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<br>Ann Arbor and Flint campuses in Michigan<br><br>REPORT NUMBER(S) 2016-002 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-01988 | 21-00215-04 | 10/17-21/16 |

**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 G. Gattone, Jr. & Zahid Sulaiman | Robert G. Gattone, Jr.<br>Zahid Sulaiman | 11/1/16<br>11/1/16 |
| BRANCH CHIEF | Aaron T. McCraw | | 11/1/16 |

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

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| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87134 | 02.01 through 02.07 |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02110 | 2 | Mark Driscoll, RSO | (734) 647-2251 |

☑ Main Office Inspection  Next Inspection Date: 10/17/2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

## PROGRAM SCOPE

The licensee is authorized to conduct medical broad scope activities that includes use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee maintained a student population of 43,625 at the main campus in Ann Arbor, Michigan. The license also authorizes licensed activities to be conducted at facilities in Dearborn, Flint, Belleville, and Pellston, Michigan. The licensee's RPC had designated approximately 250 individuals as authorized users, and about 1,500 people worked as supervised users. The licensee utilized licensed materials for medical applications and research and development. Medical use was conducted at the University of Michigan Hospital, Cardiovascular Center, C.S. Mott Children's Hospital, and Von Voigtlander Women's Hospital. At the University of Michigan 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 Cardiovascular Center. Radiation Oncology transitioned exclusively to HDR. In addition, Radiation Oncology has not performed interstitial LDR treatments for many years. Manual brachytherapy activities included iodine-125 seeds for ocular melanoma treatments, and yttrium-90 TheraSpheres® for neuroblastoma treatments. The licensee also has a blood bank that utilized a self-shielded irradiator for irradiating biological materials. Radioactive materials for research and development were located at approximately 900 laboratories within a few dozen buildings. Research and development activities were trending down and primarily involved biological research with millicurie quantities of carbon-14, hydrogen-3, iodine-125, phosphorus-32, and sulfur-35. Occasional iodine-125 iodinations were done with 5 to 10 millicuries. The licensee also maintained and operated three self-shielded cesium-137 irradiators for research and development.

Performance Observations

The inspectors: (1) reviewed selected RPC activities, including meeting minutes and authorized user approvals; (2) reviewed the licensee's responses to contamination events; (3) reviewed selected records pertinent to high dose rate (HDR) treatments, including written directives, treatment plans and pre- and post- treatment verification records;

(Safety Verbiage Continued on Part 2)

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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(Continued)

(Safety Verbiage Continued from Part 3)

(4) observed pre-treatment checks prior to HDR treatment; (5) observed an HDR treatment and the licensee's post treatment patient survey; (6) observed that the HDR device was secured; (7) observed a licensee staff member demonstrate how HDR spot checks were done; (8) reviewed the licensee's 2015 program audit report; (9) observed human researchinvolving ([methyl-carbon-11]N-acetyl-N-(2-methoxybenzyl)-2-phenoxy-5-pyridinamine) (PBR28) for Positron Emission Tomography, iodine-131 MIBG, and radium-223 Xofigo; (10) observed rubidium-82 generator elutions and administration of rubidium-82 chloride; (11) observed a nuclear medicine technologist conduct a dose measurement of rubidium-82 chloride; (12) interviewed selected staff regarding rubidium-82 generator check-in procedures, initial calibration, daily instrument calibration, daily strontium-82 and strontium-85 break through calculations, waste disposal, generator disposal, and operating and emergency procedures; (13) toured selected research labs and observed the use of licensed material, including radioactive waste and spill response; (14) toured the decommissioned dental research facility and reviewed the licensee's close-out survey report; (15) conducted independent measurements of selected surfaces with NRC owned, calibrated survey instruments; (16) reviewed records of package receipts, waste disposal, radiation safety training, hazmat training, and sealed source leak tests and inventories; (17) reviewed the external dosimetry records for 2015 and the maximum dose to the whole body and extremity were 1,750 millirems (mrem) and 20,282 mrem, respectively; (18) observed selected staff wearing their dosimeter badges; (19) observed that selected licensed material was secured as required; (20) verified that the licensee implemented corrective actions for the violations identified during the last inspection; (21) reviewed several written directives and supporting documents pertinent to iodine-125 eye plaque brachytherapy treatments; (22) reviewed internal dosimetry records and noted that there were no doses that exceeded NRC regulatory requirements; and (23) noted that the licensee had not received SIR Spheres yet.

No violations of NRC requirements were identified during this inspection.

**Gattone, Robert**

**From:** Mark Driscoll <drisc@umich.edu>
**Sent:** Tuesday, November 01, 2016 1:45 PM
**To:** Gattone, Robert
**Subject:** [External_Sender] NRC Inspection Report

Bob:

I acknowledged receipt of the attached document (NRC 591M 10-2016).

Mark

On Tue, Nov 1, 2016 at 1:58 PM, Gattone, Robert <Robert.Gattone@nrc.gov> wrote:

> Mark,
>
> Please respond to this message as acknowledgement of your receipt of the attached report.
>
> **From:** Gattone, Robert
> **Sent:** Tuesday, November 01, 2016 12:56 PM
> **To:** Driscoll, Mark <drisc@umich.edu>
> **Cc:** Sulaiman, Zahid <Zahid.Sulaiman@nrc.gov>
> **Subject:** NRC Inspection Report
>
> Mark,
>
> Attached is the document as we previously discussed.