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
Washington University in St. Louis Campus Box 8053 660 S. Euclid Avenue St. Louis, Missouri 63110-1093 REPORT NUMBER(S) 2022001	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
030-02271, 030-38167	24-00167-11, 24-00167-14	March 7-10, ~~2017~~ 2022

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	Geoffrey Warren / Luis Nieves Folch		3/10/22
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.04.01 09:41:13 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Washington University in St. Louis	030-02271, 030-38167	24-00167-11, 24-00167-14

4. Report Number(s):	5. Date(s) of Inspection:
030-02271/2022001, 030-38167/2022001	March 7-10, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Geoffrey Warren, Sr. HP; Luis Nieves Folch, HP	02210, 03210	2 (both)	87126,87127,87134

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Maxwell Amurao, Ph.D, RSO	maxwell.amurao@wustl.edu	314-362-2988

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	03/07/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of operations under Washington University in St. Louis's two NRC licenses: (1) NRC License No. 24-00167-11, a Type A medical and research broad scope license and (2) NRC License No. 24-00167-14 authorizing cyclotron production of licensed materials. Facilities inspected during this inspection included the main medical campus and surrounding facilities, the Danforth campus, and Barnes-Jewish West County Hospital.

The Type A medical broad scope licensee used a large variety of isotopes in medical and research applications. The radiation safety committee had approved radiation users under approximately 250 medical and research permits, of which around 150 were active permits, and oversaw around 1200 trained radiation workers. Research laboratories used predominantly microcurie quantities of carbon-14, tritium, iodine-125, phosphorus-32, and sulfur-35. In addition, the licensee possessed blood and research irradiators as described on the license. Research included both animal and human (medical) research. The radiation safety office included eleven full-time technical staff including the radiation safety officer as well as five part-time administrative staff.

The licensee operated multiple nuclear medicine areas, including Barnes-Jewish North and South areas, Children's Hospital, and West County and South County cardiology facilities. At these facilities, nuclear medicine technologists performed a wide variety of diagnostic procedures using technetium-99m, fluorine-18, xenon-133 and other isotopes. In addition, nuclear medicine staff performed hyperthyroidism treatments and whole-body scans using iodine-131 in capsule form. All areas received unit doses from licensed pharmacies or from the licensee's cyclotron operations.

The radiation oncology department performed therapy procedures using: (1) a Leksell Gamma Knife Icon gamma stereotactic radiosurgery (GSR) unit, (2) two high dose rate remote afterloader (HDR) units, (3) brachytherapy sealed sources (eye plaques and permanent prostate implants), (4) yttrium-90 microspheres procedures for liver cancer, and (5) a variety of radiopharmaceutical materials, including iodine-131, lutetium-177, and radium-223. The oncology department was staffed with multiple authorized user oncologists, authorized medical physicists, dosimetrists, and radiation therapists. The licensee had authorized around 70 authorized medical users, including authorized user physicians, authorized medical physicists, and authorized nuclear pharmacists.

Under the cyclotron license, the licensee operated one Siemens RDS Eclipse (11 MeV protons), one TR-19 (19 MeV protons), and one CS-15 (15 MeV protons) for the production of materials for transfer to its broad scope license. These materials included fluorine-18, carbon-11, oxygen-15, nitrogen-13, copper-64, and zirconium-89. The licensee considered materials to be transferred to the broad scope license when they were transferred from the

Materials Inspection Record (Continued)

cyclotron, so all chemical processing of cyclotron-produced materials was performed under the broad scope license. These materials were used for medical or research purposes under the broad scope license or distributed to client facilities in multiple states. In addition, the licensee possessed a JSW Model 168 cyclotron.

Performance Observations: The inspectors toured a variety of facilities and observed audits of research laboratories, including leak tests, inventory, surveys, and interviews; an HDR source replacement by contractor personnel; an yttrium-90 microspheres procedure; a radium-223 radiopharmaceutical therapy procedure; several diagnostic procedures including dose preparation and disposal, contamination cleanup, and routine cyclotron operations. In addition, licensee personnel described or demonstrated laboratory use of licensed materials, general security of licensed materials, emergency procedures, a variety of therapeutic and diagnostic medical procedures including planning and administration, patient release calculations for iodine-131 procedures, GSR and HDR daily checks, morning nuclear medicine checks, daily and weekly contamination surveys in nuclear medicine, ordering and receipt of laboratory materials, tracking and inventory or licensed materials, calibration of survey instruments, waste pickup and tracking, and waste shipment for disposal. The inspectors noted no concerns with these activities.

The inspectors reviewed radiation safety committee minutes; program and laboratory audits; written directives, treatment plans, and treatment documentation for all modalities of therapeutic procedures; inventory and tracking records; dosimetry records; transfer of sealed sources for disposal, and other documents. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of radiation dosimetry records indicated no exposures of concern. Review of radiation safety committee minutes indicated good attendance, discussion of appropriate topics. and appropriate oversight of of the radiation safety program. The inspectors performed independent and confirmatory radiation measurements that were consistent with licensee survey records and postings.

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