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) 2019002	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	24-00167-11	April 1-5, 2019

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 / Zahid Sulaiman	GW / Zahid Sulaiman	4/5/19
BRANCH CHIEF	Aaron McCraw		4/12/19

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126, 87127, 87134	03.01 - 03.07, 03.01 - 03.07, 03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110	2	Maxwell Amurao, Ph.D., RSO	(314) 362-2988

☑ Main Office Inspection Next Inspection Date: 04/01/2020

☑ Field Office Inspection South County and Danforth Campus

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, announced inspection, performed concurrently with an inspection of the licensee's cyclotron license, NRC License No. 24-00167-14. This Type A medical broad scope licensee used a large variety of isotopes in medical and research applications. The radiation safety committee had approved approximately 170 medical and research permit users, of whom around 100 were active users, and oversaw around 1200 trained radiation workers. Research laboratories used predominantly microcurie quantities of carbon-14, tritium, iodine-125 (I-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 administrative support. Under this license, licensee staff received material from cyclotrons and from gallium-germanium generators operated by the licensee, performed chemical procedures on those materials, and shipped some of these materials commercially to clients in multiple states.

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. These facilities employed around 17 technologists, performing a wide variety of diagnostic procedures using technetium-99m, fluorine-18 (F-18), xenon-133 and other isotopes. These procedures included a monthly total of around 1500 diagnostic procedures and around 30 hyperthyroidism treatments and whole-body scans using iodine-131 (I-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 ViewRay (VR) unit, (2) a Leksell Gamma Knife Icon gamma stereotactic radiosurgery (GSR) unit, (3) two high dose rate remote afterloader (HDR) units, and (4) a variety of radiopharmaceutical materials. The cancer center was staffed with around 23 oncologists and over 30 authorized medical physicists, dosimetrists, and radiation therapists. The cancer center annually performed approximately 500 HDR procedures, 380 GSR procedures, 500 VR procedures, 31 I-125 prostate seed implants, 28 I-125 eye plaques, 136 I-131 hyperthyroid and thyroid cancer ablations using capsules, 127 yttrium-90 (Y-90) microsphere procedures, 77 lutetium-177 (Lu-177) dotatate procedures, and 44 radium-223 advanced radiation therapy procedures.

(Continued on Part 2)

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

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(Continued)

Performance Observations: The inspectors toured a variety of facilities and observed one VR treatment, two HDR procedures, two GSR procedures, two Lu-177 administrations, three I-131 therapy administrations, and three diagnostic administrations of licensed materials, including planning, preparation, and followup to the procedures. In addition, the inspectors observed security of licensed materials in a variety of settings, package receipt and return surveys, gallium-germanium generator elution and dose preparation, generator breakthrough testing, and research laboratory use of licensed materials. Licensee staff demonstrated and described morning checks in nuclear medicine, daily nuclear medicine surveys, daily and monthly HDR and GSR checks, planning of therapeutic procedures, chemical preparation of F-18 compounds, ordering and receipt of licensed materials, tracking of licensed materials, pickup and storage of waste materials, waste shipments, sewerage disposal, calibration of survey instruments, housekeeping in licensed material use areas, packaging and shipment of cyclotron-produced materials, and other topics. 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.