

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2056 WESTINGS AVENUE, SUITE 400 NAPERVILLE, IL 60563-2657

November 27, 2024

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. 03001988/2024001(DRSS), 03038353/2024001(DRSS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Dear Karl Fischer:

On September 16-20, 2024, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine 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 22, 2024. The purpose of the inspection was to review activities performed under two 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 procedures for medical administrations requiring a written directive, and of security-related information. 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 NRC'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 20, 2024, 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 30, 2024, the inspectors completed their in-office review and informed you of the results of their review.

Based on the results of this inspection, the NRC has determined that three violations of NRC requirements occurred regarding activities performed under License No. 21-00215-04. The violations, all of a security-related and administrative nature, were evaluated in accordance with the NRC Enforcement Policy, available at http://www.nrc.gov/about-

Enclosures 1 and 3 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 1 and 3, this transmittal letter and Enclosure 2 are decontrolled.

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nrc/regulatory/enforcement/enforce-pol.html, and were each categorized at a Severity Level IV. Two violations were identified by the inspectors and as such are cited in the enclosed non-public Noticed of Violation (Enclosure 1). Details regarding the violations, their root cause, and corrective actions taken are described in the non-public Security Addendum to the inspection report (Enclosure 3).

The NRC has concluded that information regarding the reason for these violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in Enclosure 3. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

The third violation was identified by your program through audit activities. Because you identified the violation, corrected it promptly, and because the violation is not repetitive from inadequate corrective action or willful, this violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. If you contest the NCV or its significance, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

No violations of NRC requirements were identified during this inspection regarding activities performed under License No. 21-00215-07.

In accordance with the NRC's "Agency Rules of Practice and Procedure" 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 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. However, because this issue involves security-related information, the enclosures to this letter and any response you provide will not be made available electronically for public inspection. If you do respond, please mark the top of each page with "Security-Related Information – Withhold Under 10 CFR 2.390". 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.

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K. Fischer

Please feel free to contact Ryan Craffey, Mary Casto, or Daniel Fiedorek of my staff if you have any questions regarding this inspection. Ryan can be reached at <u>ryan.craffey@nrc.gov</u> or 630-829-9655. Mary can be reached at <u>mary.casto@nrc.gov</u> or 630-829-9837. Daniel can be reached at <u>daniel.fiedorek@nrc.gov</u> or 630-829-9836.

Sincerely,

Signed by Edwards, Rhex on 11/27/24

Rhex Edwards, Chief Materials Inspection Branch Division of Radiological Safety and Safeguards

Docket Nos.	030-01988	
	030-38353	

License Nos. 21-00215-04 21-00215-07

Enclosures:

- 1. Notice of Violation (Non-public)
- 2. IR Nos. 03001988/2024001(DRSS) and 03038353/2024001(DRSS)
- 3. Security Addendum to Inspection Report (on-public)

cc w/o encl 1 and 3: Danielle Sheen – Executive Director, Environment, Health and Safety State of Michigan

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Letter to K. Fischer from R. Edwards dated, November 27, 2024.

SUBJECT: NRC ROUTINE INSPECTION REPORT NOS. 03001988/2024001(DRSS), 03038353/2024001(DRSS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

DISTRIBUTION w/encl: Jack Giessner Mohammed Shuaibi David Curtis Jonathan Feibus Diana Betancourt-Roldan Kenneth Lambert Geoffrey Edwards Jason Draper MIB Inspectors

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OFFICE	RIII-DRSS	RIII-DRSS	RIII-DRSS	RIII-DRSS
NAME	MCasto:brt	DFiedorek	RCraffey	REdwards
DATE	11/25/24	11/22/24	11/22/24	11/27/24

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U.S. Nuclear Regulatory Commission

Region III Docket No. 030-01988 030-38353 License Nos. 21-00215-04 21-00215-07 Report Nos. 03001988/2024001(DRSS) 03038353/2024001(DRSS) Licensee: The Regents of the University of Michigan Facilities: Campus of the University of Michigan Ann Arbor, MI Brighton Center for Specialty Care Brighton, MI September 16-20, 2024 Inspection Dates: In-office review through October 22, 2024 October 30, 2024 Exit Meeting Date: Inspectors: Ryan Craffey, Senior Health Physicist Mary Casto, Health Physicist Daniel Fiedorek, Health Physicist Rhex Edwards, Chief Approved By: Materials Inspection Branch Division of Radiological Safety and Security

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Enclosure 2

EXECUTIVE SUMMARY

The Regents of the University of Michigan NRC Inspection Report Nos. 03001988/2024001(DRSS) and 03038353/2024001(DRSS)

This was an announced routine inspection of activities performed under two U.S. Nuclear Regulatory Commission materials licenses maintained by the Regents of the University of Michigan. License No. 21-00215-04 authorized the University 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. License No. 21-00215-07 also authorized the University to produce radiochemicals using cyclotrons for research and transfer to authorized recipients (primarily the University itself).

The on-site inspection was performed September 16-20, 2024, at the campus of the University of Michigan in Ann Arbor, and at the Brighton Center for Specialty Care in Brighton. The inspectors performed additional in-office review through October 22, 2024, to continue their evaluation of procedures for medical administrations requiring a written directive, and their review of security-related information.

Based on the results of this inspection, the NRC determined that three violations of NRC requirements occurred. The violations were of a security-related and administrative nature. The inspectors identified two of the violations, and the licensee identified the third during audit activities. Details regarding the violations, their root cause, and corrective actions are described in the non-public Security Addendum to this report.

REPORT DETAILS

1 Program Overview and Inspection History

The Regents of the University of Michigan maintained three NRC Materials Licenses authorizing the use of 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 campus enrolled around 52,000 students and employed around 32,000 academic, medical and administrative staff, 24,000 of which were employed by Michigan Medicine. 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. At the time of the inspection, there were 126 active users, and 461 areas of use approved by the RSS. 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, Kellog Eve Center, and the Brighton Center for Specialty Care. 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) at Mary Sue Coleman Hall, Biological Sciences Building (BSB), the Chemistry Building, the Nuclear Engineering Research Facility (NERF), and the North Campus Research Complex (NCRC). The University had not performed licensed activities at the Flint Campus, Domino's Farms Corporation, or at temporary job sites since at least 2014. Two researchers occasionally used small amounts of unsealed radiolabeled material at the Dearborn campus, and small quantities of mixed 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) and carbon-11 (C-11) gas multiple times a day, and occasionally nitrogen-13 (N-13) and gallium-68 (Ga-68). 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.

The University also maintained a special nuclear material (SNM) license (SNM-179, Docket No. 070-00192) for nuclear engineering research and instructional purposes. The licensee still possessed a limited number of SNM sources; however, this license was not inspected at this time as it is on a different inspection frequency than the others.

All three licenses were most recently inspected during the week of September 12, 2022. No violations of NRC requirements were identified as result of that routine inspection.

2 Radiation Safety Service

2.1 Inspection Scope

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.

2.2 Observations and Findings

The inspectors observed RSS staff perform survey instrument calibrations, reviewed the implementation of procedures for radioactive waste handling, and examined a selection of records including RPC meeting minutes, authorized user approvals, program audits and incident reports, personnel dosimetry reports, ALARA notifications, contamination exposure evaluations, and notices of deficiency issued to authorized users by RSS.

During a review of radiation safety program audit records, the inspectors noted a licensee-identified finding regarding periodic audits of nuclear medicine areas. Although the inspectors confirmed that at a minimum, the licensee audited each at least annually per regulatory requirements, some were not audited at least quarterly, per RSS expectations. The inspectors discussed this matter with RSS and found that the licensee did not have a formal tracking method or mechanism for timely completion of these audits, other than relying on staff to know when their assigned areas were due for an audit. The inspectors discussed the value of effective tracking mechanisms in ensuring compliance and effective oversight of licensed activities. Future inspections should continue to evaluate the licensee's timely completion of these audits.

The inspectors also visited the North Campus Transfer Facility where radioactive waste was prepared for disposal. The inspectors interviewed staff to discuss procedures for collecting waste from campus, logging it at the transfer facility, and preparing it for disposal, as well as after-hours spill response. The inspectors confirmed that the radioactive waste handling bay was checked for contamination every week and air monitor filters were counted according to facility policies.

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

3 Diagnostic Use of Radiopharmaceuticals

3.1 Inspection Scope

The inspectors visited University Hospital, the Cardiovascular Center, and the Brighton Center for Specialty Care to evaluate the licensee's diagnostic use of radiopharmaceuticals. The inspectors interviewed RSS personnel, authorized users, and technologists, and reviewed a selection of records related to this use.

3.2 Observations and Findings

The inspectors observed numerous administrations of radiopharmaceuticals containing iodine-123, technetium-99m, fluorine-18 (F-18) and rubidium-82 (Rb-82). The University Hospital and Cardiovascular Center used automated infusion machines for administrations of F-18 and Rb-82 radiopharmaceuticals, respectively. The inspectors noted that the use of these machines notably reduced exposures to staff in the radiopharmacy and in injection rooms.

Licensee staff were knowledgeable of radiation protection principles and regulatory requirements. They used adequate ALARA practices, personnel dosimetry, and calibrated and operable radiation detection instruments throughout. Independent surveys by the inspectors found no evidence of residual contamination or exposures to members of the public above regulatory limits.

The inspectors also confirmed that all facilities inspected were adequately posted, and that all licensed material inspected was adequately secured and accounted for. The inspectors also reviewed a selection of RSS audits, dose calibrator quality assurance records for both infusion machines, and routine nuclear medicine records.

3.3 Conclusions

The inspectors reviewed a selection of activities related to the diagnostic use of radiopharmaceuticals and had no observations or findings in this area.

4 Therapeutic Use of Radiopharmaceuticals

4.1 Inspection Scope

The inspectors visited University Hospital and the Brighton Center for Specialty Care to evaluate the therapeutic use of radiopharmaceuticals. They interviewed RSS personnel, authorized users, authorized medical physicists, and technologists, and reviewed a selection of records related to this use.

4.2 Observations and Findings

The inspectors observed two lutetium-177 (Lu-177) Lutathera treatments, one Lu-177 Pluvicto treatment, and one liquid I-131 treatment, including dose preparation and delivery and waste handling. The inspectors noted that one Lu-177 Lutathera dose was adjusted at the Authorized User's direction; the inspectors confirmed that the written directive was revised accordingly prior to administration.

Licensee staff were knowledgeable of radiation protection principles and regulatory requirements. The used adequate ALARA and contamination control practices, personnel dosimetry, and calibrated and operable radiation detection instruments throughout. Independent surveys by the inspectors found no evidence of residual contamination or exposures to members of the public above regulatory limits.

The inspectors reviewed a selection of around 150 written directives along with associated treatment planning and verification documentation for therapeutic administrations of I-131, Lu-177, and radium-223 Xofgio, and found that the licensee's procedures continued to provide high confidence that each would be performed in accordance with the written directive. The inspectors also reviewed room surveys as well as release calculations and instructions for a variety of therapeutic administrations.

4.3 <u>Conclusions</u>

The inspectors reviewed a selection of activities related to the therapeutic use of radiopharmaceuticals and had no observations or findings in this area.

5 Brachytherapy

5.1 Inspection Scope

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 use of licensed material for brachytherapy.

5.2 Observations and Findings

A. Intravascular Brachytherapy (IVB)

The inspectors observed two intravascular brachytherapy treatments using strontium-90 (Sr-90), including real-time treatment planning by the authorized user and interventional radiologist in the operating room.

The Sr-90 treatment device was adequately shielded and handled by the attending medical physicist until treatment. Independent and confirmatory surveys of the unit noted no unusual readings. Adequate emergency response equipment was readily available throughout the treatments, which both proceeded without issue according to treatment checklists which provided high confidence that the treatment would be performed in accordance with the written directive.

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During the treatments, the inspectors noted that the authorized user provided an oral directive to the medical physicist for both treatments, specifying vessel diameter (and thus dose) and injury length (and thus number of steps) while in the operating room's sterile field. The authorized user promptly signed both written directives upon completing the treatment and leaving the sterile field. The licensee confirmed that this was standard practice for IVB treatments.

The inspectors reviewed the licensee's basis for providing an oral directive as standard practice. The authorized user confirmed that they do not know patient-specific treatment parameters (treatment site and dose) until entering the sterile field to confer with the interventional radiologist already present in the sterile field to discuss and evaluate the status of the intervention and to evaluate the patient's anatomy under fluoroscopy to determine the required treatment parameters. The authorized user confirmed that the condition of the anesthetized patient undergoing this procedure calls for prompt action, and that a delay to leave the sterile field to sign a written directive prepared by the medical physicist would jeopardize the patient's health.

The inspectors confirmed that the authorized user was intimately involved in each step of the procedure and was present in the operating room for all measurements used in calculating the therapeutic dose to be administered. The inspectors further determined that it was not possible to estimate the treatment dose prior to placing the patient under anesthesia and making the requirement measurements, and that the AU could only sign the written directive prior to administration if they (1) were not sufficiently involved in taking the measurements required to determine the dose; or (2) left the sterile field in the operating room in order to sign the written directive. Either action could jeopardize the anesthetized patient's health by requiring a delay to provide a signed written directive. Therefore, the inspectors concluded that an oral directive was acceptable under the circumstances per 10 CFR 35.40(a)(1).

B. Other Brachytherapy

The inspectors observed two high dose rate (HDR) remote afterloading brachytherapy treatments iridium-192 (Ir-192), as well as spot checks of the licensee's HDR unit.

The HDR vault remained adequately posted, and the HDR unit remained adequately secured and in good condition. Independent surveys of the unit noted no unusual readings. Emergency procedures and contact information was current and readily available at the treatment console. Licensee staff were knowledgeable of HDR operation and emergency response procedures, wore personnel dosimetry as required, and used calibrated and operable survey instruments appropriately during and after treatment.

The inspectors reviewed a selection of written directives and associated treatment planning, verification, and release documentation for Ir-192 HDR, yttrium-90 (Y-90) microsphere, and iodine-125 (I-125) eye plaque brachytherapy treatments, and found that the licensee's procedures continued to provide high confidence that each modality would be performed in accordance with the written directive.

The inspectors reviewed a selection of activities related to the use of licensed material for brachytherapy and identified no violations of regulatory requirements in this area.

6 Cyclotron Operations

6.1 Inspection Scope

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

6.2 Observations and Findings

The inspectors observed five cyclotron runs over three days (three for carbon-11 (C-11) and two for F-18) including synthesis, quality control, and delivery. The inspectors also observed three elutions of Ge/Ga generators kept in the cyclotron facility, including quality control and delivery. All vials were adequately labeled prior to loading and adequately shielded for handling and delivery.

The cyclotron facility remained adequately posted and adequately secured or under control and constant surveillance of licensee staff. Independent surveys of the facility found no evidence of residual contamination in restricted areas or exposures in unrestricted areas above regulatory limits to the public. Licensee personnel were knowledgeable of cyclotron operations including synthesis and material handling and implemented available ALARA practices effectively. The inspectors also traced portions of the licensee's air effluent handling system and confirmed that at least six of the building's strobic fans were in operation at any given time, consistent with license commitments.

The inspectors reviewed the circumstances of an inadvertent release of C-11 CO_2 into the cyclotron chemistry area on January 4, 2024. The release was due to a misunderstanding during delivery line realignment which resulted in a cyclotron delivering approximately 500 millicuries (mCi) into the cyclotron chemistry room atmosphere instead of a hot cell for synthesis. Area exposure monitors alarmed within moments of the delivery proceeding and the staff immediately exited and secured the area while the C-11 was evacuated by the area's monitored ventilation system. Upon verifying that area exposure and ventilation monitors had returned to background, the staff reentered the room approximately 10 minutes later.

The inspectors confirmed that this occurrence did not meet any reportability criteria based on activity and short duration of area restrictions. The inspectors reviewed the licensee's response and found it adequate for the circumstances. The inspectors also reviewed the licensee's investigation report, agreed with the root cause determination, and found the licensee's actions in response to be adequate to address the potential for recurrence.

The inspectors reviewed the University's cyclotron operations and identified no violations of regulatory requirements in this area.

7 Academic Use of Licensed Material

7.1 Inspection Scope

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.

7.2 Observations and Findings

The inspectors toured laboratories in BSB, BSRB, LSI, MS-II, MSRB-I, MSRB-III, the Brehm Center for Diabetes Research, the Chemistry Building, and the NERF. Each area inspected was adequately posted, and all licensed material stored in these areas was adequately secured and accounted for. Facilities and equipment including survey instruments and shielding appeared adequate for the ongoing uses of licensed material.

The inspectors observed demonstrations of self-shielded irradiator and custom 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.

The licensee had recently acquired depleted uranium (DU) for research of fluorinated salts at the NERF building. The inspectors discussed with the principal investigator and other users their plans for using the DU, as well as contamination control measures, waste handling processes, material accounting and security measures, personnel monitoring methods, and emergency procedures. The inspectors also discussed personnel safety practices with the principal investigator due to the other non-radioactive hazards present in the research. The inspectors reviewed the RSS approval for the DU research and discussed special conditions included in the approval with the principal investigator. The inspectors observed the storage location of the DU in the NERF building as well.

The inspectors also evaluated the licensee's use of a custom-built beam irradiator containing cesium-137, also in the NERF building, which was primarily used for irradiating samples for researchers in other departments and classroom demonstrations. The inspectors reviewed the approval for the irradiator and interviewed the principal investigator about material security and access control measures, personnel monitoring methods, utilization longs, operating and emergency procedures, and unit maintenance. The inspectors verified all postings were adequate and the unit remained secured when not under direct observation of an authorized user.

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

8 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings on September 20, 2024, at the conclusion of the onsite inspection. The inspectors completed their in-office review on October 22, 2024, and informed the RSO of the results during a final inspection exit meeting on October 30, 2024.

LIST OF ENVIRONMENT, HEALTH & SAFETY PERSONNEL CONTACTED

Marco Camacho – Health Physicist

- # Debbie DeNapoli Director of Safety Management Services
- # Karl Fischer, CHP Radiation Safety Director (RSO)
- # Adam Goldsmith Health Physics Technician
- # Levi Klankowski Health Physics Technician
- # Alexis Marsh Intern
- # Liana Mulet Health Physicist
- # Rob Newton Senior Health Physicist
- # Dennis Palmieri, MPH, JD Senior Health Physicist, Health Physics Coordinator
- # Shawn Rice Health Physics Technician
- # Marina Roelofs Co-Interim Associate Vice President for Facilities and Operations
- # James Washington RDRC-SHUR Administrator
- # Attended preliminary exit meeting on September 20, 2024

LIST OF MEDICAL USE PERSONNEL CONTACTED

Smita Chauhan – Nuclear Medicine Technologist Austin Falbe – Nuclear Medicine Technologist Joseph Finch – Nuclear Medicine Technologist

- # Karolyn Hopfensperger Clinical Assistant Professor of Radiation Oncology David Hubers, RPh – Clinical Pharmacist Megan Janisch – Nuclear Medicine Technologist Matt Kazmierski, RPh – Clinical Pharmacist Specialist
- # Choonik Lee, PhD Director, Brachytherapy Physics and Clinical Associate Professor of Radiation Oncology
 Benson Lin – Nuclear Medicine Technologist
 Kelly Lindberg – Nuclear Medicine Technologist
 Kayla Miller – Nuclear Medicine Technologist
- # Katie Woch Naheedy, MS Quality Safety Officer
- # Regan Newton Senior Healthcare Administrative Manager
- # Jeremy Niedbala Nuclear Laboratory Technologist Supervisor
- # Joann Prisciandaro, PhD Program Director, Clinical Physics and Clinical Professor of Radiation Oncology

Paul Reder – Nuclear Medicine Technologist

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Peter Siekierski – Nuclear Medicine Technologist Ben Viglianti, MD, PhD – Clinical Associate Professor of Radiology and Service Chief of Nuclear Medicine

Attended preliminary exit meeting on September 20, 2024

PARTIAL LIST OF CYCLOTRON PERSONNEL CONTACTED

Juan Camarena Diaz – Radiochemist Technical Specialist Alexandra Dumond – Senior Research Laboratory Specialist Jessica Gomez Lopez – Intermediate Research Lab Specialist Charles Schneider – Biomedical Engineering Technician – Radiology Cyclotron Technician

- # Peter Scott, PhD Professor of Radiology, Program Assistant of Cyclotron Facility and Division Chief, Nuclear Medicine
- # Attended preliminary exit meeting on September 20, 2024

LIST OF ACADEMIC USE PERSONNEL CONTACTED

Emily Bristow – Intermediate Research Laboratory Specialist Cleo Burnett – Associate Research Laboratory Specialist Adrien Chauvier – Senior Research Laboratory Specialist James Hogan – Intermediate Research Laboratory Specialist David Karnak, PhD – Senior Research Laboratory Specialist Theresa Keeley – Associate Research Laboratory Specialist Dennis Larkin – Senior Research Laboratory Specialist Randy Stockbridge – Associate Professor of Molecular, Cellular and Developmental Biology and Associate Professor of Biophysics

INSPECTION PROCEDURES USED

IP 87126 – Broad-Scope Academic and Research & Development Programs

- IP 87134 Medical Broad-Scope Programs
- IP 87143 Self-Shielded Irradiator and Calibrator Devices