

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
St. John's Mercy Medical Center
615 S. New Ballas Road
St. Louis, MO 63141

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

REPORT NUMBER(S) 2010-001

3. DOCKET NUMBER(S)
030-02283

4. LICENSEE NUMBER(S)
24-00794-03

5. DATE(S) OF INSPECTION
November 3-4, 2010

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

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	Deborah A. Piskura	<i>[Signature]</i>	11/4/2010
Branch Chief	Tamara E. Bloomer	<i>[Signature]</i>	11/16/10

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE St. John's Mercy Medical Center 615 S. New Ballas Road St. Louis, MO 61341 REPORT NUMBER(S) 2010-001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4351	
3. DOCKET NUMBER(S) 030-02283	4. LICENSE NUMBER(S) 24-00794-03	5. DATE(S) OF INSPECTION Nov. 3-4, 2010	
6. INSPECTION PROCEDURES 87130, 87131, & 87132	7. INSPECTION FOCUS AREAS 03.01-03.08		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02240	2. PRIORITY 2	3. LICENSEE CONTACT Robert Turco, Ph.D., RSO	4. TELEPHONE NUMBER 314-251-6657
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- Main Office Inspection Next Inspection Date: Nov. 2012
- Field Office Inspection 607 S. New Ballas Road, St. Louis, MO and 15945 Clayton Road, Ballwin, MO
- Temporary Job Site Inspection _____

PROGRAM SCOPE

This licensee was a large medical institution (1,000+ bed hospital) and conducted licensed activities at eight locations in the suburban St. Louis area. This licensee's authorization included materials in Sections 35.100, 35.200, 35.300, 35.400, 35.500, Sr-90 in IVB devices (note these devices had not been used since the previous inspection), Ir-192 in two HDR units, and other licensed material for R&D uses; no research protocols were conducted at the time of this inspection. The licensee established an RSC to review and approve users. The daily radiation safety activities were managed by a contract RSO/chief medical physicist, an assistant RSO, a staff physics trainee. The licensee's consulting RSO audited the radiation safety program on a quarterly basis.

Collectively, the nuclear medicine departments performed approximately 15,000+ diagnostic nuclear medicine procedures annually which included a full spectrum of diagnostic imaging studies. The majority of licensed activities were performed by the main hospital (40-60 studies daily) and the adjacent heart hospital. The licensee received Mo-99/Tc-99m generators. The department maintained an active therapy program and administered numerous I-131 dosages for CA, whole body follow up studies, and hyperthyroidism. Radioiodine dosages were prepared on site by the nuclear pharmacy staff (liquid and capsules). Occasionally, the department administered P-32 (sodium phosphate), Sr-89 Metastron, Sm-153 Quadramet, I-131 Bexxar, and Y-90 Zevalin dosages; 15-20 treatments collectively in a year.

The radiation therapy activities under this license were performed at the main hospital in St. Louis as well as an outpatient clinic in Ballwin, Missouri. The radiation oncology department was staffed with 7 MPs, 5 dosimetrists, and 4 authorized users. The majority of the department's activities involved the HDR unit. Although the licensee possessed Cs-137 brachytherapy "tube" sources, they remained in storage since the previous inspection. The licensee administered 20-25 I-125 permanent prostate implants each year. The licensee possessed two HDR units and administered approximately 150 patient treatments per year; the majority of these treatments were for breast, bronchial/lung, and gynecological cancers. All HDR patient treatments were administered by the attending radiation

oncologist, the authorized medical physicist, and a therapy technologist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer. The department within the main hospital operated an active PET center.

This inspection consisted of interviews with select licensee personnel; a review of select records; tours of the nuclear medicine and radiation oncology departments; and independent measurements. The inspector observed the administration of several diagnostic nuclear medicine and PET procedures. The inspector observed the administration of two dosages of I-131 for treatments of thyroid cancer and hyperthyroidism. The inspector also observed the licensee staff administer a patient treatment utilizing its HDR unit at the main hospital. The inspection included observations of dose calibrator QA checks, generator elutions, HDR QA and safety checks, security of byproduct material, use of personnel monitoring, package receipts, and patient surveys.