UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 27, 2017

Mr. Terrance Alexander
Executive Director, EHS
The Regents of the University of Michigan
1239 Kipke Drive
Ann Arbor, MI 48109-1010

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03001988/2017001(DNMS) – THE REGENTS OF THE UNIVERSITY OF MICHIGAN RADIATION SAFETY SERVICE: OCCUPATIONAL SAFETY & ENVIRONMENTAL HEALTH, UNIVERSITY OF MICHIGAN

Dear Mr. Alexander:

On October 2, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) completed an in-office review of several non-reportable incidents involving licensed radioactive materials that occurred under your license since the last routine NRC inspection in 2016. The NRC initiated this in-office review shortly after a telephone conversation between Mr. Robert Gattone of my staff and Mr. Mark Driscoll, your Radiation Safety Officer, on July 5, 2017. During the call, Messrs. Gattone and Driscoll discussed three non-reportable incidents identified and evaluated by your radiation safety staff. Mr. Gattone conducted a meeting by telephone with Mr. Driscoll and others of your staff on October 4, 2017, to discuss the inspector's findings.

The NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the in-office review consisted of selected examination of procedures and representative records, and phone calls with personnel.

Based on the results of the in-office review, the NRC has determined that seven Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations concerned the licensee's: (1) failure to wear gloves when transferring a vial containing radioactive material into a shielded container involving potentially contaminated items, contrary to Condition 26 of NRC License No. 21-00215-04 (the license); (2) failure to adequately monitor feet prior to leaving the radiopharmacy, contrary to Title 10 *of the Code of Federal Regulations* (CFR) Section 20.1501(a); (3) failure to request Environmental Health & Safety (EHS) approval of a shipment that was sent, contrary to Condition 26 of the license; (4) failure to label a limited quantity (LQ) package "UN2910", contrary to 10 CFR 71.5(a) and 49 CFR 172.301(a); (5) failure to provide hazmat training to an individual, contrary to 10 CFR 71.5(a) and 49 CFR 172.702(a); (6) failure to verify that a transferee's license authorizes receipt of the type, form, and quantity of byproduct material to be transferred, contrary to 10 CFR 30.41(c); and (7) administration of a

dosage to a patient that differed from the prescribed dosage by more than 20 percent, contrary to 10 CFR 35.63(d).

The enclosed Summary of Incidents provides details of the incidents, the NRC's evaluation, the violations, and the licensee's corrective actions. All seven violations were self-identified, non-repetitive, and corrected in a timely manner; therefore, all seven violations are being treated as non-cited violations in accordance with Section 2.3.2 of the NRC Enforcement Policy. Accordingly, you are not required to respond to this letter unless the description in the enclosure does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, please submit the information in accordance with the methods described in 10 CFR 30.6(a)(1) and (b)(2).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Gattone if you have any questions regarding this correspondence. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01988
License No. 21-00215-04

Enclosure:
Summary of Incidents

cc: State of Michigan

Letter to Terrence Alexander from Aaron McCraw dated October 27, 2017.

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DATE	.10/23/2017		10/27/2017					

OFFICIAL RECORD COPY

SUMMARY OF INCIDENTS

1) Technetium-99m Myoview Spill on February 14, 2017

Safe Use of Unsealed Licensed Material

A radiopharmacy technologist dropped a shielded container with a vial of technetium-99m (Tc-99m) Myoview, containing approximately 1,250 millicuries (mCi), inside the nuclear medicine (NM) dispensing area. Subsequently, the radiopharmacy supervisor attempted to transfer the vial to a transfer pig without wearing gloves. The broken vial was potentially contaminated because most of the radioactive liquid remained in the broken vial. The radiopharmacy supervisor noted that some of the material escaped from the vial. The broken vial and the potentially contaminated transfer pig were placed in a secured area for decay-in-storage.

Condition 26 of the licensee's broadscope medical license states, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in documents, including enclosures such as the application dated February 24, 2011, which states on Page A-2, that the Division of Nuclear Medicine has developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of Title 10 *of the Code of Federal Regulations* (CFR) Sections 20.1101 and 20.1301. The licensee's applicable written procedures for safe use of unsealed licensed material states, in part, that "Disposable gloves shall be worn when working with radioactive material or potentially contaminated items when practicable." The licensee self-identified the failure to wear gloves when transferring the vial containing radioactive material into a shielded container involving potentially contaminated items as a violation of Condition 26 of the license.

Subsequently, the radiopharmacy supervisor identified contamination on his/her fingertips (maximum of about 8,000 counts per minute on the left thumb). The licensee used VARSKIN to determine that the radiopharmacy supervisor's skin on the left thumb received 508 millirad.

The licensee surveyed the affected areas in and around the NM dispensing area on February 14 through 17, 2017. The residual contamination was below the action level for restricted areas in NUREG-1556, Vol. 9, Appendix R.

Shortly after the violation was identified, the licensee implemented corrective actions to prevent a similar violation including reminding NM staff to wear required personal protective equipment when handling potentially contaminated items.

Radioactive Spill Response

The licensee conducted area surveys and identified areas of contamination on the floor outside the radiopharmacy. As such, the licensee believes that an NM staff member did not adequately monitor his/her feet prior to leaving the radiopharmacy. The licensee restricted the nuclear pharmacy overnight to allow for radioactive decay to reduce the radiation levels before conducting more surveys and decontamination.

Title 10 CFR 20.1501(a) states, "Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that: (1) May be necessary for the licensee to comply

with the regulations in this part; and (2) Are reasonable under the circumstances to evaluate: (i) The magnitude and extent of radiation levels; and (ii) Concentrations or quantities of residual radioactivity; and (iii) The potential radiological hazards of the radiation levels and residual radioactivity detected." The licensee self-identified the failure to adequately monitor feet prior to leaving the radiopharmacy, as evidenced by the presence of contamination on the floor outside the radiopharmacy, as a violation of 10 CFR 20.1501(a).

Shortly after the spill was identified, the licensee implemented corrective actions including reminding NM staff members to monitor their feet for contamination prior to leaving the radiopharmacy and stopping work to assess contamination when an incident occurs that may involve the spread of contamination.

2) Shipping Incident on March 13, 2017

Shipment Approval

A lab manager attempted to ship a sample containing 1.3 mCi of phosphorous-32 (P-32) (Limited Quantity [LQ]) to the University of Rochester Medical Center (URMC) via common carrier without notifying the Radiation Safety Service (RSS), resulting in RSS not approving the shipment. The package was subsequently returned to the lab by the common carrier.

Condition 26 of the license states, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in documents, including enclosures including the application dated February 24, 2011, which states on Page 10-10, "As part of the materials accountability system, Occupational Safety and Environmental Health (OSEH)/Radiation Safety Service (RSS) must approve all transfers of licensed materials to other institutions or facilities." The licensee self-identified the failure to request RSS approval of the shipment as a violation of Condition 26 of the license.

As corrective action, the lab manager committed to having RSS perform shipping of all radioactive packages off campus. In addition, the RSO consulted with the licensee's Radiation Policy Committee (RPC) which resulted in issuance of a "Notice of Deficiency" to the lab manager on August 25, 2017, to document the issue and remind them that, unless otherwise authorized by RSS, only RSS can ship radioactive material off campus. The licensee also sent a mass email notice on August 28, 2017, to all authorized users reminding them of this requirement. In addition, RSS revised its website on August 31, 2017, to emphasize this requirement.

The lab manager also offered the package for shipment without the UN2910 label. The lab manager used the same shipping box that was used for receipt from the vendor, which was labeled UN2915 instead of UN2910.

Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397. Title 49 CFR 172.301(a) states, in part, that each person who offers a hazardous

material for transportation in a non-bulk packaging must mark the package with the identification number (preceded by “UN”) as appropriate for the material as shown in the 49 CFR 172.101 “Hazardous Materials Table”. The 49 CFR 172.101 Hazardous Materials Table states that radioactive material, excepted package-limited quantity of material has identification number UN2910. The licensee self-identified the failure to label the LQ package “UN2910” as a violation of 10 CFR 71.5(a) and 49 CFR 72.301(a).

As corrective action in June 2017, the lab manager committed to having RSS perform shipping, including package labeling, of all radioactive packages off campus.

Hazardous Materials Training

The lab manager who attempted to ship the P-32 to the URMC did not have DOT-required hazardous materials (hazmat) training, in accordance with 10 CFR 71.5(a) and 49 CFR 172, Subpart H, as of March 13, 2017.

Title 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in 49 CFR Parts 107, 171-180, and 390-397. Title 49 CFR 172.702(a) requires that a hazmat employer shall ensure that each of its hazmat employees get hazmat training in accordance with the requirements in Subpart H, including initial and recurrent hazmat training. The licensee self-identified the failure to provide hazmat training to the lab manager as a violation of 10 CFR 71.5(a) and 49 CFR 172.702(a).

As corrective action in June 2017, the lab manager committed to having RSS perform shipping (including package labeling) of all radioactive packages off campus, eliminating the need for this individual to be trained in hazmat transportation.

Verification Before Shipment

On March 13, 2017, RSS did not have an updated copy of the URMC radioactive material license authorizing receipt of P-32 when the shipment occurred.

Title 10 CFR 30.41(c) states before transferring byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. The licensee self-identified the failure to verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred as a violation of 10 CFR 30.41(c).

As corrective action, on March 14, 2017, RSS requested a copy of the URMC radioactive material license and a copy of the license was received on March 16, 2017. On March 20, 2017, RSS completed the shipment to URMC via common carrier. URMC received the package on March 21, 2017.

3) Multi-Gated Acquisition Scan Underdose on May 12, 2017

A patient was scheduled to undergo a routine multi-gated acquisition (MUGA) scan on May 11, 2017. An Ultratag kit and a dose syringe containing 35 mCi of Tc-99m sodium pertechnetate were dispensed for the patient study. For medical reasons, the patient was admitted to the hospital, and the MUGA scan was not performed. The MUGA scan was rescheduled for the following afternoon. Because the radiopharmacy staff left the Cardiovascular Center (CVC) for the day before the study was to be conducted, the patient's Ultratag kit and the syringe containing 35 mCi of Tc-99m sodium pertechnetate were not picked up and remained on the counter in the radiopharmacy.

The following morning, the nuclear medicine technologist (NMT) assigned to perform the patient's rescheduled MUGA scan (different NMT than the previous day) noticed the afternoon scan was an inpatient and believed it was possible to complete the patient's scan in the morning. Per routine procedure, the NMT paged the radiopharmacy to indicate the afternoon scan was being rescheduled and a dose would be required, and paged the radiopharmacy again when the inpatient arrived for the scan. Having provided 45 minutes of notice, the NMT reported to the radiopharmacy and retrieved the Ultratag kit and the unused dose syringe without realizing it was the same dosage that was dispensed the day before.

The NMT verified the patient's information and prescribed scan on the label; however, the NMT did not verify the calibration time on the label. The NMT then proceeded to label the dosage to the patient's red blood cells using the Ultratag kit and administered the dose to the patient. As a result, the patient was administered 4.5 mCi instead of the 35 mCi prescribed dosage, which was an administered dosage that differed from the prescribed dosage by more than 20 percent. The licensee used the Ultratag package insert and an independent internal dosimetry reference to determine that the incident did not constitute a medical event per 10 CFR 35.3045(a)(1).

The inspector also used the Ultratag package insert to determine that the highest radiation dose to the patient was 0.495 rads to the spleen and that the administered dose did not differ from the prescribed dose (3.85 rads to the spleen) by more than 50 rem to an organ. As such, the inspector independently confirmed that the incident was not a medical event per 10 CFR 35.3045(a)(1).

Title 10 CFR 35.63(d) states unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. The licensee self-identified the administration of a dosage that differed from the prescribed dosage by more than 20 percent as a violation of 10 CFR 35.63(d).

As corrective action, the licensee's NM staff were retrained on May 12, 2017, pertinent to the root causes of the incident. On August 2, 2017, the licensee revised its procedure for identification of patients to include verification of the administration date and time on the dose label. The NMT supervisor emphasized the importance of verifying the administration date and time on the dose label, in addition to the routine requirements for verifying patient identity, during an NM department meeting on August 31, 2017. On September 8, 2017, the licensee distributed to all NMTs the revised procedure.