

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: The Regents of the University of Michigan OSEH - Radiation Safety Service 1239 Kipke Drive Ann Arbor, MI 48109 REPORT NUMBER(S) 2019001		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 November 5-8, 2019

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:

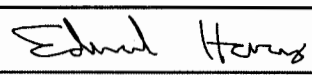
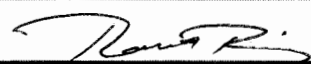
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Edward F. Harvey		11/21/2019
BRANCH CHIEF	Robert Ruiz		11/25/19

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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The Regents of the University of Michigan
 OSEH - Radiation Safety Service
 1239 Kipke Drive
 Ann Arbor, MI 48109

REPORT NUMBER(S) 2019001

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

November 5-8, 2019

6. INSPECTION PROCEDURES USED

87125

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

03210

2. PRIORITY

2

3. LICENSEE CONTACT

Mark Driscoll, RSO

4. TELEPHONE NUMBER

(734) 647-2251

☒ Main Office Inspection

Next Inspection Date: November 5, 2021

☐ Field Office Inspection☐ Temporary Job Site Inspection**PROGRAM SCOPE**

This was a routine inspection of an academic institution authorized for radionuclide production and PET studies using two PETtrace cyclotrons on its campus in Ann Arbor, Michigan. The licensee employed four authorized individuals with access to the cyclotron vault, two of which were authorized to perform target rebuilds. The licensee relied on the manufacturer for most of the maintenance and services. At the time of the inspection, the licensee produced C-11 gas, N-13 liquid, and F-18 liquid approximately 5-10 times per day depending on the isotope, during normal business hours starting at 6:00 am. All byproduct material produced by the cyclotron was transferred to the university's medical broad scope license upon exiting the cyclotron vault. The licensee removed the Ionetix SC-12SC that was previously used at their facility on March 5, 2019. The device was replaced with a new PETtrace model that was undergoing operational testing at the time of the inspection.

The inspector toured the cyclotron facility in Ann Arbor to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory surveys of the facility and found no indications of residual contamination or any exposures to members of the public in excess of regulatory limits. The cyclotrons were not operating at the time of the inspection due to the operational testing of the new PETtracer unit. The licensee's staff demonstrated and discussed the implementation of procedures for cyclotron operations, including maintenance, area surveys, effluent monitoring, and waste handling. Through these observations and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of available records relating to the use of the cyclotron, including area surveys, training documentation, audits, exhaust releases, and dosimetry.

No violations of NRC requirements were identified during this inspection.