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 Indianapolis, IN pharmacy REPORT NUMBER(S) 2016-001	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	June 16, 2016

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	Deborah A. Piskura, Senior Health Physicist	Deborah A. Piskura	6/16/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		6/28/16

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
87127 & 87125	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

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

☐ Main Office Inspection Next Inspection Date: June 16, 2018

☑ Field Office Inspection 1345 West 16th St., Indianapolis, IN pharmacy

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of the cyclotron production (-01) and distribution (-02MD) licenses. The licensee used its cyclotron daily to produce F-18 and N-11 for PET imaging agents; the majority of production involved F-18 FDG. The production operations stopped at approximately 9:00am. The owner of the unit, IU Medical Center resumed operations for R&D purposes. One individual served as the cyclotron engineer and operated/maintained the cyclotron. As material was produced, it was transferred via shielded lines to a hot cell. Once the radiopharmaceuticals were compounded and removed from the hot cell, the material was packaged for transfer to the company's radiopharmacy license (-02 MD) for distribution. This pharmacy distributed 50-60 doses daily to its customers in the central Indiana area. The pharmacy was staff with 3 ANPs and 2 pharmacy technicians. The licensee utilized a courier contractor to transport the doses. The licensee's corporate office conducted annual audits of the radiation safety program (last Feb. 3-4, 2016). The site RSO conducted monthly audits of the radiation safety program. The maximum whole body and extremity exposures were reported (in millirem) as follows:

	YTD 4/30/2016	2015	2014
WB	645	1,701	1,369
Extremity	7,740	14,100	10,380

This inspection consisted of interviews with select licensee personnel; a review of select records; and independent surveys. The inspector toured the facility and observed operations. The inspector observed cyclotron operations and safety checks, surveys, and F-18 chemistry, purification, and QA/QC. For the pharmaceutical operations, the inspector observed early and mid-morning runs. These observations included dose calibrator QC/QA tests, drawing doses, packaging doses for shipment, and conducting surveys for compliance with NRC and DOT requirements. The inspector observed the licensee personnel performing the following radiation safety practices:

-All pharmacy personnel wore their assigned dosimetry
-Staff performed personal surveys prior to leaving the restricted area
-Staff wore gloves/protective clothing & used tongs/remote handling tools & remote manipulators while handing RAM
-No evidence of eating or drinking in the restricted areas