



**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Saint Louis University Office of Environmental Health and Safety 1402 South Grand Blvd St. Louis, MO 63104  REPORT NUMBER(S) 2016-001	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532
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3. DOCKET NUMBER(S)  030-11789	4. LICENSE NUMBER(S)  24-00196-07	5. DATE(S) OF INSPECTION  June 20 - 22, 2016
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6. INSPECTION PROCEDURES USED 87130, 87131 & 87134	7. INSPECTION FOCUS AREAS 03.01-03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 02110	2. PRIORITY 2	3. LICENSEE CONTACT Mark G. Haenche, RSO	4. TELEPHONE NUMBER (314) 977-6885
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Main Office Inspection                      Next Inspection Date: 06/22/2018  
 Field Office Inspection    3635 & 3655 Vista Ave, St. Louis, MO  
 Temporary Job Site Inspection    1034 S Brentwood Blvd., St. Louis, MO

**PROGRAM SCOPE**

This was a routine inspection of a private educational institution authorized under NRC license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, 35.500, Yttrium-90 (Y-90) microspheres, and byproduct materials with atomic numbers 1-83 for medical and R&D uses. The licensee operated a Type A broad scope program and established a radiation safety committee (RSC) to review and approve uses, users, and facilities. The nuclear medicine department was staffed with three full-time nuclear medicine technologists (NMT), two full-time NMT in PET department and four PRNs who performed approximately 200 diagnostic nuclear medicine procedures monthly, primarily HIDA, bone scan, lung scan using Xe-133, thyroid, renal scan, PET studies using F-18, cardiac stress test and approximately 4 Ra-223 Xofigo treatments per month. The licensee also performed approximately 40 Y-90 treatments, 35 iodine-131 (I-131) hyperthyroid and cancer therapy annually. The nuclear medicine department at 1034 South Brentwood Blvd, St Louis, MO was staffed with one full time NMT who performed approximately 60 cardiac stress test monthly. The licensee received unit doses, bulk Tc-99m, and I-131 in capsule form from a licensed radiopharmacy.

**Performance Observations:**

The inspector observed one Y-90 treatment to a patient; reviewed treatment plan and written directives, observed NMT conduct dose calibration, measurement, dose administration, final survey of the interventional radiologist suite and final dose measurement, with no issues noted. The inspector interviewed staff involved in the Y-90 treatment and determined they were knowledgeable of operating and emergency procedures. The inspector also observed an administrations of Tc-99m to patients. The inspection consisted of interviews with select licensee personnel; review of select records; tours of the nuclear medicine department, select research laboratories, waste storage facility, and independent measurements. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste and disposal procedures. The inspector: (1) visited four R&D labs and observed the use of byproduct material in R&D application; (2) observed the lab-tech demonstrate the use, handling, and disposal of radioactive materials, and response to a radioactive material spill.

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The inspector reviewed the following records: RSC minutes, annual radiation program safety audits, package receipts, waste disposal records, radiation safety training, DOT Hazmat training, sealed source leak tests and inventory. The inspector reviewed dosimetry records for 2014 and 2015, indicating the maximum annual dose to be 195 mrem - DDE, and 1,410 mrem - SDE. The inspector also reviewed one fetal dose monitoring record and noted the fetal exposure was within regulatory limits. The inspector performed independent radiation measurements of the nuclear medicine hot lab, imaging, injection rooms, R&D laboratories and waste storage facility; the inspector's surveys were consistent with the licensee's survey results. The inspector re-verified the licensee corrective actions for the violations identified during the previous inspection dated April 7, 2014.

No violations of NRC requirements were identified during this inspection.

*[Handwritten signature]*  
ATM 6/21/16