Enclosure 6-INSPECTION RECORD

Region III
License No. 21-00215-04

Inspection Report No. 03001988/2014-002(DNMS)
Docket No. 030-01988

Licensee (Name and Address):
The Regents of the University of Michigan Radiation Safety Service
1239 Kipke Drive
Ann Arbor, Michigan 48109-1010

Licensee Contact: Mark Driscoll
Priority: 2

Telephone No. (734) 647-2251
Program Code: 02110

Date of Last Routine Inspection: June 24, 2014
Date of This Inspection: June 23 through 27, 2014, with continued in-office review through August 5, 2014

The in-office review included receipt and review of information that was unavailable during the onsite inspection including information pertinent to potential security-related violations.

Type of Inspection: ( ) Initial (X) Announced ( ) Unannounced
(X) Routine ( ) Special

Next Inspection Date: October 15, 2015

In accordance with NRC Manual Chapter 2800, the next routine inspection will be conducted in the fall of 2015 because of the large scope of the radiation protection program, the many locations of use, and the reduced number of available licensee staff in the summer due to vacations.

( ) Normal (X) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
(x) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: Robert G. Gattone, Jr. for
Bill C. Lin, Health Physicist
Date: August 19, 2014

Robert G. Gattone, Jr.
Robert G. Gattone, Jr., Senior Health Physicist
Date: August 7, 2014

Approved:
Aaron T. McCraw, Chief, MIB
Date: August 21, 2014

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

Amendment No.	Date	Subject
Amendment #101	09/30/2013	Added radium-223 for medical use
Amendment #102	02/19/2014	Added new materials and uses to the license

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection that was conducted on June 24, 2013, resulted in two Severity Level III security-related violations and a civil penalty.

3. INCIDENT/EVENT HISTORY:

No licensee events were reported since the last NRC inspection. No open Nuclear Materials Event Database (NMED) items were pending for this licensee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

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 approximately 42,000 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 350 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 Radiation Safety Officer (RSO) was located within its Occupational Safety & Environmental Health (OSEH) department. The OSEH department was overseen by an Executive Director, who reported to the Associate Vice President for Facilities and Operations. Approximately 13 staff members worked in the RSS. The RSS staff conducted instrument calibrations, conducted leak tests, and reviewed authorized user applications. The RSS technicians were involved with package delivery and receipt, laboratory reviews, confirmatory surveys, laboratory close-out, and assistance to research and development staff regarding radiation safety matters.

Medical use was conducted at the University of Michigan Hospital, Cardiovascular Center, C.S. Mott Children's Hospital, and Von Volgflander 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 University of Michigan Hospital. Manual brachytherapy activities included iridium-192 ribbons for cervical and lip cancer treatments at the University of Michigan Hospital, iodine-125 seeds for eye treatments, and yttrium-90 TheraSpheres® for neuroblastoma treatments at the Cardiovascular Center. The University of Michigan 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 1200 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. The licensee also maintained and operated three self-shielded cesium-137 irradiators for research and development.

2. SCOPE OF INSPECTION:

Inspection Procedures Used: 87134, 87137

Focus Areas Evaluated: 03.01 through 03.09

The inspection included the Ann Arbor Campus, Dearborn Campus, and the Beck Road Facilities in Belleville, Michigan.

The inspectors reviewed applicable records, interviewed applicable staff members and/or observed licensed activities to assess: (1) the licensee's ability to administer high dose rate remote afterloader (HDR) treatments in accordance with the written directives; (2) HDR Quality Control (QC) checks; (3) source exchange of the irridium-192 source in the Varian HDR unit; (4) security of brachytherapy sources; (5) administration of radiopharmaceutical therapy in accordance with the written directives, including iodine-131 treatments for thyroid cancer and radium-223 (Xofigo) for prostate cancer treatments; (6) Radiation Policy Committee activities; (7) the annual ALARA audit record for 2013; (8) safe use of licensed material; (9) staff preparation and administration of licensed materials; (10) QC and breakthrough testing for administrations of rubidium-82 from Bracco Diagnostics CardioGen-82 generators; (11) molybendum-99 breakthrough from a molybendum-99/technetium-99m generator; (12) bioassays; (13) annual safety training; and (14) hazmat training.

At the U-M hospital Radiation Oncology Department, the inspectors observed the licensee administer an HDR treatment that was done in accordance with the written directive. The inspectors observed the licensee's Medical Physicist perform all of the necessary checks on the HDR unit prior to administration of the HDR treatment. The inspectors also observed Varian Medical Systems conduct a source exchange for the HDR unit as authorized by its NRC license. In addition, the inspectors observed that all brachytherapy sources were properly secured and all applicable leak tests and radiation surveys were performed. The inspectors also reviewed selected brachytherapy written directives involving yttrium-90 TheraSpheres, HDR, and iodine-125 eye plaques. No medical events were identified.

The inspectors reviewed the licensee's program for administering rubidium-82 from Bracco Diagnostics CardioGen-82 generators. U-M Hospital scheduled a maximum of 4 patients per day for diagnostic cardiac imaging using Rb-82, with an average schedule of 15 patients per week. The licensee's nuclear pharmacist demonstrated how the infusion system was checked daily prior to the first administration, including the QC and/or breakthrough test for strontium. The inspectors reviewed records for 2013 and 2014 and did not identify any instances where strontium breakthrough levels exceeded the permissible requirements in 10 CFR 35.204.

The inspectors also reviewed the licensee's molybendum-99/technetium-99m generator records for any molybendum-99 breakthrough. The inspectors reviewed records for 2013 and 2014 and did not identify any instances where molybendum-99 breakthrough levels exceeded the permissible requirements in 10 CFR 35.204. In addition to observing the licensee's nuclear pharmacist elute the rubidium-82 and molybendum099/technetium-99m generators, the inspectors observed the pharmacist perform dose calibrator calibration, prepare two Xofigo unit dosages, and conduct waste disposal surveys. The inspectors also observed the licensee's NMT administer licensed material to patients. The NMT used dosimetry badges, syringe shields, and performed all of the applicable surveys. The inspectors randomly selected written directive records relative to iodine-131 thyroid cancer treatment, Ra-223 (Xofigo), and iodine-131 MIBG, and no medical events were identified.

The inspectors toured the licensee's U-M Hospital, Cardiovascular Center, C.S. Mott Children's Hospital, including the waste disposal room. The inspectors also reviewed selected records involving the 2013 Annual ALARA audit, bioassays, waste disposal surveys, dose calibrator calibration, leak tests, sealed source inventories, annual radiation safety training, hazmat training, safe use of radioactive materials, Radioactive Drug Research Committee minutes, and Radiation Policy Committee minutes.

Based on review of records and discussions with selected licensee staff members, the inspectors determined that approvals for non-human research, including animal studies were done as required. In addition, the inspectors observed authorized staff members demonstrate how Positron Emission Tomography was conducted on rodents, primates, and pigs using flourine-18 and carbon-11 labeled molecules. The inspectors: (1) observed a staff member demonstrate how the material was measured and administered using time, distance and shielding to reduce radiation dose; (2) observed a staff member demonstrate how survey instrument operability checks were done prior to use on a given day; (3) observed a staff member demonstrate how radioactive waste was disposed of; (4) observed a staff member demonstrate how to respond to a radioactive spill; and (5) observed a staff member conduct a physical inventory of sealed sources, and all of the sources were accounted for based on the previous inventory record.

At the Beck Road facility, the inspectors: (1) observed that radioactive waste was secured as required, (2) observed that the facility was posted as required; (3) noted that received phosphorus-32 waste was analyzed to verify that no other radionuclides were present prior to placing the waste into decay-in-storage; (4) observed that selected fire extinguishers were charged and checked per the associated tags affixed to them; (5) observed a staff member demonstrate how he conducted personal radiation surveys; and (6) observed a staff member demonstrate how he would respond to a leaking container of radioactive liquid waste.

At the Dearborn facility, the inspectors: (1) noted that about seven authorized users used sealed and unsealed licensed material for instruction and research and development; (2) reviewed selected sealed source physical inventory records; (3) observed a Senior Health Physicist demonstrate how he would respond to a damaged leaking package containing licensed material; (4) observed a Director of Laboratories demonstrate how he conducted radiation surveys of packages containing licensed material upon receipt; (5) observed a Director of Laboratories demonstrate how he would respond to lost or stolen licensed material; (6) observed that licensed material was secured as required; (7) observed a Senior Health Physicist conduct a physical inventory of sealed sources selected by the inspector, and the selected sources were accounted for based on the previous physical inventory record; (8) observed an authorized user demonstrate how radioactive waste was handled; (9) observed an authorized user and a student demonstrate how they would respond to a radioactive spill; (10) observed a student working under the supervision of an authorized user don personal protective equipment when handling carbon-14; (11) reviewed selected leak test records; (12) reviewed selected sealed source inventory records; and (13) reviewed the licensee's permit for an authorized user's approval for licensed material use at the facility.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The NRC inspectors conducted independent radiation surveys in the iodine-131 administration room, waste disposal room, hot lab, and brachytherapy source storage area. No unusual radiation levels were detected and radiation levels were within regulatory limits.

Using an NRC-owned and calibrated survey instrument, the inspectors: (1) measured a maximum of 0.8 milliroentgen per hour at selected surfaces in the lab where Positron Emission Tomography was conducted on rodents, primates, and pigs using flourine-18 and carbon-11 labeled molecules; (2) measured a maximum of 0.05 milliroentgen per hour at selected surfaces of radioactive waste containers at the Beck Road facility; and (3) 0.3 milliroentgen per hour at selected surfaces of the safe where all licensed material was stored at the Dearborn facility.

4. VIOLATIONS, NON-CITED VIOLATIONS, AND OTHER SAFETY ISSUES:

No safety violations of NRC Regulatory requirements were identified; however, a security-related violation was identified and it is discussed in a separate document that is inaccessible to the public.

5. PARTIAL LIST OF PERSONNEL CONTACTED:

Terrance Alexander, Executive Director of the OSEH
Stuart Berry, Senior Hazmat Engineer
*Mark Driscoll, RSO/Director
*Karl Fischer, Senior Health Physicist
*Russell Garcia, Health Physicist
Ray Hutchinson, Associate Dean
Bob Koeppe, Radiology Supervisor
Eric Kolb, Technical Support Manager
*Joseph Miklos, Coordinator/Senior Health Physicist

Nour Nasiri, Student
Bob Neuman, Chief of University of Michigan Police
Ruthann Nichols, Professor and Chair of the Radiation Policy Committee
Peter Olkers, Authorized User
*Dennis Palmieri, Senior Health Physicist
Joann Prisciandono, Associate Professor, Radiation Oncology
Bob Quatro, Director of Laboratories
Carol Quesada, Supervised User
Peter Scott, Assistant Professor of Radiology/Director of Radiochemistry
Phil Sherman, Manager of Pre-Clinical Imaging
Stan Uitti, Health Physicist
Patricia Ward, Director, Regulatory Affairs

Use the following identification symbols:
* Partial list of individuals that participated in the final exit meeting conducted by telephone on August 5, 2014

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