NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
St. John's Mercy Medical Center 615 S. New Ballas Road St. Louis, MO 63141 REPORT **2006-001 & -002**	**U.S. Nuclear Regulatory Commission** **Region III** **2443 Warrenville Road** **Suite 210** **Lisle, Illinois 60532-4351**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02283	24-00794-03	June 9 , 2006

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) was/were discussed involving the following requirement(s) and Corrective Action(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.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

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**	DAPiskura	**6/09/06**

NRC FORM 591M PART 3
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
St. John's Mercy Medical Center REPORT **2006-001 & 2006-002**	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02283	24-00794-03	June 8-9, 2006

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87131 and 87132	03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	G 2	Robert F. Turco, Ph.D., RSO	314.251.6933 X27551

[X] Main Office Inspection — Next Inspection Date: June 2008

[X] Field — Cancer Center, 607 South New Ballas Road, St. Louis, MO

[ ] Temporary Job Site

PROGRAM SCOPE

This licensee was a large medical center (900-bed hospital), authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (Ir-192 within an HDR unit) and 35.1000 P-32 and Sr-90 IVB devices. The licensee possessed Cs-137 sources within a blood irradiator unit and an instrument calibrator. In addition, the licensee possessed various isotopes for R&D studies.

The nuclear medicine department was staffed with 13 full-time technologists who performed approximately 1000+ diagnostic nuclear medicine procedures per month. Nuclear medicine activities were performed in two separate areas within the medical center (diagnostic studies within the radiology department and cancer support studies at the cancer center). In addition, the hospital was authorized to perform imaging and radiopharmaceutical therapy at a separate satellite hospital. The licensee received a Mo-99/Tc-99m generator on a weekly basis. The hospital performed a full spectrum of nuclear diagnostic imaging studies and dispensed its doses using the OmniCell system. Typically, in a year the hospital administered 20-30 I-131 thyroid carcinoma therapies, 55-60 hyperthyroidism treatments, and 60+ whole body follow up studies. The hospital obtained its I-131 in liquid form. The department established venting procedures for the liquid I-131 vials and stored this material within a fume hood (equipped with charcoal filters). The RSO audited the radiation safety program on a quarterly basis and reported his findings to the RSC.

The radiation therapy activities were performed by three contract medical physicists and three contract dosimetrists and 13 therapy technologists. Brachytherapy activities included I-125 and Pd-103 permanent implants (70-100 cases annually. The department maintained two strontium-90 eye applicators and numerous cesuim-137 brachytherapy sources in secure storage; these sources had not been used since the previous inspection Although the licensee was approved for 35.1000 material, the hospital transferred its IVB units to the manufacturer for disposal. The department administered 4-6 Sm-153 dosages annually for treatment of metastatic bone disease. The department possessed an HDR unit and administered approximately 200 patient treatments per year; the majority of these treatments were for bronchial, breast, and gynecological cancers. All HDR patient treatments were administered by the attending oncologist, the medical physicist and a therapist (note that the physician operated the controls to the HDR unit). All source exchange, maintenance, and repairs on the HDR unit were performed by the manufacturer

This inspection consisted of interviews with licensee personnel, a review of select records, tours of the blood bank, nuclear medicine and radiation oncology departments, and independent measurements. The activities in the R&D laboratories were not reviewed during this inspection. The inspector observed nuclear medicine personnel dispense, prepare, assay and administer numerous doses for various imaging procedures. The inspection included observations of security of byproduct material, use of personnel monitoring, dose calibrator QA checks, package receipts and surveys, and area surveys. The inspector observed one HDR brachytherapy treatment. The inspector reviewed the written directive and the treatment plan for the case and interviewed the attending authorized physician user.