

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

The Regents of the University of Michigan  
University of Michigan PET Cyclotron Facility  
Ann Arbor, Michigan

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38353

4. LICENSE NUMBER(S)

21-00215-07

5. DATE(S) OF INSPECTION

6/15/15, with in-office review  
through 6/29/15

**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	Robert G. Gattone, Jr.	<i>Robert G. Gattone, Jr.</i>	6/29/15
BRANCH CHIEF	Aaron T. McCraw	<i>[Signature]</i>	6/30/15

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87125	7. INSPECTION FOCUS AREAS  02.01 through 02.07		

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 03210	2. PRIORITY 2	3. LICENSEE CONTACT Mark Driscoll, RSO	4. TELEPHONE NUMBER (734) 647-2251
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☒ Main Office Inspection      Next Inspection Date: 06/15/2017

☐ Field Office Inspection

☐ Temporary Job Site Inspection

**PROGRAM SCOPE**

The in-office review included receipt and review of information that was unavailable during the onsite inspection, including training and audit records. The licensee used a PETtrace cyclotron to produce radionuclides for PET studies and research, including fluorine-18 liquid, nitrogen-13 liquid, and carbon-11 gas. The licensee was planning to install an Ionetix SC-12SC miniature cyclotron within the PETtrace cyclotron vault in the summer of 2015. The PETtrace cyclotron vault had not been modified to accommodate the miniature cyclotron. Cyclotron maintenance was not scheduled during the week of the onsite inspection.

**Performance Observations**

The inspector: (1) noted that GE Healthcare maintained and repaired the PETtrace cyclotron; (2) noted that three authorized users were authorized for maintenance and minor repair of the cyclotron; (3) reviewed records of the 2013 and 2014 audits of the radiation protection program; (4) observed that licensed material was secured as required; (5) observed that selected licensee survey instruments were calibrated as required; (6) used an NRC owned, calibrated survey instrument to measure 0.015 milliroentgen per hour (mR/hr) at a shielded work area in the maintenance bay room; (7) observed that calibrated and appropriate licensee survey instruments were kept in the maintenance bay room; (8) noted that cyclotron targets were not re-used; (9) observed an authorized user use an ion chamber survey instrument prior to entering the cyclotron vault to verify that the dose rate was < 50 mR/hr; (10) observed that a Medi Smarts Rotem vault monitor read 16.6 mR/hr and was used to check the exposure rate prior to vault entry; (11) observed an authorized user demonstrate how he had done cyclotron maintenance on leaking cyclotron cooling water hoses and noted that appropriate personal protection clothing and whole body and extremity badges were donned; (12) noted that an authorized user positioned his dosimeters to read the maximum doses during maintenance activities; (13) observed an authorized user demonstrate how to respond to a radioactive spill based on a scenario posed by the inspector; (14) observed an authorized user conduct a personal radiation survey when exiting the vault and he knew the action level and how to respond if the action level was exceeded; (15) observed an authorized user demonstrate how he would respond to a personal contamination event based on a scenario posed by the inspector; (16) observed a senior health physicist demonstrate how he would respond to a personal contamination event based on a scenario posed by the inspector; (17) reviewed dosimeter badge records showing that the highest annual whole body and extremity doses received by radiation workers were 610 and 18390 millirem, respectively; (18) reviewed training records for selected authorized users; and (19) reviewed an authorized user's permit that was approved by the Radiation Safety Committee.