UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

November 17, 2022

NMED 210369 (closed)

Mr. Karl W. Fischer, M.Eng., CHP
Director, Radiation Safety Service
The Regents of the University of Michigan
1239 Kipke Drive
Ann Arbor, MI 48109

SUBJECT: NRC ROUTINE INSPECTION REPORT NOS. 03001988/2022001(DRSS), 03038353/2022001(DRSS), AND 07000192/2022001(DRSS) – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Dear Mr. Fischer:

On September 12 through 16, 2022, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine team inspection at the campus of the University of Michigan in Ann Arbor and at the Brighton Center for Specialty Care in Brighton, with continued in-office review through October 11, 2022. The purpose of the inspection was to review activities performed under all three of the University's NRC licenses to ensure that activities were being performed in accordance with NRC requirements. The in-office review included additional evaluation of the broad scope program's completion of safety evaluations of proposed uses of byproduct material. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your licenses 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 licenses. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. On September 16, 2022, at the conclusion of the on-site inspection, the inspectors held a preliminary exit meeting with you and other representatives of the University. On October 11, 2022, the inspectors completed their in-office review and informed you of the results of their review.

Based on the results of this inspection, no violations of NRC requirements were identified, and no response to this letter is required.

In accordance with the NRC's "Rules of Practice" in 10 CFR 2.390, a copy of this letter, its enclosure, and any response, if you provide one, will be made available electronically for public

Enclosures 2 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 2, this transmittal letter and Enclosure 1 are decontrolled.

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, any 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. Craffey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at ryan.craffey@nrc.gov or 630-829-9655.

Sincerely,

Michael A. Kunowski Signed by Kunowski, Michael on 11/17/22

Michael A. Kunowski, Chief
Materials Inspection Branch
Division of Radiological Safety and Safeguards

Docket Nos. 030-01988
030-38353
070-00192
999-90003

License Nos. 21-00215-04
21-00215-07
SNM-179
GL per 10 CFR 31.5(a)

Enclosures:
1. Inspection Report Nos.
   03001988/2022001(DRSS),
   03038353/2022001(DRSS)
   and 07000192/2022001(DRSS) (public)
2. Security Addendum to Inspection Report (non-public)

cc w/o encl 2: Henry Baier – Associate Vice President for Facilities & Operations
Danielle Sheen – Executive Director, Environment, Health and Safety
State of Michigan

Letter to K. Fischer from M. Kunowski, dated November 17, 2022.

SUBJECT: NRC ROUTINE INSPECTION REPORT, NOS. 03001988/2022001(DRSS), 03038353/2022001(DRSS), AND 07000192/2022001(DRSS) – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

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OFFICE	RIII-DRSS		RIII-DRSS		RIII-DRSS		RIII-DRSS	
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DATE	11/17/22		11/17/22		11/17/22		11/17/22	

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01988, 030-38353, 070-00192
License Nos.	21-00215-04, 21-00215-07, SNM-179
Report Nos.	03001988/2022001(DRSS) 03038353/2022001(DRSS) 07000192/2022001(DRSS)
NMED No.	210369 (closed)
Licensee:	The Regents of the University of Michigan
Facility:	Campus of the University of Michigan Ann Arbor, MI Brighton Center for Specialty Care Brighton, MI
Inspection Dates:	September 12 – 16, 2022 In-office review through October 11, 2022
Exit Meeting Date:	October 11, 2022
Inspectors:	Ryan Craffey, Senior Health Physicist Jason Draper, Health Physicist Luis Nieves, Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Radiological Safety and Security

Enclosure 1

[redacted]

EXECUTIVE SUMMARY

The Regents of the University of Michigan
NRC Inspection Report, Nos. 03001988/2022001(DRSS), 03038353/2022001(DRSS), and 07000192/2022001(DRSS)

This was an announced routine team inspection of activities performed under three USNRC materials licenses maintained by the Regents of the University of Michigan. The University was authorized by License No. 21-00215-04 as a Broad Scope Medical Institution to use byproduct material for a wide variety of medical and academic uses, and to use source material for shielding. The University was also authorized by License No. 21-00215-07 to produce radiochemicals using cyclotrons for research and transfer to authorized recipients (primarily the University itself); and was authorized by License No. SNM-179 to use special nuclear material, primarily for nuclear engineering research.

The on-site inspection was performed September 12-16, 2022, at the campus of the University of Michigan in Ann Arbor and at a satellite medical facility in Brighton. The inspectors performed additional in-office review through October 11, 2022, to continue their evaluation of the broad scope program's completion of safety evaluations of proposed uses of byproduct material.

Based on the results of this inspection, no violations of NRC requirements were identified.

REPORT DETAILS

1 Program Overview and Inspection History

The Regents of the University of Michigan maintained three NRC Materials Licenses authorizing the use byproduct, source, and special nuclear material at the University's academic and medical campuses in Ann Arbor and at additional satellite campuses and facilities. The main academic campus in Ann Arbor enrolled over 48,000 students and employed over 25,600 academic and administrative staff. The medical campus enrolled over 2,000 students and employed over 21,200 medical and administrative staff. The University maintained a Radiation Safety Service (RSS) within the Office of Environment, Health, and Safety which provided for the routine implementation and oversight of all licensed activities. The University also maintained a Radiation Policy Committee (RPC) which met quarterly as well as a Subcommittee on the Human Use of Radioisotopes (SHUR) which met as necessary to review and approve proposed uses and users of licensed material and to provide high-level oversight of RSS and licensed activities.

License No. 21-00215-04 (Docket 030-01988) authorized the University to use byproduct material for diagnostic and therapeutic medical purposes, academic and medical research, educational instruction and demonstration, irradiation of biological materials, radiopharmaceutical preparation for noncommercial transfer, possession of source material for shielding, calibration and standardization, and possession of incidentally activated material and waste in interim storage. This license also authorized the use of material at the University's satellite campuses in Flint and Dearborn, The Domino's Farm Corporation in Ann Arbor, a waste storage facility in Belleville, a biological research station in Pellston, a specialty medical center in Brighton, and temporary job sites in NRC jurisdiction. Active locations of medical use included the University Hospital (with compounding radiopharmacy), Cardiovascular Center (with dispensing radiopharmacy), Rogel Cancer Center, Mott Children's Hospital, Voigtlander Women's Hospital, and Kellogg Eye Center. Notable locations of academic use included the Medical Science Buildings (MS-I and -II), Medical Science Research Buildings (MSRB-I, -II, and -III), Taubman Biomedical Science Research Building (BSRB), Life Sciences Institute (LSI), Chemistry Building, Michigan Memorial Phoenix Project Facility, and the North Campus Research Complex (NCRC). At the time of the inspection, there were 98 active clinical trials, and 151 active academic users. The licensee had not performed licensed activities at the Flint Campus, Domino's Farms Corporation, or at temporary job sites since at least 2014. One researcher occasionally used small amounts of unsealed radiolabeled material at the Dearborn campus, and small quantities of radioactive waste were occasionally stored at the Beck Road Facilities in Belleville.

License No. 21-00215-07 (Docket 030-38353) authorized the University to produce radiochemicals using cyclotrons for transfer to authorized recipients and for research. At the time of the inspection, the University operated two GE PETtrace™ cyclotrons at the MS-I Cyclotron and Radiochemistry Facility to produce flourine-18 (F-18), carbon-11 (C-11) gas, nitrogen-13 (N-13), and gallium-68 (Ga-68) five to ten times a day. All material was transferred to the University's broad scope license upon exiting the cyclotron vaults. The University mostly produced isotopes for its own diagnostic and clinical research use, but on rare occasions sent material to authorized recipients at

other institutions for clinical research. The University employed two individuals that performed routine maintenance on the cyclotrons and had a contract with the cyclotron manufacturer for more involved projects.

License No. SNM-179 (Docket No. 070-00192) authorized the University to possess and use a wide range of byproduct, source, and special nuclear material for research; however, many of these authorizations were for material previously transferred from the licensee's research reactor license (No. R-28), which was terminated in 2015. As of 2019, the licensee had transferred or disposed of most of these materials such that at the time of the inspection, it possessed only a limited number of SNM sources for nuclear engineering research and instructional purposes.

All three of the University's licenses were most recently inspected during the week of November 4, 2019. No violations of NRC requirements were identified as result of these inspections.

2 Radiation Safety Service

2.1 Inspection Scope

During the week of September 12, 2022, the NRC inspectors reviewed RSS, RPC, and SHUR activities, interviewed RSS staff and management, and examined a selection of records related to the implementation of the University's radiation protection program. The inspectors performed additional in-office review through October 11, 2022.

2.2 Observations and Findings

The inspectors accompanied RSS staff on periodic audits and surveys of several laboratories, observed demonstrations of the implementation of procedures for incoming package receipt, survey instrument calibration, and radioactive waste handling, and reviewed a selection of records, including RPC meeting minutes, authorized user approvals, program audits and incident reports, personnel dosimetry reports and ALARA notifications.

During a review of authorized users and uses, the inspectors noted that in 2015 the University had approved an applicant in the Department of Nuclear Engineering and Radiological Sciences to use a QSA Global 959M radiographic exposure device containing a category 3 quantity of iridum-192 to perform density measurements on simulated nuclear reactor fuel bundles for fluid dynamics research. The approval included several special conditions and pre-work conditions that the applicant was required to meet before approval would be granted by the RPC. The licensee had previously documented that the conditions were satisfied, and the application approved, on August 12, 2016. However, the inspectors were unable to confirm from observations of the facility, evaluations of the equipment, and interviews with laboratory staff that these conditions had been fully satisfied, and the RSS personnel who substantiated the completion of all pre-work conditions had since retired.

The inspectors considered this a performance concern per NRC Inspection Manual Chapter 2800 as it related to the completion of safety evaluations of proposed uses of

byproduct material per Title 10 of the *Code of Federal Regulations* (10 CFR) 33.13(c) and requested that the licensee provide clarification and additional information to address the concern, with specific regard to the approval of operating and emergency procedures, equipment maintenance, and training on the safe use of this device. In correspondence dated September 23, 2022, and October 10, 2022, the licensee provided clarification and additional information that satisfactorily addressed the inspectors' concerns.

2.3 Conclusions

The inspectors reviewed a selection of program oversight activities and identified no violations of regulatory requirements in this area.

3 Medical Use under the Broad Scope Program

3.1 Inspection Scope

During the week of September 12, 2022, the inspectors toured several medical use facilities, interviewed RSS personnel, authorized users, authorized medical physicists, and technologists, and reviewed a selection of records related to the medical use of licensed material.

3.2 Observations and Findings

The inspectors observed one iridium-192 (Ir-192) high dose rate (HDR) remote afterloading brachytherapy treatment, one yttrium-90 (Y-90) microspheres treatment, one iodine-131 (I-131) MIBG inpatient treatment, three lutetium-177 (Lu-177) treatments, one liquid I-131 treatment, and numerous diagnostic administrations of radiopharmaceuticals including Ga-68 and F-18 positron-emitters, various technetium-99m (Tc-99m) radiopharmaceuticals, and xenon-133 gas for lung scans. The inspectors also observed the elution and preparation of F-18, Tc-99m, I-131, and Lu-177 doses at the University's Hospital's compounding radiopharmacy, as well as HDR pre-treatment quality assurance checks at the Cancer Center. Licensee staff were knowledgeable of radiation protection principles and regulatory requirements, and used adequate ALARA practices, personnel dosimetry, and calibrated and operable radiation detection instruments. Independent surveys by the inspectors found no evidence of residual contamination or exposures to members of the public above regulatory limits.

The inspectors confirmed that all facilities inspected were adequately posted, and that all licensed material inspected was adequately secured and accounted for, including the HDR unit, two intravascular brachytherapy (IVB) devices containing strontium-90 (Sr-90) source trains, and miscellaneous sources and waste in the radiation oncology hot lab.

The inspectors reviewed a selection of over 300 written directives and associated treatment, verification, and release documentation for Ir-192 HDR, Sr-90 IVB, Y-90 microsphere, liquid I-131, I-131 MIBG, Lu-177, and radium-223 therapies, and confirmed that the licensee's various procedures provided high confidence that each modality would be performed in accordance with the written directive. The inspectors also reviewed a selection of routine nuclear medicine records, additional quality assurance

checks, source exchange documentation, and operator training records for the HDR unit, sealed source leak tests for the IVB devices, and inpatient exposure and survey records.

3.3 Conclusions

The inspectors reviewed a selection of activities related to the medical use of licensed material and had no findings in this area.

4 Academic Use under the Broad Scope Program

4.1 Inspection Scope

During the week of September 12, 2022, the inspectors toured a variety of academic use laboratories, interviewed RSS personnel as well as authorized and supervised users, and reviewed a selection of records related to the academic use of licensed material.

4.2 Observations and Findings

The inspectors toured academic use laboratories in BSRB, LSI, MS-II, MSRB-II, the Chemistry Building, the Kinesiology Building, the Brehm Center for Diabetes Research, and Michigan Memorial Phoenix Project facility. The inspectors also toured the licensee's on-campus hazardous waste facility at the North Campus. Each area inspected was adequately posted, and all licensed material stored in these areas was adequately secured and accounted for. The inspectors observed demonstrations of self-shielded irradiator use, discussed the safe use of radiolabeled compounds and sealed sources with authorized and supervised users, discussed the collection and handling of radioactive waste, performed independent surveys, and reviewed a selection of records including use logs, area surveys, and training records.

4.3 Conclusions

The inspectors reviewed a selection of activities related to the academic use of licensed material and had no findings in this area.

5 Irradiator Removal

4.1 Inspection Scope

On September 13, 2022, the inspectors observed the preparation and removal of a self-shielded irradiator, interviewed personnel from the University and an authorized service provider, and reviewed a selection of records related to the operation.

4.2 Observations and Findings

The inspectors observed the after-hours dismantling, removal, and packaging for shipment of an MDS Nordion Gammacell 40 Extractor self-shielded irradiator from LSI, including facility and security preparations. The operation, part of the National Nuclear

Security Administration's Off-Site Source Recovery Program, was managed by Los Alamos National Laboratory, and was performed by Best Theratronics (NRC License No. 45-31299-01, Docket No. 030-37620).

The inspectors observed personnel from the authorized service provider dismantle the irradiator and secure both sources in their shielded positions, while University personnel and members of local law enforcement provided direct control and constant visual surveillance of the device and its departure from the facility. Independent surveys during the operation confirmed that both sources remained fully shielded throughout. Service provider personnel performed and analyzed leak tests of the sources prior to shipment and prepared the irradiator's packaging. The inspectors reviewed the results of these tests, confirmed that the irradiator was packaged, marked, and labeled for shipment appropriately, and that the device was transferred out the University's possession at the conclusion of the operation.

4.3 Conclusions

The inspectors observed the irradiator removal operation in full and had no findings in this area.

6 Review of NMED 210369

6.1 Inspection Scope

During the week of September 12, 2022, the inspectors reviewed the licensee's response to the discovery of a leaking nickel-63 (Ni-63) foil source, including the licensee's written report.

6.2 Observations and Findings

The inspectors discussed the leaking source with RSS staff and reviewed a selection of records related to its discovery and resolution, including leak test results, area surveys, and transfer documentation. The inspectors noted that on August 2, 2021, RSS personnel had removed an electron capture device (ECD) containing the 15 mCi Ni-63 foil source from a gas chromatograph (GC) to facilitate scheduled disposal of the device. Although semi-annual leak tests of the ECD had not indicated excess removeable contamination since it was installed in 2009, the leak test that the licensee performed after removing the ECD from the GC indicated removeable contamination of 240 becquerels (Bq), which exceeded the reporting threshold in 10 CFR 31.5(c)(5) of 185 Bq. The licensee performed a second leak test to confirm the presence of removeable contamination and performed contamination surveys to identify additional areas of contamination. Removeable contamination was found inside the GC, so the licensee decontaminated the device and performed a follow-up survey to verify that no removeable contamination remained. The licensee packaged the ECD as radioactive waste and transferred it along with other radioactive waste to a licensed broker on September 29, 2021.

The inspectors also confirmed that the licensee's written report dated August 24, 2021, contained all required information and had been submitted in a timely manner. The

licensee noted, however, that the ECD serial number reported as U16038 was incorrect; it was in fact U15213.

6.3 Conclusions

The inspector reviewed the licensee's response to a leaking Ni-63 foil source and had no findings in this area. The NRC's review of this event is closed.

7 Cyclotron Operations

7.1 Inspection Scope

On September 13, 2022, the inspectors observed the production of licensed material, interviewed cyclotron personnel, and reviewed a selection of records related to the University's cyclotron operations.

7.2 Observations and Findings

The inspector toured the cyclotron facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory surveys of the facility and found no indications of residual contamination or any exposures to members of the public above regulatory limits. The inspector observed two cyclotron runs: one for F-18 and another for N-13. The licensee's staff demonstrated and discussed the implementation of procedures for cyclotron operations, including maintenance, area surveys, air effluent monitoring, and waste handling. Through these observations and discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspectors also independently assessed the licensee's air effluent monitoring methods and results.

7.3 Conclusions

The inspectors reviewed the University's cyclotron operations and had no findings in this area.

8 Special Nuclear Material

8.1 Inspection Scope

During the week of September 12, 2022, the inspectors toured the University's facilities for use of special nuclear material (SNM), interviewed personnel involved in this use, and reviewed a selection of records related to SNM use.

8.2 Observations and Findings

The inspectors toured the Michigan Memorial Phoenix Project facility, performed independent radiation surveys, and interviewed authorized users, researchers, and radiation safety staff who handled and used the sources. The inspectors also reviewed a selection of records associated with the licensed activities including inventories, leak

tests, and transfer and disposal records as well as verified the accuracy of the information tracked by the Nuclear Materials Management and Safeguards System (NMMSS).

The inspectors found that the licensee stored licensed material safely and securely and had appropriate postings commensurate to the radiological conditions. The inspectors also found that licensee staff who used and handled licensed sources wore appropriate dosimetry, were familiar with the radiological hazards associated with the materials and were knowledgeable of the radiation safety practices and the licensee's procedures. The records review showed that the licensee performed the required inventory verification and leak tests at the appropriate periodicity, and that the NMMSS inventory and transfer information was accurate.

8.3 Conclusions

The inspectors reviewed the University's use of special nuclear material and had no findings in this area.

9 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings on September 16, 2022, at the conclusion of the onsite inspection. The inspectors completed their in-office review on October 11, 2022, and informed the RSO of the results later that day. No violations of NRC requirements were identified.

LIST OF ENVIRONMENT, HEALTH & SAFETY PERSONNEL CONTACTED

Mike Dressler – Manager, HMM
\# Karl Fischer, CHP – Director, RSS
\# Yuanqing Guo – Senior EHS Representative, RSS
\# Rob Newton – Senior EHS Representative, RSS
\# Dennis Palmieri, MPH, JD – Coordinator, RSS
\# Justin Quinn – EHS Representative II, RSS
Shawn Rice – EHS Representative I, RSS
\# Danielle Sheen, CIH – Executive Director

\# Attended preliminary exit meeting on September 16, 2022

PARTIAL LIST OF OTHER PERSONNEL CONTACTED

Robert Ackerman – Clinical Division Manager, Nuclear Medicine
Taehwan Ahn, PhD – Research Fellow, Nuclear Engineering and Radiological Sciences
\# Henry Baier – Associate VP, Facilities & Operations
Joe Finch – Nuclear Medicine Technologist
Kristie Jensen – Registered Nurse, Mott Children's Hospital
Shruti Jolly, MD – Associate Chair, Radiation Oncology
David Karnak, PhD – Research Lab Specialist
Matt Kazmierski, RPh – Clinical Pharmacist Specialist
Choonik Lee, PhD – Director, Brachytherapy Physics
Carea Mullin – Research Technician Associate
Katie Naheedy, MS – Quality Safety Officer, Radiation Oncology
\# Joann Prisciandaro, PhD – Professor, Radiation Oncology
Maryam Shirmohammad, PhD – Research Fellow, Radiation Oncology
Peter Siekierski – Nuclear Medicine Technologist
Nancy Tena – Clinical Nurse Specialist, Mott Children's Hospital
Ben Viglianti, MD, PhD – Nuclear Medicine Service Chief
Andrew Weeden – Nuclear Medicine Technologist
Lisa Young – Radiation Therapy Dosimetrist

\# Attended preliminary exit meeting on September 16, 2022

INSPECTION PROCEDURES USED

IP 87126 – Broad-Scope Academic and Research & Development Programs
IP 87134 – Medical Broad-Scope Programs
IP 87140 – Source, SNM, and Other Alpha Emitter Use Programs
IP 87143 – Self-Shielded Irradiator and Calibrator Devices