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 St. Louis, Missouri Campus REPORT NUMBER(S) 2017-002	Region III 2443 Warrenville Rd. Lisle, IL 60532 ~~Select a location (Use keyboard arrows to select).~~ . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02271	24-00167-11	3/27-31/17

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 INSPECTORS	Robert G. Gattone, Jr. Geoffrey M. Warren	Robert G. Gattone, Jr. [signature]	3/31/17 3/31/17
BRANCH CHIEF	Aaron T. McCraw	[signature]	4/6/17

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
Washington University in St. Louis Selected locations on the St. Louis, Missouri Campus REPORT NUMBER(S) 2017-002	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	3/27-31/17

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134	03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110	2	Sue Langhorst, RSO	(314) 362-2988

☑ Main Office Inspection Next Inspection Date: 03/27/2017

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The Radiation Safety Officer/Radiation Safety Director reported to the Assistant Vice Chancellor for Environmental Health and Safety. The radiation safety personnel were supervised by 2 health physicists who reported to the Associate RSO. The licensee's radiation safety staff included 13 full-time technical staff who were assigned specific duties relating to the radiation safety program to ensure compliance with NRC regulatory requirements.

The licensee has a very large, active, Type A broad scope medical program. The licensee is a privately owned and operated university with approximately 14,500 students, 3,650 faculty members, and about 670 research laboratories approved for radioactive material use. Washington University and Medical Center has approximately 250 authorized users of licensed radioactive material. The licensee has a Radiation Safety Committee that approves a variety of uses including medical diagnostic and therapeutic procedures, human research, and non-human research and development. The license authorized the use of byproduct materials with Atomic Numbers 1-83 and transuranics (Atomic Numbers 84-103) for medical diagnosis, therapy and research in humans; and non-medical research and development (including animal studies), instrument calibration, student instruction, and in-vitro studies. In addition, the license authorized the use of: (1) two remote afterloader brachytherapy devices for physics quality assurance testing, dosimetry measurements, medical use (including research in humans) and irradiation of animals; (2) five self-shielded irradiators for the irradiation of various materials, including blood and blood products; (3) a Leksell Gamma Stereotactic Radiosurgery Unit (a.k.a. Gamma Knife Perfexion) for the treatment of humans, human research studies, and non-human research studies (including animal studies); and (4) a ViewRay device for medical use, research and development (including animal studies), prototype testing, and calibration. The licensee has a commercial nuclear pharmacy for PET radiopharmaceuticals. The licensee possessed, used, and stored radioactive material at two research facilities; Danforth Campus (including Tyson Research Center) and Washington University School of Medicine. In addition, the licensee used licensed material at six Washington University Medical Center facilities which include Barnes-Jewish Hospital, Heart Care Institutes, St. Louis Children's Hospital, Washington University School of Medicine, and Howard Hughes Medical Institute.

(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

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(Continued)

Performance Observations

The inspectors: (1) noted that the licensee received an Eckert and Ziegler GalliaPharm Germanium (Ge)-68/Gallium (Ga)-68 generator (generator) and the licensee had not commercially distributed the Ga-68 from the generator; (2) observed the licensee conduct an elution of a generator; (3) used NRC owned, calibrated survey meters to conduct independent surveys of selected areas, including a measurement of 120 milliRoentgens per hour (mR/hr) at the surface of a shielded container containing a fresh Ga-68 eluate; (4) noted that selected individuals that handled the shielded container containing the Ga-68 eluate did not hold it in hand very long, and they wore whole body and ring dosimeters; (5) interviewed applicable staff members and reviewed selected records regarding Lutitium-177 Dotatate treatments; (6) reviewed selected Radiation Safety Committee meeting minutes; (7) observed that licensed material in Olin Residence Hall was secured in the proper rooms; (8) observed that several licensee survey instruments were calibrated; (9) verified that a vendor was authorized to repair and maintain irradiators; (10) observed an authorized user demonstrate how an irradiator was used for research; (11) toured selected research labs and observed that licensed material was secured and safely used; (12) reviewed a sample of supervised user training and retraining records; (13) reviewed selected records and interviewed selected staff members to determine that the licensee's generator Ge-68 breakthrough limit was per the applicable NRC guidance and the licensee was aware of the notifications if a Ge-68 breakthrough limit is exceeded; (14) reviewed program review and laboratory audit documentation; (15) reviewed dosimetry, bioassay, and air sampling information to determine whether any licensee staff received radiation exposures of regulatory concern; (16) observed radiation safety staff preparing for and performing audits of laboratories; (17) observed survey meter testing and interviewed radiation safety staff about meter calibration and maintenance; (18) observed the operation of cyclotrons to produce materials for patient procedures and research; (19) interviewed licensee staff about preparation of cyclotron-produced materials for use and commercial distribution; (20) observed two therapeutic administrations using the ViewRay device and interviewed medical staff about treatment preparation and plan approvals; and (21) interviewed radiation safety and laboratory staff about inventory of licensed materials, leak testing of sealed sources, and radiation contamination surveys.

No violations of NRC regulatory requirements were identified.