



Materials Inspection Report

1. Licensee/Location Inspected: Saint Louis University Office of Environmental Health and Safety 1402 South Grand Blvd. St. Louis, MO 63104 Report Number(s) 2025001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2056 Westings Avenue, Suite 400 Naperville, IL 60563-2657
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3. Docket Number(s) 030-11789	4. License Number(s) 24-00196-07	5. Date(s) of Inspection May 22-23, 2025
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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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))

 - B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	ZAHID SULAIMAN <small>Digitally signed by ZAHID SULAIMAN Date: 2025.06.09 12:37:33 -05'00'</small>
BRANCH CHIEF	Rhex A. Edwards, Chief, MIB (for RE)	<i>Rhex Edwards</i> <small>Digitally signed by RYAN CRAFFEY Date: 2025.06.13 08:44:24 -05'00'</small>



Materials Inspection Record

1. Licensee Name: Saint Louis University		2. Docket Number(s): 030-11789		3. License Number(s) 24-00196-07	
4. Report Number(s): 2025001			5. Date(s) of Inspection: May 22-23, 2025		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02110	8. Priority: 2	9. Inspection Guidance Used: 87126, 87134	
10. Licensee Contact Name(s): Kevin Ferguson, RSO		11. Licensee E-mail Address: kevin.ferguson@slu.edu		12. Licensee Telephone Number(s): (314) 977-6896	

13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		<input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		05/22/2027 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Location(s) Inspected List:
 Main Hospital: 1201 South Grand Blvd., St. Louis, MO
 Research Laboratory:
 North Campus: Macelwane Hall, 3507 Laclede Ave., St. Louis, MO
 South Campus: Edward A. Doisy Research Center 1100 South Grand Blvd., St. Louis, MO

17. Scope and Observations:
 This was a routine, unannounced inspection of a multi-site broad scope medical and research and development licensee with facilities located at Saint Louis University (SLU), in St. Louis, Missouri. The licensee was authorized to possess and use a variety of types of radioactive material for medical diagnosis, therapy, and research in humans in accordance with any applicable U.S. Food and Drug Administration requirements; research and development as defined in 10 CFR 30.4, including animal studies and in-vitro studies; instrument calibration; and student instruction.

The licensee had an active Radiation Safety Committee (RSC) that was responsible for oversight of licensed activities and approval of authorized users and principal investigators or research permit holders. R&D was performed at various RSC approved locations throughout SLU's campus. At the time of the inspection, there were 10 research permit holders. Two of the laboratories were storing material and seven of the laboratories were actively using byproduct material. The research laboratories primarily use the carbon-14, hydrogen-3, and iodine-125 radionuclides. The licensee had a full-time Radiation Safety Officer (RSO) that was supported by an assistant RSO and one health physicist technician.

The main hospital nuclear medicine department was staffed with six nuclear medicine technologists (NMTs) who rotate between the nuclear medicine clinic, PET clinic, and theranostics administrations. The NMTs performed approximately 16-20 administrations of unsealed byproduct material not requiring a written directive on a daily basis at the nuclear medicine and PET clinics. The licensee performed administrations of unsealed byproduct material requiring a written directive for the following therapeutic procedures: 49 lutetium-177 (46 Pluvicto and 3 Dotatate); 24-30 iodine-131 (hyperthyroid and thyroid ablation, capsule form), 86 yttrium-90 (Y-90, 52 TheraSpheres and 34 SIRSpheres), 7 Eye90 microspheres (first case performed on 10/24/24), 2 actinium-225 (Ac-225) with 4 fractions each under drug research and development studies, and 19 cesium-131 (cs-131, gammatile, first case performed on 01/11/24) brachytherapy procedures in the last year.

Materials Inspection Record (Continued)

PERFORMANCE OBSERVATIONS

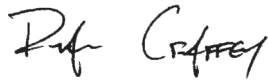
This inspection consisted of a tour of the nuclear medicine department, PET clinic, research laboratories; interviews with select licensee personnel; a review of select records; an observation of security of the materials; and independent measurements. The inspector observed two diagnostic administrations of licensed materials including dose preparation and disposal. The inspector verified the location of sealed sources from the licensee's most recent inventory, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures. The inspector had the NMT describe and demonstrate the Y-90 dose preparation, pre- and post-vial dose measurement, and dose calculation to the treatment sites. At the time of inspection, the AU for the Cs-131 gamma-tile manual brachtherapy procedure was not available. However, through telephone communication and with the support of dosimetrist, the inspector had the AU described the pre- and post-written directives and treatment plans, with no issues noted. Through these demonstrations and discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements. The inspector also reviewed RSC's approval process of two authorized users for manual brachytherapy procedures using cesium-131 gamma-tiles.

The inspector reviewed the following records: quarterly audits, radiation safety committee minutes, written directives, package receipts, waste disposal records, master inventory tracking system, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, spill report, sealed source leak tests and inventory, daily area surveys, weekly wipe tests, and dosimetry records. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector reviewed and verified the following corrective actions and recommend that previous violations be closed (EN 56337, IR 03011789/2023001 (DRSSS)). The inspector reviewed and verified that: (1) the licensee trained NMTs on February 2 and 3, 2023, on the importance of visually inspecting and performing radiation surveys of each shipping package before placing it in the hallway for disposal, (2) a specific area was designated for the exclusive placement of incoming therapy dose shipments in the hot lab, (3) the licensee developed procedure for the disposition of empty therapy dose shipment boxes titled "Disposition of Empty Radiopharmaceutical Therapy Containers for Nuclear Medicine", (4) a camera was installed inside the nuclear medicine hot lab, outside the hot lab, inside the PET-CT hot lab, and outside the PET-CT hot lab area, and (5) the licensee provided annual refresher training to NMTs on the updated procedures, last annual refresher completed was on February 2025. These actions appeared satisfactory to address the potential for recurrence, and the violation had not occurred again since.

No violations of NRC requirements were identified as a result of this inspection.

Signature and Date - Branch Chief



Digitally signed by RYAN CRAFFEY
Date: 2025.06.13 08:43:30 -05'00'