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) 2018001	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	May 23-24, 2018

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	Ryan Craffey	Ryan Craffey	5/24/18
BRANCH CHIEF	Aaron McCraw		06/01/2018

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87125	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03210 / 02500	2	Joel Readinger, RPh - RSO	(317) 278-9600

☐ Main Office Inspection Next Inspection Date: 05/23/2020

☑ Field Office Inspection 1345 West 16th Street, Indianapolis, IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine 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. At the time of the inspection, the licensee produced 70-100 doses containing F-18 per day (mostly FDG with occasional amyvid and NaF). Two pharmacists, one chemist, one technologist, and one cyclotron engineer were involved in the production of these doses. The engineer worked from 6:00 pm to 2:00 am, while the production staff worked from 12:00 am until around 9:00 am, 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 10:30 pm and 3:30 am and ending around 3:00 am and 6:00 am, with doses out by 5:00 am and 8:00 am, respectively. The licensee retained the services of third party couriers to deliver doses to clients throughout central Indiana and eastern Illinois.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Indianapolis to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector observed various aspects of production on the licensee's second run, including cyclotron unloading, FDG synthesis, remote dose drawing, package preparation, and vehicle loading. The inspector conducted independent surveys of restricted and unrestricted areas before, during, and after production, and interviewed the licensee's staff to discuss implementation of procedures for cyclotron maintenance, FDG production, radioactive waste handling, air effluent monitoring, and the use of electronic personnel dosimetry. The inspector found that the staff were knowledgeable of radiation protection principles, and implemented adequate engineering and process controls to minimize occupational radiation exposures.

The inspector also reviewed a selection of records, including internal and external health physics audits, dose calibrator quality control records, annual COMPLY runs, hazmat refresher training for couriers, and personnel dosimetry reports, which recorded maximum annual exposures of 2,345 millirem whole-body, and 25,675 millirem extremity in 2017.

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