

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Washington University in St. Louis 660 S. Euclid Avenue Campus Box 8053 St. Louis, Missouri 63110-1093</p> <p>REPORT NUMBER(S) 2019001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-38167</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-00167-14</p>	<p>5. DATE(S) OF INSPECTION</p> <p>April 1-5, 2019</p>

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. *From IR 2015-001*
- 3. The violation(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	<i>GJW / Zahid Sulaiman</i>	4/5/19
BRANCH CHIEF	Aaron McCraw	<i>AJ McCraw</i>	4/12/19

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Washington University in St. Louis 660 S. Euclid Avenue Campus Box 8053 St. Louis, Missouri 63110-1093 REPORT NUMBER(S) 2019001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
--	---

3. DOCKET NUMBER(S) 030-38167	4. LICENSE NUMBER(S) 24-00167-14	5. DATE(S) OF INSPECTION April 1-5, 2019
--------------------------------------	---	---

6. INSPECTION PROCEDURES USED 87125	7. INSPECTION FOCUS AREAS 03.01 - 03.07
--	--

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210	2. PRIORITY 2	3. LICENSEE CONTACT Maxwell Amurao, Ph.D., RSO	4. TELEPHONE NUMBER (314) 362-2988
---------------------------------	----------------------	---	---

Main Office Inspection Next Inspection Date: 04/01/2021
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, announced inspection, performed concurrently with an inspection of the licensee's broad scope medical license, NRC License No. 24-00167-11. Under this license, Washington University in St. Louis personnel operated multiple cyclotrons for the production of materials for transfer to its broad scope medical license. These materials included fluorine-18, oxygen-11, carbon-11, copper-64, zirconium-89, and other isotopes. Under the broad scope license, these materials were used for medical or research purposes or distributed to client facilities. The licensee considered materials to be transferred to the broad scope license when they were transferred from the cyclotron, so all chemical processing on cyclotron-produced products was performed under the broad scope license.

Performance Observations: The inspectors toured the cyclotron facilities and observed production of fluorine-18 and oxygen-11 and transfer of these materials from the cyclotron. Licensee personnel described cyclotron maintenance, including handling of targets and other activated components and use of personal protective equipment and monitoring devices. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of radiation dosimetry records indicated maximum exposures in 2017 of 859 mrem whole body and 12 rem extremity, and in 2018 of 851 mrem whole body and 8.0 rem extremity; no exposures were of concern. The inspector performed independent and confirmatory radiation measurements that were consistent with licensee survey records and postings. Review of radiation safety committee minutes and cyclotron audit reports indicated adequate oversight of cyclotron operations and personnel.

The licensee was cited in February 2015 for the failure of an individual to either wear an electronic dosimeter with audible or vibration alarms or to continuously monitor the work area using a survey meter with an audible alarm while handling activated cyclotron components, as required by License Condition No. 21 (now License Condition No. 19) and procedures contained in the letter dated September 1, 2010. The licensee completed corrective actions as described and the violation has not recurred. Based on this, the violation is closed.

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