ENCLOSURE 6 - INSPECTION RECORD

Region: III **Inspection Report No.** 2014-001 **License No.** 24-00167-11
Docket No. 030-02271

Licensee: Washington University in St. Louis
660 S. Euclid Avenue
St. Louis, MO 63110-1093

Locations Inspected: Washington University in St. Louis and Washington University Medical Center, including 4540 Scott Avenue, St. Louis; 4560 McKinley Avenue, St. Louis; and 4921 Parkview Place, St. Louis

Licensee Contact: Susan Langhorst, RSO **Telephone No**. 314-362-2988

Program Code: 02110 **Priority**: 2

Type of Inspection: ( ) Initial (X) Routine (X) Announced
( ) Special ( ) Unannounced

Last Inspection Date: 10/21-25/13 **Date of This Inspection**: 11/3-7/14 with in-office review through 12/22/14

The in-office review included receipt of information that was unavailable during the onsite inspection, including information about malfunctions of Mark I Model 30 irradiators.

Next Inspection Date: 11/03/2016 (X) Normal ( ) Reduced

In accordance with MC2800, Region III management determined that the licensee's large program scope and multiple locations of use warrant announced annual inspections (conducted by two inspectors) such that about half of the inspection (if it was conducted biennially) is conducted each year. The aforementioned next inspection date is to document achievement of completing the full inspection biennially.

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

(X) No violations cited, clear letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspectors Robert G. Gattone, Jr., Senior Health Physicist

Robert D. Gattone, Jr. Date 12/29/14
Signature

Ryan Craffey, Health Physicist

Robert D. Gattone, II for R.C.
Signature

Date 12/29/14

Approved Aaron T. McCraw, Chief, MIB

Signature

Date: 12/29/14

PART I - LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
79	11/22/13	Changed some possession limits and authorized medical use of the ViewRay device
80	2/24/14	Changed possession limits, added two cyclotron vaults, added one new cyclotron, and expanded production areas to the existing East Building Cyclotron Facility

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection of this licensee was on 10/21-25/13. No violations of NRC requirements were identified.

3. INCIDENT/EVENT HISTORY:

There were no open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

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 3 senior health physicists, who reported to the Associate RSO. The licensee's radiation safety staff included 14 individuals who were assigned specific duties relating to the radiation safety program to ensure compliance with license 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 13,000 students, 3,000 faculty members, and about 700 research laboratories. Washington University and Medical Center has approximately 300 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 afterloading 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 prototype teletherapy unit combined with a Magnetic Resonance Imaging (MRI) system (a.k.a. ViewRay device) for medical use.

The licensee has a 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.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87134

Focus Areas Evaluated: 1 and 2

The inspectors: (1) confirmed with Radiation Safety staff that the licensee had not yet removed any generally-licensed sources for decommissioning; (2) confirmed through interviews of staff present for a gamma knife treatment that the licensee continues to adhere to existing requirements for physical presence of Authorized Users during such treatments; (3) confirmed through a review of selected approvals that eight Authorized Users of radioactive material for research had adequate qualifications and were appointed in writing by the RSC; (4) reviewed the circumstances surrounding four recent Notices of Violation issued by Radiation Safety to Authorized Users and confirmed that the corrective actions taken appeared to be adequate; (5) verified that orders for radioactive material from outside companies were approved by Radiation Safety staff prior to purchase; (6) verified that selected authorized users who had ordered material from outside companies were authorized for the nuclides and quantities requested; (7) reviewed selected records relating to the receipt of packages containing radioactive material for research; (8) toured eight authorized research laboratories and observed the safe and secure use of radioactive material by licensee staff; (9) observed one routine laboratory inspection conducted by Radiation Safety staff; (10) confirmed that the licensee used the COMPLY code appropriately to demonstrate compliance with air effluent release limits; (11) observed the preparation, delivery and use of two quantities of Fluorine-18 produced at one of the licensee's cyclotron facilities; (12) verified that selected authorized users who had ordered material from the licensee's cyclotron facility were authorized for the nuclides and quantities requested; (13) reviewed the licensee's

initial and refresher training materials including training slides and examinations; (14) evaluated the knowledge of selected supervised radiation workers through interviews; (15) reviewed records relating to the licensee's last routine waste pickup, including material accountability and transportation documentation; (16) verified that the appropriate staff had been trained in accordance with U.S. DOT requirements at the required intervals; (17) interviewed staff and reviewed records relating to the receipt and use of activated rock samples; (18) observed a licensee staff member use the J.L. Shepherd Mark I Model 30 irradiator Serial No. 1177 to irradiate mice; (19) observed a licensee staff member demonstrate how she would respond to conflicting source position indicators, low air pressure indicators, and response to a radiation alarm on a J.L. Shepherd Mark I Model 30 irradiator; (20) reviewed selected Radiation Safety Committee meeting minutes; (21) noted that the licensee had not yet received lead-212 and it did not plan to use it in the future; (22) noted that the licensee had not used the Viewray device for gated therapies, research, or animal studies; (23) reviewed calendar year 2013 audit records; (24) reviewed records regarding licensee approvals of four physician authorized users for Viewray medical use; (25) noted that the AECL Gammacell 40 Serial 53 irradiator was at the authorized location; (26) observed a licensee physicist demonstrate how she had done checks of an ion chamber's operability prior to first use on a given day; (27) observed demonstrations of how Viewray medical treatments were planned, including post patient positioning MRI imaging prior to treatment; (28) reviewed selected Viewray treatment records; (29) reviewed selected Viewray pre- and post-treatment images and records; (30) noted that, prior to each Viewray treatment fraction, the fraction treatment plan is run on a phantom to verify that the delivered dose is within 3 percent of the prescribed dose; (31) observed that the Viewray emergency procedures were posted at the Viewray console; (32) observed records of Viewray treatments showing that revised written directives were done as required; (33) noted that applicable Viewray authorized users and authorized medical physicists remain in the Department during Viewray treatments and they are immediately available if needed; (34) reviewed selected daily, weekly, and monthly Viewray check records; (35) reviewed the Viewray full calibration record from November 2013; (36) observed selected records of Viewray acceptance testing that was conducted in November 2013; (37) observed a Research Assistant demonstrate how she had labeled antibodies with iodine-124 with low millicurie quantities using personal protection equipment, time, distance and shielding to reduce radiation dose; (38) observed a Research Assistant demonstrate how she would respond to a radioactive spill, dispose of licensed material by decay-in-storage, and conduct area surveys; (39) noted that observed licensee survey instruments were calibrated as required; and (40) reviewed internal and external dosimetry records for 2013 and 2014 (through 9/14/14) and the maximum whole body, extremity, and organ doses were 1079 millirems, 12960 millirems, and 64 millirems, respectively.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent surveys of selected areas where radioactive material was used and stored in research laboratories. The inspectors also toured the licensee's central waste storage facility and conducted independent surveys of the facility.

Using a Ludlum 2403 survey meter with a Model 44-38 energy-compensated GM detector calibrated on July 23, 2014, the inspectors measured a maximum of 0.08 milliroentgen per hour at the external surface of a J. L. Shepherd Mark I Model 30 Serial 1111 irradiator and an AECL Gammacell 40 irradiator.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A minor violation of 10 CFR 30.34(c) and License Condition 21 was identified. Specifically, the licensee identified two J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator malfunctions (i.e., timer and turntable malfunctions) and did not notify the NRC Region III Office immediately, as required. The violation was minor because the timer and the turntable malfunctions did not compromise safe operation of the irradiator. The licensee stated that it did not notify the NRC about the malfunctions because it interpreted that notification was required only if the door interlock was inoperable.

During an Academic/Commercial Call, an OGC representative stated that the violation was valid (i.e., any malfunctions of J. L. Shepherd and Associates, Mark I Cesium-137 Irradiators must be immediately reported to the NRC Region III office by telephone). The licensee did not dispute the violation and implemented corrective actions. Specifically, the licensee committed to immediately notify the Region III Office by telephone when it identifies any malfunction of a J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator. In addition, the licensee committed to inform applicable staff of the requirement and the need to notify radiation safety staff about any J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator malfunctions so that the required notification is made timely.

5. PERSONNEL CONTACTED:

Kinda Abdin, Radiation Safety Specialist III
Mairio Bradley, Radiation Safety Specialist I
Mickey Croyle, Health Physicist I
Briana Davis, Health Physicist II
Daniel Doenes, Health Physicist I
Olga Green, Health Physicist
Kevin Hardcastle, Information Technologist
Emma Hooks, Director, Environmental Health and Safety
Jenny Kalishman, Authorized User
#Sue Langhorst, RSO
Hannah Luehmann, Research Assistant

Maryann Lockett, Compensation Analyst
Dave Luechtefeld, Health Physicist I
Tiffany Reese, Instructor
Molly Romine, Research Consultant
W. John Smith, Associate RSO
Leanne Stewart, Manager of Employee Relations
Dan Szatkowski, Health Physicist
Connie Turnbough, Administrative Coordinator
Tom Voller, Lab Manager
Karen Young, Environmental Health and Safety Assistant

Attended exit meeting on December 22, 2014.

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