NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
PETNET Solutions, Inc. 810 Innovation Drive Knoxville, TN 37932 REPORT NUMBER(S) 2021-001	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	4/15-28/2021

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	Joel Readinger, RSO		
NRC INSPECTOR	Robert G. Gattone, Jr.	Robert G. Gattone Digitally signed by Robert G. Gattone Date: 2021.04.28 13:00:46 -05'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.04.29 05:14:12 -05'00'	

NRC FORM 592M
(10-2020)

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:
2021-001	4/15-28/2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Robert Gattone	03210 / 02500	2	87125

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Joel Readinger, RPh, RSO	Joel.Readinger@Petnetsolutions.com	317-278-9600

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☐ Main Office ☐ Field Office ☐ Temporary Job Site ☑ Remote	04/15/2023 ☐ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was announced remote inspection of a cyclotron facility authorized for the production of PET radiopharmaceuticals at a facility in Indianapolis, Indiana, and for distribution of these products to authorized recipients. The licensee produced 70-100 doses containing F-18 per day (mostly FDG with occasional amyvid and NaF). Two pharmacists, one technologist, and one cyclotron engineer were involved in the production of these doses. The engineer worked from 4:00 pm to 12:00 am, while the production staff worked from 12:00 am until 9:00am, when the licensee transferred operation of the cyclotron to IU Medical Center staff in an adjacent laboratory for R&D use. The licensee scheduled two runs daily, commencing production around 10:30pm and 3:30am and ending around 3:00am and 6:00am, with doses out by 5:00am and 8:00am, respectively. The licensee retained the services of third party couriers to deliver doses to clients throughout central Indiana and eastern Illinois.

The inspector: (1) observed records for 2020 and 2019 regarding radiation badges with the doses who used the badges, and there were no issues; (2) observed records for sealed source inventories and leak tests, and there were no issues; (3) observed the latest three records for wipe surveys and ambient exposure rate surveys done in the hot cell door, and the counter, and the cyclotron control and there were no issues; (4) observed annual records for the COMPLY applications results about radioactive material air effluents released into the environment for 2018, 2019, 2020 and there were no issues; (5) noted that the effluent monitor is an Ultra Electronics PET System and the PET pharmacy and cyclotron are exhausted through one stack and all radioactive effluents pass through the monitor and there were no issues; (6) observed a photo showing that radioactive materials are secured; (7) observed a photo showing a door with a sign stating, "Caution Radiation Area", and another door showing "Caution Radioactive Materials"; (8) observed photos showing appropriate survey meters; (9) observed several records for HAZMAT training certificates and no issues; (10) observed calibration records for survey meters and there were no issues; (11) observed dose calibrator calibration records and there were no issues; (12) observed a photo showing a person using PPE (i.e., gloves, protective gown); (13) observed a photo showing a person handling a sealed source while using a long forceps to handle the sealed source to minimize radiation dose to the handler; (14) observed a photo showing the dose calibrator and it was applicable; (15) observed a photo showing the "Ultra Stack Monitor and there were no issues; and (16) observed records for ALARA audits records per 10 CFR 20.1101(c)for 2018, 2019, and 2020 and there were no issues.