NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
PETNET Solutions, Inc. 810 Innovation Drive Knoxville, TN 37932 **Report Number(s)** 2023001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-38156 / 030-38158	41-32720-01 / 41-32720-02MD	July 20, 2023

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M. Sulaiman Date: 2023.08.11 13:53:30 -05'00'
BRANCH CHIEF	Rhex Edwards, Chief, MIB	Digitally signed by Rhex A. Edwards Date: 2023.08.17 06:57:00 -05'00'

Add Continuation Page

NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
PETNET Solutions, Inc.	030-38156 / 030-38158	41-32720-01 / 41-32720-02MD

4. Report Number(s):	5. Date(s) of Inspection:
2023001	July 20, 2023

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	03210/ 02500	2	87125, 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Heather McClley, RPh, RSO	Heather.fry@petnetsolutions.com	Work: 317-278-9600

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☐ Hybrid	
☑ Routine ☐ Announced	☑ Main Office ☐ Field Office	07/20/2025 ☑ Normal ☐ Extended
☐ Non-Routine ☑ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Location(s) Inspected List:
Main office: 1345 W 16th Street, Indianapolis, IN 46202

17. Scope and Observations:

This was an unannounced routine inspection of a cyclotron production facility located in Indianapolis, Indiana. The licensee was authorized to produce, prepare, and distribute radioactive drugs to authorized clients. The licensee used its cyclotron to produce flourine-18 (FDG), and occasionally 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 around Indianapolis, Ohio, Kentucky, and Michigan areas. The licensee was staffed with two authorized nuclear pharmacists (ANPs), two pharmacy technicians, two biomarker specialists, and a cyclotron engineer. The licensee's three production runs occurred between 12:00 am and 9:00 am, Monday - Friday. The licensee transferred operation of the cyclotron to IU Medical Center staff in an adjacent laboratory for R&D use after the production run. The radiochemical produced by the cyclotron was transfered via shielded lines to a hot cell to be processed and developed for distribution. The licensee contracted out the shipping of the materials to a delivery company, which staffed five drivers. The licensee performed quarterly audits of the drivers. The inspector observed the delivery driver blocked and braced the package and placed the bill of lading next to the driver side, no issues were noted.

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, cyclotron production was in-process. The inspector observed and had the ANP demonstrate a variety of activities: the production run, client order processing, kit labeling and preparation, dose drawing, client package preparation, DOT package labeling, package surveys, as well as client package return and waste handling. The inspector observed 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 inspector observed and had the biomarker specialist demonstrated the F-18 chemistry process (GC, TLC, PTS, PH), radionuclide purity check, QA/QC, and synthesis process. The inspector had the licensee's staff demonstrate the implementation of procedures for cyclotron operations, byproduct materials productions, preventative maintenance, area surveys, and waste handling. The inspector observed that staff wore their assigned dosimetry ring and body badge, wore gloves and protective clothing while handling radiochemical, and monitored

Materials Inspection Record (Continued)

their hands and feet for contamination before exiting the restricted area. Interviews with licensee staff and demonstrations indicated the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed the dose calibrator constancy, linearity, and accuracy; well counter efficiency test, survey meter calibration, weekly wipes and daily survey records; waste disposals records and waste shipment manifest; DOT hazmat training; radionuclide purity check; sealed source inventory and leak test reports; and annual air emission report dated March 3, 2023. The inspector reviewed a selection of records relating to the use of the cyclotron, monthly target preventative maintenance log, QA/QC process, area surveys, lock-out/tag-out training, quarterly internal and annual audits (June 6-8, 2023), and exhaust system performance log.

The inspector reviewed the dosimetry records for 2022 through April 30, 2023 indicating the maximum annual dose to be 2.8 rem - DDE and 14.34 rem - SDE. The inspector reviewed two declared pregnancy fetal monitoring reports and the result were within the regulatory limits. 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.

Signature and Date - Branch Chief

Digitally signed by Rhex A. Edwards
Date: 2023.08.17 06:56:30 -05'00'