

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: PETNET Solutions, Inc. 3635 Vista Ave. St. Louis, Missouri REPORT NUMBER(S) 2014-001	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) 030-38230 and 030-38228	4. LICENSE NUMBER(S) 41-32720-03 and 41-32720-04MD	5. DATE(S) OF INSPECTION June 6, 2014
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6. INSPECTION PROCEDURES USED 87125, 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07, 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210, 02500	2. PRIORITY 2	3. LICENSEE CONTACT John Beyer, R.Ph, RSO	4. TELEPHONE NUMBER (314) 577-8800
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Main Office Inspection Next Inspection Date: June 6, 2016

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced, inspection. At this facility, PETNET operated a cyclotron for production of fluorine-18 (F-18) under the -03 license and a radiopharmacy for production and distribution of F-18 FDG, NaF, and other chemical forms under the -04MD license. At this site, the company employed two pharmacists, one production technologist, and one cyclotron engineer, and the licensee used contract couriers to deliver doses. The licensee had 17 regular customers located in Missouri and Illinois, and distributed 20-40 doses daily. The cyclotron engineer typically worked evenings. Two or three cyclotron runs were scheduled daily, unloading between 4:00 and 6:30 am. Shipments were typically shipped out of the facility by 8:00 am. The maximum dose received by licensee personnel in 2013 was 1764 mrem whole body and 14.0 rem extremity, and for 2014 to date, 420 mrem whole body and 10.2 rem extremity.

Performance Observations: The inspector observed F-18 receipt from the cyclotron, QC sample collection and evaluation, dose drawing, dose packaging and surveys, package preparation and survey, package labeling, shipping paper preparation, daily surveys, and package return surveys. Licensee personnel demonstrated chemistry reagent setup and dose calibrator constancy, and described waste disposal, shipping paper placement, package blocking and bracing, cyclotron operation and maintenance, oversight of cyclotron operation, emergency procedures, and control of public dose. The inspector noted no concerns with these activities. The inspector observed that the licensee used remote handling systems and a hot cell for dose preparation and long-handled tools and proper shielding for doses outside the hot cell. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector observed that the garden area remains off limits to visitors, though the licensee has requested removal of the restriction.