



**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  PETNET Solutions, Inc. 810 Innovation Drive Knoxville, TN 37932 Royal Oak, MI facility  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)  030-38347	4. LICENSE NUMBER(S)  41-32720-06	5. DATE(S) OF INSPECTION  December 18, 2014
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6. INSPECTION PROCEDURES USED  87125	7. INSPECTION FOCUS AREAS  03.01-03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03210	2. PRIORITY  2	3. LICENSEE CONTACT  Wayne Melchior, PharmD., RSO	4. TELEPHONE NUMBER  (248) 849-8622
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Main Office Inspection                      Next Inspection Date:                      Dec. 2016  
 Field Office Inspection    3601 West 13 Mile Rd, Royal Oak, MI  
 Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a routine inspection of the PETNET Royal Oak cyclotron production license. The licensee used its cyclotron daily to produce F-18 for PET imaging agents; the majority of production involved F-18 FDG. One individual serving as the cyclotron engineer operated the cyclotron. Production activities typically ran between 11:00 pm to 2:00pm. As material was produced, it was transferred via shielded lines to a hot cell. Once the radiopharmaceuticals were developed and removed from the hot cell, the material was packaged for transfer to the company's radiopharmacy license (-05 MD) for distribution. The licensee's corporate office conducted quarterly audits of the radiation safety program (last August 2014).

Individuals operating the cyclotron as well as the individuals handling the materials wore whole body and extremity (right and left rings) dosimetry. The maximum whole body and extremity exposures were reported (in millirem) as follows:

YTD 2014	2013	2012
577	1,120	1,442
5,970	6,590	11,200

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. The inspector also reviewed the corrective actions for violations of 10 CFR 20.1902(b)(2) and 20.1904(a) that were identified during the previous inspection. No violations of NRC requirements were identified during this inspection. The previous violations are closed.