
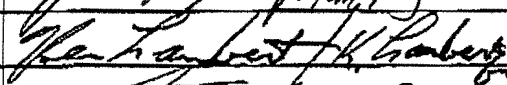


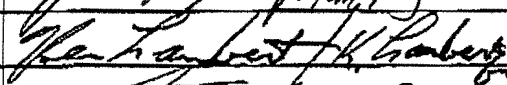


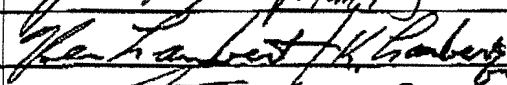


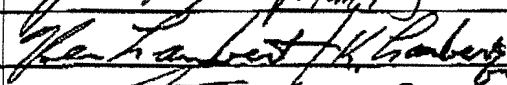


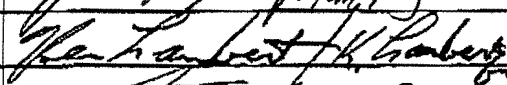


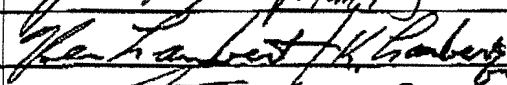



NRC FORM 591M PART 1 <small>(07-2012) 10 CFR 2.201</small>		U.S. NUCLEAR REGULATORY COMMISSION																															
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION																																	
1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 1345 West 16th Street Indianapolis, IN REPORT NUMBER(S) 12-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352																															
3. DOCKET NUMBER(S) 030-38158	4. LICENSE NUMBER(S) 41-32720-02MD	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:																																	
1. Based on the inspection findings, no violations were identified.																																	
2. Previous violation(s) closed.																																	
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.																																	
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)																																	
License Condition 21 of NRC License No. 41-32720-02MD requires, in part, that the licensee to conduct its program in accordance with application, dated September 4, 2009. Item 10, Section 6 of the application requires, in part, to monitor hands, feet and clothing upon exiting the restricted areas; and items take out of the restricted area must be surveyed to prevent inadvertent transfer of contamination/exposure to an unrestricted area. Contrary to the above contract courier drivers failed to conduct personal surveys prior to exiting the restricted area and the licensee failed to conduct surveys of equipment carts used to transport containers containing licensed materials out of the restricted area.																																	
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.																																	
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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
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38158

4. LICENSE NUMBER(S)

41-32720-02MD

5. DATE(S) OF INSPECTION

7/24/2012

(Continued)

The licensee sent a letter dated July 30, 2012 describing their corrective actions. The licensee will prohibit entry of drivers and their carts into the restricted areas. The licensee will deliver radioactive material cases to the restricted area boundary on a cart. The drivers, without entering the restricted area, will transfer the cases to carts in the unrestricted area. The licensee will also conduct training for all contract couriers regarding these requirements. The licensee will also mark the floor at the restricted area entrance with magenta/yellow hashed tape to clearly delineate the area.

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 1345 West 16th Street Indianapolis, IN REPORT NUMBER(S) 12-01	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-38158	4. LICENSE NUMBER(S) 41-32720-02MD	5. DATE(S) OF INSPECTION 7/24/2012
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6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 3.01-3.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	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 under License No. 41-32720-02MD to prepare and distribute radiological drugs in accordance with 10 CFR 32.72 and also non-medical use; specifically fluorine-18, nitrogen-13, carbon-11, oxygen-15. The licensee is authorized to possess hydrogen-3 as a incidental isotope of production. Cobalt-57, cesium-137, and sodium-22 are also authorized to be possessed by the licensee for calibration purposes.

PERFORMANCE OBSERVATIONS

The inspectors noted that radioactive materials were appropriately secured from unauthorized removal or access. The inspectors reviewed: (1) licensees computer verification programs for ensuring commercial nuclear pharmacies requesting materials have authorization to receive these materials; (2) instrument calibration and response check programs including dose calibrator checks; (3) corporate radiation safety audits; (4) annual radiation program reviews; (5) inventory records and leak test results; (6) air sampling equipment calibration and operation; and (7) training records for laboratory staff and drivers. The inspectors observed/discussed: (1) surveying and labeling of packages before shipment; (2) HP staff performing routine surveys; (3) personnel wearing appropriate PPE and required dosimetry; (4) that radioactive material packages were blocked and braced in delivery vehicles; and (5) shipping papers were complete and stored in appropriate locations in delivery vehicles. The inspectors determined that drivers were knowledgeable about transportation requirements and emergency procedures. 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.

The inspectors identified a violation involving the licensee's contract courier drivers' failure to survey hands, feet, clothing, and items upon exiting restricted areas in accordance with License Condition (LC) 21 of the license. LC 21 requires the licensee to conduct its program in accordance with its application that included procedures on the safe use of radioactive materials. The licensee implemented appropriate corrective actions which included retraining drivers to not enter the restricted areas and modifying the process to move radioactive material containers from the restricted area.

ATM