NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
The Regents of the University of Michigan Radiation Safety Service: Occupational Safety & Environmental Health, University of Michigan Ann Arbor, Belleville, and Dearborn, MI REPORT NUMBER(S) 2019004	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01988	21-00215-04	11/4-8/2019

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 violations(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 Gattone / Edward Harvey	Robert Gattone, Jr. / Edward Harvey	11/19/2019
BRANCH CHIEF	Rob Ruiz		11/21/19

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(Continued)

Program Scope

The licensee was authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-00215-04 to conduct medical broad scope activities that included use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee maintained a student population of 46,200 at the main campus in Ann Arbor, Michigan. The license also authorized licensed activities to be conducted at facilities in Dearborn, Flint, Belleville, Brighton, and Pelliston, Michigan. The licensee's RPC designated approximately 190 individuals as Authorized Users, and about 1,000 people worked as Supervised Users. The licensee utilized licensed materials for medical applications and research and development.

The licensee's Radiation Safety Service (RSS), led by the RSO, was located within its Department of Environment, Health & Safety (EHS). The EHS department was overseen by an Executive Director, who reported to the Associate Vice President for Facilities and Operations. Approximately 13 staff members worked in RSS. The RSS staff conducted instrument calibrations, conducted leak tests, and reviewed Authorized User applications. RSS technicians were involved with package delivery and receipt, laboratory reviews, confirmatory surveys, laboratory closeouts, and assistance to research and development staff regarding radiation safety matters.

Medical use was conducted at University Hospital, Cardiovascular Center, Kellogg Eye Center, C.S. Mott Children's Hospital, Von Voigtlander Women's Hospital, and the Brighton Center for Specialty Care. At University Hospital, the licensee used licensed materials under the authorities of Title 10 of the Code of Federal Regulations (CFR) 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. Radiopharmaceutical therapies included iodine-131 metaiodobenzylguanidine (MIBG) human research cancer treatments at the C.S. Mott Children's Hospital. Radiation Oncology included HDR. In addition, Radiation Oncology had not performed interstitial LDR treatments for many years. Manual brachytherapy activities included iodine-125 seeds for ocular melanoma treatments and yttrium-90 TheraSpheres® for hepatocellular carcinoma.

Radioactive materials for research and development were located in approximately 750 radiation rooms within approximately 60 buildings. Research and development activities were trending downward and primarily involved biological research with millicurie quantities of carbon-14, hydrogen-3, iodine-125, phosphorus-32, and sulfur-35. The licensee also maintained and operated three self-shielded cesium-137 irradiators for research and development.

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Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134	03.01 through 03.07, and 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110	2	Mark Driscoll, RSO	(734) 834-9333

☑ Main Office Inspection Next Inspection Date: 11/04/2021

☑ Field Office Inspection Belleville and Dearborn, Michigan

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The inspectors: (1) observed a fire extinguisher that was checked at the appropriate frequency and its contents were proper; (2) noted that the licensee had not implemented actions pursuant to License Condition 27 because no caregiver exceeded 2 rem; (3) reviewed selected dosimeter badge records for 2018 and 2019 (through 9/28/19) and the whole body and extremity doses were well below the occupational dose limits; (4) reviewed selected records for hydrogen-3 and iodine-131 and the doses were within the occupational dose limits for 2019 through September 2019; (5) reviewed selected records for Radiation Safety Committee meetings; (6) verified that the licensee implemented corrective actions for previously identified violations; (7) reviewed how the licensee determined the air effluents for 2018 by way of the COMPLY code, and the dose to the public was less than 10 millirem; (8) reviewed selected records for iodine-125 eye plaque treatments; (9) noted that the licensee conducted post-treatment ambient exposure rate surveys of the patient and the high dose rate afterloader device; (10) observed a nuclear medicine technologist wearing proper personal protection equipment (PPE) while preparing and administering iodine-131 to a patient; (11) observed selected survey instruments and noted they were calibrated as required; (12) interviewed an authorized user to obtain how phosphorous-32 (P-32) was used for research, and how PPE was used; (13) observed selected individuals demonstrate how they would respond to a P-32 spill based on a scenario posed by the inspectors; (14) used an NRC-owned survey meter that was calibrated to conduct independent ambient exposure rate surveys in locations where radioactive material was used; (15) observed a therapeutic administration of lutetium-177 Dotatate; (16) observed an authorized user demonstrate various interlock checks that were completed prior to the use of an irradiator; (17) verified that the authorized user was present, the treatment plan was verified, the written directive was signed and complete, the daily spot checks were completed, and the patient and the device were surveyed for the fourth of four fractions of a gynecological HDR treatment; (18) reviewed the documentation for releases to sanitary sewers to verify they were within regulatory limits; (19) noted that principal activities had ceased at the location in Pelliston, Michigan on June 16, 2017, and surveys were performed and the facility was deemed releasable on May 23, 2017; (20) evaluated the licensee's measures for hazard communication, exposure control, and material security at the long term hazardous material storage facility in Belleville, Michigan and reviewed applicable waste manifest records; (21) toured two research labs at the location in Dearborn, Michigan and interviewed authorized users regarding the safe use of radioactive material;

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PROGRAM SCOPE

(22) reviewed leak test and inventory records for various sealed sources possessed under the license; and (23) reviewed training records for individuals authorized to handle radioactive material.

No violations of more than minor significance were identified as a result of this inspection.