Solutions, Inc.  
810 Innovation Dr.  
Knoxville, TN 37932  
Location Inspected: Royal Oak, MI facility  
REPORT NUMBER(S) 2022001

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

February 2, 2022

## 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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman	Digitally signed by Zahid M. Sulaiman Date: 2022.02.16 16:35:00 -06'00'
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski	Digitally signed by Michael A. Kunowski Date: 2022.02.25 14:32:06 -06'00'



## Materials Inspection Record

1. Licensee Name: PETNET Solutions, Inc.		2. Docket Number(s): 030-38346		3. License Number(s) 41-32720-05MD	
4. Report Number(s): 2022001			5. Date(s) of Inspection: February 2, 2022		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02500		8. Priority: 2	9. Inspection Guidance Used: 87125, 87127
10. Licensee Contact Name(s): Wayne Melchior, RSO		11. Licensee E-mail Address: wayne.melchior@petnetsolutions.org		12. Licensee Telephone Number(s): (248) 898-1642	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 02/02/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

## 16. Scope and Observations:

This was an unannounced routine inspection of a radiopharmacy located in Royal Oak, Michigan. The licensee was authorized to produce, prepare, and distribute radioactive drugs to authorized clients. The licensee used its cyclotron to produce fluorine-18 (FDG), and nitrogen-13 (N-13) labeled ammonia; the majority of production involved F-18 FDG. The licensee dispensed approximately 90-100 unit doses daily and distributed to customers in the Detroit metropolitan, upper peninsula Michigan, and around Toledo, Ohio areas. The licensee's three production runs occurred between 12:00 am and 9:00 am, Monday - Friday. The radiochemical produced by the cyclotron was transferred via shielded lines to a hot cell to be processed and developed for distribution. The licensee was staffed with three authorized nuclear pharmacists (ANPs), a pharmacy technician, a chemist, and a cyclotron engineer. The licensee contracted out the shipping of the materials to a delivery company, which staffed with 10 drivers. The licensee performs quarterly audits of the drivers.

## PERFORMANCE OBSERVATIONS

This inspection consisted of interviews with select licensee personnel; a review of select records; a tour of the facility; and independent measurements. At the time of inspection, no licensed activities was conducted. The inspector had the ANP demonstrate a variety of activities: the production run, clients order processing, kit labeling and preparation, dose drawing, client package preparation, DOT package labeling, package surveys, and as well as client package return and waste handling. The ANP discussed and demonstrated how the radiochemicals are developed and processed in the hot cell, the use of robotic arms to draw doses, and how the packages are prepared for distribution. The ANP also demonstrated the F-18 chemistry process, radionuclide purity check, and QA/QC process. The inspector observed that staff wore the assigned dosimetry ring and body badge, wore gloves and protective clothing while handling radiochemical, and monitored their hands and feet for contamination before exiting the restricted area. Interviews with licensee staff and through demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed the dose calibrator constancy, linearity, accuracy; well counter efficiency test, survey meter calibration, weekly wipes and daily survey records; waste disposals records and waste shipment manifest; DOT hazmat training; annual audits; radionuclide purity check; sealed source inventory and leak test reports; and annual air emission report dated March 5, 2021. The inspector reviewed the dosimetry records for 2020 through December 31, 2021 indicating the maximum annual dose to be 0.963 rem - DDE and 13.74 rem - SDE. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.

Materials Inspection Record (Continued)