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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
Trinity Health - Michigan d/b/a St. Mary Mercy Hospital Livonia, MI REPORT 2007-001	**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
030-08159	21-14849-01	February 28, 2007

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)

Cs^{137} brachytherapy sources were not physically inventoried at semi-annual frequencies as required by 10CFR 35.67(g). Last physical inventory was performed on Oct. 10, 2003. Licensee staff misunderstood the requirement to inventory these sources which were in storage. The licensee will conduct a physical inventory by the end of the week of Feb. 26, 2007.

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	C. W. Lauderbach, JR.	C W Lauderbach JR	2/28/2007
NRC INSPECTOR	**Deborah A. Piskura**	D A Piskura	2/28/2007

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
Trinity Health-Michigan d/b/a St. Mary Mercy Hosp REPORT **2007-001**	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87131, 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
02120	G 3	Nader Mohtadi, M.D., RSO	734.655.4800

[X] Main Office Inspection — Next Inspection Date: Feb. 2010

[ ] Field

[ ] Temporary Job Site

PROGRAM SCOPE

This licensee was a medical institution, authorized to use licensed material permitted by Sections 35.100, 35.200, 35.300, and 35.400. The nuclear medicine department was staffed with five technologists who performed approximately 350 diagnostic nuclear medicine procedures per month. The licensee received unit doses and bulk Tc-99m from a licensed radiopharmacy. The hospital performed a full spectrum of nuclear diagnostic imaging studies. Typically, in a year, the hospital administered 1-2 iodine-131 thyroid carcinoma therapies, 20 hyperthyroidism treatments, and 1-2 whole body CA follow up studies. The hospital obtained its I-131 in capsule form. The department administered 1-2 Sm-153 dosages annually. The licensee retained the services of a consulting physicist to audit the nuclear medicine radiation safety activities on a quarterly basis.

The radiation therapy department was staffed with 1 contract medical physicist, 1 dosimetrist, and 2 physicians (authorized users). The department used I-125, Pd-103, and Cs-131 for permanent prostate implants to treat approximately 80 cases per year. Every other year, the licensee used Ir-192 seeds in ribbon for temporary lung implants (last case 12/2005). The licesee returned the Ir-192 seeds to the manufacturer after completion of the treatment. The oncology department possessed 7 Cs-137 tube sources however the licensee had not used its Cs-137 sources for temporary implants since 2002.

This inspection consisted of interviews with licensee personnel, a review of selected records, tours of the nuclear medicine and radiation oncology departments, and independent measurements. The inspector observed licensee nuclear medicine personnel prepare, assay and administer several unit doses for cardiac 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.

One violation of NRC requirements was identified concerning the licensee's failure to conduct sealed source inventories of the Cs-137 brachytherapy sources at semi-annual intervals, as required by Section 35.67(g). The physical inventory was last performed on 10/10/2003. The hospital staff failed to recognize that although the sources had not been used since 2002 and remained in secured storage, the licensee was still required to perform semi-annual physical inventories. The staff confused the provisions in Section 35.67(f) which allows the licensee not to perform leak tests on sealed sources in storage. The staff erroneously believed that since their sources were "in storage" they were not required to perform semi-annual physical inventories as well. Since the authorized medical physicist was not on site during the inspection to perform an immediate inventory, the licensee committed to perform a physical inventory of the brachytherapy sources ASAP. The licensee also committed to add a reminder to the department calender. On 3/2/2007, the medical physicist informed the inspector that he performed an inventory of all sources within the cesium safe and he accounted for all sources.