

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Washington University in St. Louis 660 S. Euclid Avenue St. Louis, MO 63110-1093 REPORT NUMBER(S): 11-01		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532	
3. DOCKET NUMBER(S) 030-02271		4. LICENSEE NUMBER(S) 24-00167-11	
		5. DATE(S) OF INSPECTION January 24-27, 2011	

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 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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on January 25, 2011, the licensee did not secure from unauthorized removal or limit access to licensed materials located in a laboratory at the BJC Institutes of Health building, which is a controlled area.

The licensee implemented corrective actions that included securing the door to the lab. Additional corrective actions included posting a sign on the door to the lab instructing the staff that the door is to remain locked at all times.

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	Susan M. Langhorst, RSO	<i>Susan M. Langhorst</i>	2/8/2011
NRC INSPECTOR	Ken Lambert / Deborah Piskura	<i>Ken Lambert</i> <i>Deborah Piskura</i>	2/3/11
Branch Chief	Tamara E. Bloomer	<i>T. Bloomer</i>	2/4/11

Docket File Information
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6. INSPECTION PROCEDURES 87126		7. INSPECTION FOCUS AREAS 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02110	2. PRIORITY 2	3. LICENSEE CONTACT Sue Langhorst, Ph.D., RSO	4. TELEPHONE NUMBER 314-362-2988
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Main Office Inspection Next Inspection Date: January 2013
 Field Office Inspection Barnes Jewish West County, Creve Coeur, MO
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This broad scope licensee was an educational institution, which used a variety of isotopes in medical, research, and teaching applications. In addition, the licensee operated two offsite facilities, performing mostly cardiac studies located in Creve Coeur and Green Park, Missouri. The radiation safety committee, which met at appropriate intervals, approved approximately 350 authorized users. The licensee operated at three medical centers (Barnes-Jewish South, Barnes-Jewish North, and Children's Hospital) on the Washington University in St. Louis campuses. The licensee had a large nuclear medicine program conducting approximately 1350 procedures monthly in multiple nuclear medicine areas. The most common procedures were cardiac, bone, and lung studies. Doses were primarily technetium-99m prepared from generators. Whole body scans using liquid iodine-131 were also performed.

The radiation oncology department operated two high dose rate (HDR) remote after loading units and a Leksell Perfexion Gamma Knife unit. The department also administered permanent seed implants, temporary ocular implants and microsphere therapies. In addition, the department administered iodine-131, in liquid form, for hyperthyroid and thyroid ablation treatments. The department administered approximately 200-250 HDR patient treatments per year; the majority of these treatments were for breast, bronchial/lung, and gynecological cancers. Approximately 250 treatments for various brain diseases were administered utilizing the gamma knife unit. All HDR and gamma knife patient treatments were administered by the attending radiation oncologist, the medical physicist, and a therapy technologist. Service, maintenance, and source exchanges were performed by the respective device manufacturer. The department performed 25 permanent prostate implants per year (1-125). The licensee also administered 50-55 I-125 temporary ocular implants annually. The radiation therapy department involving gamma knife activities was staffed with 5 medical physicists (gamma knife physicists), 5 physicians authorized users, and 8 neurosurgeons.

Performance Observations

The inspectors toured all three nuclear medicine areas on the Washington University campus as well as the Creve Coeur site. The inspectors observed dose preparation and patient administrations, including the administration of liquid iodine-131. The inspectors discussed or had university staff demonstrate package receipt surveys, daily and weekly surveys, and generator elutions. The inspectors reviewed dose calibrator daily constancy, quarterly linearity and annual accuracy tests. The inspectors discussed irradiator operations with blood bank staff. The inspectors performed independent radiological surveys, with results similar to licensee survey data. The inspectors observed the licensee utilizing its HDR units and the gamma knife unit for patient treatments. The inspectors reviewed the written directives for the procedures; observed the licensee staff performing daily QA checks; and observed the patient treatments. The inspector also interviewed the respective physician authorized users who attended the patients. In addition, the inspector observed the licensee perform the treatment planning for a gamma knife patient treatment.

The inspectors reviewed dosimetry data for nuclear medicine, pharmacy cyclotron, radiation oncology, and select medical research staff and noted that the maximum whole body and extremity exposure were 1746 mrem WB and 8820 mrem extremity for 2009; and 890 mrem WB and 27,730 mrem extremity for 2010. The high extremity dose was due to development of a new investigational drug involving gallium-68. The licensee is currently reviewing the exposure and working with the individual to reduce future doses.

The inspectors identified one severity level IV violation involving the failure to secure radioactive materials stored in a lab in the BJC Institutes of Health research building. Corrective actions included securing the door to the lab and posting a notice on the door to the lab instructing staff that the door should remain locked at all times. The quantity of radioactive materials in the lab was in aggregate less than 1000 times the quantities listed in Appendix C to 10 CFR Part 20.