

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| 1. LICENSEE/LOCATION INSPECTED: Saint Louis University Office of Environmental Health and Safety 1402 South Grand Blvd. St. Louis, MO 63104 REPORT NUMBER(S) 2021001 | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 |
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| 3. DOCKET NUMBER(S) 030-11789 | 4. LICENSE NUMBER(S) 24-00196-07 | 5. DATE(S) OF INSPECTION Remote inspection from 03/19/2021 through 04/07/2021 |
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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. 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, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and 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 | DATE |
|---------------------------|------------------------------------|---|------|
| LICENSEE'S REPRESENTATIVE | | | |
| NRC INSPECTOR | Dennis P. O'Dowd, Health Physicist | Dennis P. O'Dowd <small>Digitally signed by Dennis P. O'Dowd Date: 2021.04.16 16:53:15 -05'00'</small> | |
| BRANCH CHIEF | Michael A. Kunowski, Chief, MIB | Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.04.19 06:48:20 -05'00'</small> | |



Materials Inspection Record

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| 1. Licensee Name: Saint Louis University | | 2. Docket Number(s): 030-11789 | | 3. License Number(s) 24-00196-07 | |
| 4. Report Number(s): 2021001 | | | 5. Date(s) of Inspection: Remote inspection from 03/19/2021 through 04/07/2021 | | |
| 6. Inspector(s): Dennis P. O'Dowd, Health Physicist | | 7. Program Code(s): 02110 | 8. Priority: 2 | 9. Inspection Guidance Used: 87126, 87131, and 87134 | |
| 10. Licensee Contact Name(s): Mark G. Haenchen, M.S., J.D., Radiation Safety Officer | | 11. Licensee E-mail Address: mark.haenchen@slu.edu | | 12. Licensee Telephone Number(s): (314) 977-6885 | |
| 13. Inspection Type: <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced | | 14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote | | 15. Next Inspection Date (MM/DD/YYYY): 03/19/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change | |

16. Scope and Observations:

This was a routine inspection of Saint Louis University's (SLU) medical broad scope license. The licensee was authorized to use byproduct material with atomic numbers 1-83, and specifically listed sealed sources for medical diagnosis, therapy, and research in humans, and research and development as defined in 10 CFR 30.4. SLU was also authorized for byproduct material permitted by 10 CFR 35.100, 35.200, 35.300, 35.500, and 10 CFR 31.11. The Environmental Health and Safety (EH&S) department was staffed by 1 full-time Radiation Safety Officer (RSO) and 2 full-time health physicists (HPs). The licensee's nuclear medicine (NM) department, located at SSM Health Saint Louis Hospital, 1201 South Grand Blvd., received and used primarily unit diagnostic doses, (with bulk Tc-99m ordered for preparation and use for unscheduled studies and on weekends), from a local radiopharmacy. The NM department was staffed by 1 manager and 3 full-time certified nuclear medicine technologists (NMTs). The department performed an average of 8-10 diagnostic procedures each day. Since the last inspection, conducted in April 2018, the licensee performed about 38 iodine-131, 179 yttrium-90, 57 radium-223 Xofigo, and 33 lutetium-177 therapeutic procedures. The licensee also performed 4-6 PET procedures each day at 3655 Vista Avenue. Unit doses of 6-15 millicuries of flourine-18 were received from a local nuclear pharmacy. The licensee had a Radiation Safety Committee (RSC) that met no less than on a quarterly basis, (7 RSC meetings in 2019, and 5 RSC meetings in 2020), and was responsible for approving authorized users for both medical procedures, and research and development (R&D) studies. R&D was performed at various RSC-approved locations throughout SLU's campus, as well as at specific locations listed on the license. At the time of the inspection, the licensee had 17 RSC-approved laboratories; only one of these was active during the inspection period, with the remainder in "storage-only" status. All but two of the laboratories were located on the South campus; the 2 other laboratories were located on the North campus. One laboratory, currently in "storage-only" status, was approved for labeled iodine-125 studies, and the others were approved for low-millicurie quantities of hydrogen-3, carbon-14, sulphur-35, and/or phosphorous-32 procedures.

In accordance with current agency policy during the Covid-19 public health emergency, this inspection was announced, and performed through telephonic and video conferencing interviews with the licensee's Radiation Safety Officer (RSO) and other licensee staff, direct observations of licensed activities and facilities by the inspector in real-time via video camera, and review of requested documentation provided by the licensee via secured email as well as during the video conferencing portion of the inspection.

PERFORMANCE OBSERVATIONS

The inspector conducted a virtual tour, and made observations, of licensed activities in the NM and PET

Materials Inspection Record (Continued)

departments, 1 RSC-approved R&D laboratory (Doisy Research Center, 1100 South Grand Blvd.), the radioactive material package receipt room (Doisy Hall, 1402 South Grand Blvd.), the radiological instrument/equipment area (Doisy Hall), and the radioactive waste storage area (Doisy Hall), in order to evaluate the licensee's procedures and measures for materials security and safety, hazard communication, and exposure control. The inspector interviewed the RSO and 1 HP, the NMT manager, 2 NMTs, the Radiology Department Director, 1 PET NMT, and the primary user/laboratory worker in one of the R&D labs. The inspector observed a variety of activities during the virtual tours, including the preparation for a yttrium-90 procedure in the nuclear medicine "hot" lab, as well as other related nuclear medicine and PET department activities. Commensurate with specific duties, licensee staff were observed to be wearing appropriate protective clothing and personal dosimetry, and performed appropriate surveys and personnel contamination monitoring. Although the inspector was not able to conduct independent surveys due to the remote nature of the inspection, the inspector was able to observe the licensee's use of survey instruments, determined that survey techniques were conducted in accordance with accepted health physics practices, and that it appeared that no exposures to members of the public were in excess of regulatory limits. The survey instruments observed to be in use were shown by the licensee to be operable and properly calibrated. Licensee staff discussed and demonstrated its procedures, and through these observations, demonstrations, and discussions, the inspector found the staff to be knowledgeable of radiation protection principles, the licensee's procedures, and regulatory requirements.

The licensee's annual radiation safety audits and the minutes of the Radiation Safety Committee meetings since the last inspection were reviewed during the inspection period, as were permit reviews and authorizations, a selection of written directives issued since the last inspection, training records, records pertaining to the receipt, use, storage, and disposal of radioactive materials in the NM and PET departments, and R&D laboratories, bioassay measurement records, and personnel dosimetry records. The review of dosimetry records indicated no exposures of regulatory concern.

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

From: [Mark Haenchen](#)
To: [O'Dowd, Dennis](#)
Subject: [External_Sender] Re: Saint Louis University, Office of Environmental Health and Safety - Transmittal of Inspection Report Form 591M (Part 1), "Safety Inspection Report and Compliance Inspection" (03/19/2021 - 04/07/2021) - NRC License No. 24-00196-07
Date: Tuesday, April 20, 2021 5:23:12 PM
Attachments: [Outlook-1511803523.png](#)

Good Afternoon Dennis,

Thank you for your email yesterday (*I was on vacation yesterday and most of today, so had not read until just now*). I am confirming receipt of your email and the PDF of NRC Form 591M that was attached.

We enjoyed working with you and glad we could accommodate completion of the inspection remotely.

Sincerely,

- Mark

Mark Haenchen, M.S., J.D.
*Executive Director, Environmental Health & Safety
and Radiation Safety Officer
Research Integrity & Safety Group
Office of the Vice President for Research
Saint Louis University*

Office: (314) 977-6885
Email: mark.haenchen@slu.edu



From: O'Dowd, Dennis <Dennis.O'Dowd@nrc.gov>
Sent: Monday, April 19, 2021 4:48 PM
To: Mark Haenchen <mark.haenchen@slu.edu>
Subject: [External] Saint Louis University, Office of Environmental Health and Safety - Transmittal of Inspection Report Form 591M (Part 1), "Safety Inspection Report and Compliance Inspection" (03/19/2021 - 04/07/2021) - NRC License No. 24-00196-07

Mark G. Haenchen, M.S., J.D.
Radiation Safety Officer
Saint Louis University
Office of Environmental Health and Safety
1402 South Grand Blvd.
St. Louis, MO 63104

NRC License No. 24-00196-07
Docket No. 030- 11789

Dear Mr. Haenchen:

Please find attached a Form 591M (Part 1), "Safety Inspection Report and Compliance Inspection," signed by me and Mr. Michael Kunowski, Chief, Materials Inspection Branch, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC), Region III, issued in response to the recent routine inspection of your licensed program. This inspection was conducted remotely from March 19, 2021, through April 7, 2021. The inspection consisted of discussions and interviews with you and your staff, conducted via videoconference and telephone, direct observations by the inspector via video, and the inspector's review of pertinent requested documents provided via email and during the videoconference. Please note that there were no violations of NRC requirements identified as a result of this inspection. Therefore, it is not necessary for you to sign and return this document; however, I would appreciate an email confirming that you have received this document.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this message, and the attached report, 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.

Thank you and your staff for your cooperation during this inspection.

Dennis P. O'Dowd

Health Physicist

Materials Inspection Branch

Division of Nuclear Materials Safety

U.S. Nuclear Regulatory Commission

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