

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 810 Innovation Drive Knoxville, TN 37932 REPORT NUMBER(S) 2012-001	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) 030-38228	4. LICENSE NUMBER(S) 41-32720-04MD	5. DATE(S) OF INSPECTION July 31, 2012
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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Rita Gentilcore, R.Ph., RSO	4. TELEPHONE NUMBER (314) 577-8800
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Main Office Inspection Next Inspection Date: July 2014
 Field Office Inspection 3635 Vista Ave., St. Louis, MO
 Temporary Job Site Inspection

PROGRAM SCOPE

This initial inspection was conducted in accordance with Manual Chapter 2800; the initial license for medical distribution of PET material was issued November 2011. The licensee formerly operated under a State of Missouri registration. The St. Louis pharmacy employed two ANPs, two pharmacy technicians, and 6 contract drivers/couriers. The pharmacy served approximately 15-20 customers located in the St. Louis Metropolitan and surrounding areas and distributed approximately 30-40 doses daily. The majority of the licensee's activities involved F-18 FDG. The licensee utilized its cyclotron for the production of F-18, C-11, N-13 and O-15 (authorized under License No. 41-32720-03). The corporate office conducted annual audits of the pharmacy (last September 2011 with minor findings).

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the radiopharmacy, and independent measurements. During this inspection, 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 noted that the pharmacy personnel followed the following radiation safety practices during this inspection:

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

The maximum whole body and extremity exposures were reported (in millirem) as follows:

	YTD 2012	2011
Whole body	1,087	1,392
Extremity	19,350	13,700