NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Saint Louis University 3635 Vista Avenue St. Louis, MO 63110 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-11789	24-00196-07	April 23-24, 2018

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 violations(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	Kevin G. Null	K. G. Null	4/24/18
BRANCH CHIEF	Aaron T. McCraw		5/4/18

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Saint Louis University Office of Environmental Health and Safety 1402 South Grand Blvd. St. Louis, MO 63104 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-11789	24-00196-07	April 23 and 24, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87122, 87126, 87131, and 87134	03-01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2110	2	Mark Haenchen, RSO	(314) 977-6885

☑ Main Office Inspection Next Inspection Date: 4/24/2020

☑ Field Office Inspection 3635 & 3655 Vista Avenue, St. Louis, MO

☐ Temporary Job Site Inspection 1027 Bellevue Avenue, St. Louis, MO

PROGRAM SCOPE

This was a routine, unannounced 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 (HP's). The licensee's nuclear medicine (NM) department, located at 3635 Vista Avenue, received and used only unit diagnostic doses, and was staffed by 1 manager and 3 full-time certified nuclear medicine technologists (NMT's). The department performed an average of 8-10 diagnostic procedures each day. Since the last inspection, conducted in 2016, the licensee performed about 70 iodine-131, 100 yttrium-90, and 100 radium-223 Xofigo therapeutic procedures. The licensee also performed 2-6 PET procedures each day in the West Pavillion of the University hospital. 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 an a quarterly basis 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 22 RSC-approved laboratories on the South campus, and 1 laboratory on the North campus. One laboratory 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.

(Continued on Part 2)

NRC FORM 591M PART 2 (07-2012) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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(Continued)

PERFORMANCE OBSERVATIONS

The inspector toured and observed licensed activities in the NM and PET departments, 3 RSC-approved R&D laboratories, the radioactive material package receipt room, and the interventional radiology (IR) suite where yttrium-90 procedures were performed. The inspector interviewed the RSO and 1 HP, one NMT, the NMT manager, 1 PET NMT, and a random selection of R&D laboratory workers. The inspector observed a yttrium-90 procedure performed in the IR suite. This included a review of the written directive (WD), observations of the preparation and measurement of the dose by an NMT, surveys conducted of the IR suite and staff members after the procedure, and the results of the PET/ CT imaging of the patient to confirm that the radioactive material was administered to the location specified in the WD. The inspector also reviewed a selection of written directives issued since the last inspection, as well as records pertaining to the receipt, use, storage, and disposal of radioactive material in the NM and PET departments, and R&D laboratories.

The inspector noted that the licensee had not conducted R&D procedures in an RSC-approved laboratory located at 1027 Bellevue Avenue, since 2005. The licensee conducted a close out survey of the laboratory in 2005. Based on discussions with two EH&S staff members, procedures conducted at this location involved the use of microcurie to low-millicurie quantities of hydrogen-3 and sulphur-35. The licensee's survey from 2005 indicated that no residual contamination remained, and that all license material had been removed. While accompanied by the RSO and an HP, the inspector conducted an independent survey of the laboratory and searched for the presence of any radioactive material in storage. No radiation levels above background were identified, and no radioactive material was discovered. As a result of a review of the license's survey results from 2005 and the inspector's tour of the laboratory and independent survey, it appeared that the laboratory was suitable for release for unrestricted use. Before the end of the inspection the licensee contacted a decommissioning firm to arrange for an evaluation of the laboratory for decommissioning. The firm was scheduled to be on site during the week of April 27. The inspector advised the licensee that if the firm determined that the laboratory was unsuitable for release for unrestricted use, a notification per 10 CFR 30.36 may be required.

The maximum whole body and extremity exposures were noted in the PET department. For CY 2016, the whole body dose received was 386 millirem (mrem), and the extremity dose was 2670 mrem. For CY 2017, the whole body exposure was 329 mrem, and the extremity dose was 2561 mrem.

The inspector performed independent surveys of the NM and PET departments, various R&D laboratories and waste storage areas using a RadEyeG gamma survey meter, calibrated on September 12, 2017.

No violations or NRC requirements were identified.