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:
The Regents of the University of Michigan
Radiation Safety Service: Occupational Safety and Environmental Health, University of Michigan
Ann Arbor, Dearborn, and Belleville Campuses
REPORT NUMBER(S) 2017-002

2. NRC/REGIONAL OFFICE
Region III
2443 Warrenville Rd.
Lisle, IL 60532
Select a location (Use keyboard arrows to select). . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01988	21-00215-04	11/13-17/17

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. Ryan Craffey	Robert G. Gattone, Jr. Ryan Craffey	11/17/17 11/17/17
BRANCH CHIEF	Aaron T. McCraw		11/27/17

NRC FORM 591M PART 2
(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 Ann Arbor, Dearborn, and Belleville Campuses REPORT NUMBER(S) 2017-002	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	11/13-17/17

(Continued)

Performance Observations

The inspectors: (1) reviewed selected Radiation Policy Committee meeting minutes; (2) reviewed the licensee's 2016 annual radiation protection program audit record; (3) observed several licensee's survey meters and they were calibrated as required; (4) followed up on the Tc-99m MIP-1404 event that occurred on 10/6/16 and noted that the licensee had implemented long term corrective actions to prevent a similar event; (5) observed several licensee staff members using dosimeter badges; (6) observed licensee staff members using personal protection equipment when using unsealed licensed material; (7) conducted independent ambient exposure surveys on selected surfaces where licensed material was used; (8) reviewed selected Radioactive Drug Research Committee meeting minutes; (9) reviewed selected Subcommittee on the Human Use of Radioisotopes meeting minutes; (10) observed an authorized user demonstrate how he had used unsealed licensed material for research; (11) observed an authorized user demonstrate how he would respond to a radioactive spill based on a scenario posed by an inspector; (12) observed an authorized user demonstrate how he had conducted removable contamination surveys in the lab; (13) observed that licensed material was secured as required; (14) reviewed selected sealed source leak test records; (15) determined that the licensee's disposal of licensed material into the sanitary sewer system was as required; (16) reviewed selected sealed source physical inventory and leak test records; (17) observed authorized users produce, conduct quality control, transport, and use of (F-18) fluorodeoxyglucose (F-18 FDG); (18) noted that the dose calibrator internal to the licensee's Medrad Intego F-18 FDG remote injector was calibrated as required; (19) noted that the licensee's plan for decommissioning the North Engalls Building will involve a contractor to conduct MARSSIM activities which are expected to be completed in February 2018; (20) reviewed selected records of Y-90 microspheres (microspheres) treatments including written directives, shunt testing prior to administration, and surveys to determine how much radioactivity was administered to the patient; (21) noted that the licensee did not conduct post microspheres administration imaging of the patients to determine that the microspheres went to the intended treatment site per the applicable written directive and treatment plan; (22) noted that the licensee conducted an angiogram to assess the patients' blood flow 30 seconds before the microspheres were administered to the patient; (23) observed generator elution, Mo-99 breakthrough testing, dose dispensing, and dose quality assurance testing at the University Hospital's radiopharmacy; (24) observed numerous diagnostic and therapy administrations of radiopharmaceuticals at University Hospital and the Cardiovascular Center; (25) observed quality assurance testing of the licensee's Rb-82 generator prior to use; (26) observed the use of two of the licensee's self-shielded irradiators; (27) observed demonstrations of the safety interlocks in place at the neutron generator facility; (28) reviewed a selection of written directives and patient release evaluations for therapeutic administrations of radioactive pharmaceuticals; (29) reviewed and discussed with radiation oncology staff a selection of written directives for ocular melanoma treatments; (30) reviewed external dosimetry reports for 2016, which indicated maximum whole body and extremity doses of 1,070 millirem and 24,419 millirem, respectively; (31) reviewed internal dosimetry records for 2016; (32) reviewed documentation of minor skin contamination incidents in 2016 and 2017, including VARSKIN calculations and subsequent dose adjustments and noted that such dose adjustments were revised and added to the applicable NRC Form 5s; (33) reviewed COMPLY calculations for calendar year 2016; (34) reviewed a selection of irradiator use logs, monthly checks, and reports of annual preventative maintenance done by authorized service providers; (35) verified that the licensee had implemented corrective actions for one SLIV violation and two non-cited violations identified in IR 03001988/2015001(DNMS). The inspectors did not identify any violations of NRC regulatory requirements during this inspection.

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134 and 87137	All for 87134 and 87137

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: 11/13/2017

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee is authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-00215-04 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 44,718 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 240 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. The licensee's Radiation Safety Service (RSS), led by the RSO was located within its Department of Environmental, 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 and Von Voigtlander Women's Hospital. 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 Cardiovascular Center. Radiation Oncology transitioned exclusively to HDR; although they keep LDR on their RSS-102R radionuclide authorization. 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 hepatocellular carcinoma. University Hospital also contained a blood bank that utilized a self-shielded irradiator for irradiating biological materials. Radioactive materials for research and development were located at approximately 850 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 used phosphorus-32 and phosphorus-33 for tooth development studies at the Eisenhower Place facility.

(Safety Verbiage Continued on Part 2)