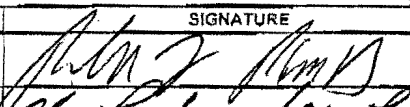
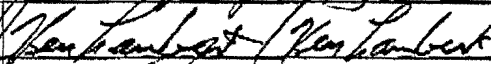
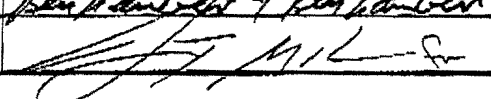


NRC FORM 591M PART 1 (07-2012) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION	
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION			
1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 1345 West 16th Street Indianapolis, IN REPORT NUMBER(S) 12 -001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 isle. IL 60532-4352	
3. DOCKET NUMBER(S) 030-38156	4. LICENSE NUMBER(S) 41-32720-01	5. DATE(S) OF INSPECTION 7/24/2012	
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:			
<div style="display: flex; flex-direction: column;"> <div style="margin-bottom: 10px;"> <input checked="" type="checkbox"/> 1. Based on the inspection findings, no violations were identified. </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> 2. Previous violation(s) closed. </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> 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. </div> <div style="margin-bottom: 10px;"> <p style="text-align: center;">Non-cited violation(s) were discussed involving the following requirement(s):</p> </div> <div style="margin-bottom: 10px;"> <p style="text-align: center;"> </p> </div> <div> <input type="checkbox"/> 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) </div> </div>			
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	Rick Grigson, Pharm.D.		8/13/12
NRC INSPECTOR	Ken Lambert / Mike Herr, CHP		8/9/12
BRANCH CHIEF	Tamara Bloomer		8/9/12

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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3. DOCKET NUMBER(S) 030-38156	4. LICENSE NUMBER(S) 41-32720-01	5. DATE(S) OF INSPECTION 7/24/2012	
6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 3.01 - 3.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 3210	2. PRIORITY 2	3. LICENSEE CONTACT Rick Grigson, R.PH., RSO	4. TELEPHONE NUMBER (317) 278-9600
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- ☒ Main Office Inspection Next Inspection Date: July 2014
- ☐ Field Office Inspection
- ☐ Temporary Job Site Inspection

PROGRAM SCOPE

PETNET Solutions is a mid-sized medical isotope manufacturing company authorized to produce, possess or handle radiochemicals for transfer to persons authorized to receive licensed material, and for the packaging and distribution of produced radiochemicals to authorized licensed recipients. The license also authorizes the possession or radioisotopes incident to radionuclide production. The licensee possesses a Siemens RDS Eclipse HP self-shielded cyclotron for the production of radiochemicals.

PERFORMANCE OBSERVATIONS

The inspectors noted that radioactive materials were appropriately secured from unauthorized removal or access. The inspectors reviewed: (1) instrument calibration and response check programs; (2) corporate radiation safety audits; (3) annual review of radiation safety program; (4) inventory records and leak test results; (5) air sampling equipment calibration and operation; (6) training records for cyclotron operators and maintenance engineers; and (7) area radiation monitoring program results. The inspectors observed/discussed: (1) HP staff performing routine surveys; (2) personnel wearing appropriate PPE and required dosimetry; (3) maintenance activities involving the cyclotron; (4) daily checks of air sampling instruments and procedures for changing high efficiency particulate air and charcoal filters; (5) Waste storage and disposal activities; and (6) that cyclotron facilities were as described in the license. The inspectors determined that licensee staff were knowledgeable regarding radiation safety and emergency procedures.

The inspectors performed independent radiological surveys using a Canberra UltraRadiac survey instrument last calibrated on October 18, 2011. Surveys were comparable with licensee survey results and were performed around the shielded cyclotron during operation and of waste storage areas.

Inspectors reviewed external dosimetry results for 2011. The maximum DDE exposure was 1289 millirem and SDE exposure was 28,820 millirem. The maximum DDE exposure for 2012 up to June was 1059 millirem and SDE exposure was 10,900 millirem.

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