



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 8/16/2012

NUMBER OF PAGES:
(including this page)

2

SEND TO: Rita Gentilcore, R.Ph.

LOCATION: PETNET

FAX NUMBER: 314 - 268 - 7507



VERIFY BY CALLING SENDER

FROM:
(SENDER)

Debbie Piskura

TELEPHONE NUMBER: 630 - 829 - 9867 FAX NUMBER: 630 - 515 - 1259

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Dear Rita,

Please disregard the 591 I issued on 7/31/2012 - there was a error on the form. I listed an incorrect docket number for the production license. Enclosed is a revised 591. The original is in the mail.

Debbie Piskura

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

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

3. DOCKET NUMBER(S)

030-38230

4. LICENSE NUMBER(S)

41-32720-03

5. DATE(S) OF INSPECTION

July 31, 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)

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.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Deborah A. Piskura, Health Physicist		8/15/2012
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB		8/15/12

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	
3. DOCKET NUMBER(S) 030-38230	4. LICENSE NUMBER(S) 41-32720-03	5. DATE(S) OF INSPECTION July 31, 2012	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.08		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210	2. PRIORITY 2	3. LICENSEE CONTACT Rita Gentilcore, R.Ph., RSO	4. TELEPHONE NUMBER (314) 577-8800
<input type="checkbox"/> Main Office Inspection Next Inspection Date: July 2014			
<input checked="" type="checkbox"/> Field Office Inspection 1909 Beltway Drive, St. Louis, MO			
<input type="checkbox"/> Temporary Job Site Inspection			

PROGRAM SCOPE

This was the initial inspection performed in accordance with MC 2800 for the -03 license authorizing the production and handling of radiochemicals. 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 Saint Louis University 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 (-04MD).

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

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 chemistry, purification, and QA/QC.

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~~030-38228~~
error

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41-32720-03

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July 31, 2012

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NRC INSPECTOR	Deborah A. Piskura, Health Physicist	<i>Deborah A. Piskura</i>	7/31/2012
BRANCH CHIEF	Tamara E. Bloomer, Chief, MIB		