Enclosure 6 - INSPECTION RECORD
Region III

Inspection Report No. 2012-001

License No. 41-32720-06
Docket No. 030-38347

Licensee (Name and Address):
PETNET Solutions, Inc.
810 Innovation Drive
Knoxville, TN 37932

Location (Authorized Site) Being Inspected: 3601 West 13 Mile Road, Royal Oak, Michigan, within William Beaumont Hospital

Licensee Contact: Wayne Melchior, Pharm. D., RSO Telephone No.: 248-898-1642

Priority: 2 Program Code: 03210
Date of Last Inspection: N/A Initial
Date of This Inspection: 10/17/2012 with continued in-office review through 11/8/2012 to review survey and training records and to discuss the licensee's procedures for handling activated targets during cyclotron maintenance activities

Type of Inspection: (X) Initial (X) Announced ( ) Unannounced
( ) Increased Controls ( ) Routine ( ) Special

Next Inspection Date: November 2014 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) **Violation(s), regional letter issued**
( ) Follow up on previous violations

Inspector(s): /T2 Bloomer for/ Date 11/26/12
Deborah A. Piskura, Health Physicist

Approved: /Tamara Bloomer/ Date 11/26/12
Tamara E. Bloomer, Chief, MIB

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
New license	August 2, 2012	

2. INSPECTION AND ENFORCEMENT HISTORY:

NA, this is an initial inspection.

3. INCIDENT/EVENT HISTORY:

None.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was the initial inspection performed in accordance with Inspection Manual Chapter (IMC) 2800 for License Number 41-32720-06 authorizing the production and handling of radiochemicals. The licensee operated a Siemens RDS-112 self-contained cyclotron unit capable of accelerating protons to energies of 11 MeV for the production of radioisotopes. The licensee used its cyclotron daily to produce C-11, F-18, O-15 and N-13 for PET imaging agents; the majority of production involved F-18. Four individuals serving as cyclotron engineers operated the cyclotron. The cyclotron was located within the William Beaumont Hospital. 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 used under the medical distribution/ radiopharmacy license (41-32720-05MD).

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 2012	
Whole body	1,034
Extremity	2,040

This inspection consisted of interviews with select licensee personnel; a review of select records; and independent measurements. The inspector toured the facility and observed operations. Licensee personnel demonstrated cyclotron operations and maintenance, F-18 and N-13 chemistry, purification, and QA/QC.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87125

Focus Areas Evaluated: 03.01 - 03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Survey Instrument Used: Canberra UltraRadiac, NRC Tag No. 33578G
Calibration Date: 12/28/2011

The inspector performed direct radiation measurements in and around the licensee's cyclotron vault, work areas, and storage areas. While measuring around a workstation within the cyclotron vault, the inspector noted readings at an area behind the L-block ranging from approximately 120 mR/hr to 350-460 mR/hr at 8 inches from the surface of cyclotron target components. These components were partially wrapped in paper towels and consisted of two Oxygen-18 targets, two aluminum nose pieces, and 1 tantalum body. The inspector noted that these target components were not labeled "Caution Radioactive Materials." In addition, since the radiation levels in this work area from these targets could result in a dose equivalent in excess of 100 mrem in 1 hour at 12 inches (30 cm) from these targets, the work area met the Part 20 definition of a high radiation area and required posting as such. Two violations of NRC requirements were identified for the licensee's failure to post a high radiation area (10 CFR 20.1902(b)(2)) and failure to label five sources of radioactive material (10 CFR 20.1904(a)).

Initial discussions with the licensee staff revealed that no one onsite was aware that these target components were placed behind the L-block on a work station. One of these components had been stored behind the L-block since the last target rebuild on October 15, 2012, which was performed by a contract service engineer. The other components had been stored in this location since the previous target rebuild activities on September 19, 2012, (performed by an on-site engineer). The licensee's procedures described in application dated July 28, 2011, Item 6, specify that sources be confined to "properly shielded containers/areas, which are appropriately marked with a radiation sign/symbol." Further, in Item 8, "Maintenance," the procedure requires the licensee to "place used targets in the designated shielded area" but does not define the shielded area. Although the workstation was partially shielded with the L-block and lead bricks, the targets were accessible by reaching around the L-block. According to the licensee's Standard Operating Procedure for Cyclotron Maintenance (RC-25), used targets are to be placed in a shielded rolling cart (aka the "bunker") within the cyclotron vault. This bunker is heavily shielded on all sides and typical radiation readings were below 2 mR/hr. The service engineer stated that he saw the targets in the work station but did not inform the site because he thought this practice must be acceptable. The Radiation Safety Officer's (RSO's) discussions with the onsite cyclotron engineer revealed that targets may have been previously stored at the workstation instead of the designated bunker. The inspector attributed the root causes of the staff's improper storage of the targets which lead to the violations identified during this inspection to inattention to detail and lack of awareness of the licensee's policies and procedures that specified the storage of targets in the bunker.

The licensee implemented the following corrective actions: (1) placed signage on the L-block alerting staff of the targets and the high radiation area until the targets were secured in the bunker on October 18, 2012; (2) conducted a training session with the staff on October 18, 2012, instructing the staff on proper storage and handling of targets; and (3) changed its survey procedures to include daily surveys of the work station in order to identify any inadvertent placement of activated materials at the workstation. The licensee intended to install an area monitor by the work station to alert staff of the presence of activated targets.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Two violations of NRC requirements were identified during this inspection:

A. 10 CFR 20.1902(b) requires that the licensee post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

Contrary to the above, between October 15 and 17, 2012, a high radiation area, at a workstation within the cyclotron vault, was not posted with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA" and the area had measurable readings ranging from 120 to 460 milliroentgens per hour.

This is a Severity Level IV Violation. (Section 6.7)

B. 10 CFR 20.1904(a) requires that the licensee ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers to take precautions to avoid or minimize exposures.

Contrary to the above, between October 15 and 17, 2012, four activated cyclotron targets did not bear labels that identified the radionuclide, or the quantity of activity, nor did they otherwise bear sufficient information to permit individuals handling or using the targets, or working in the vicinity of the targets to take precautions to avoid or minimize exposure.

This is a Severity Level IV Violation. (Section 6.7)

The inspector discussed her inspection findings with Kevin Null, Senior Reviewer. The inspector also summarized the issue involving the storage and placement of activated targets in a memo to file for the next licensing reviewer so that this issue may be resolved during a future licensing action.

5. PERSONNEL CONTACTED:

#*Wayne Melchior, Pharm.D, R.Ph. RSO
Lucas Fernandez, Manager of Field Engineering
Steven Grosch, Cyclotron Engineer
Jen Meyers, Production Technician
*#Earl Hussett, R.Ph., Pharmacy Manager
+*Frank Plastini, Regional Health Physicist
+James David Goosens, Field Service Engineer, Siemens

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting
+Individual contacted by telephone