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
Saint Mary's Health Care 200 Jefferson, S.E. Grand Rapids, Michigan 49503 REPORT 2006-001	*REGION III* US NUCLEAR REGULATORY COMMISSION 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-08291	21-01078-01	April 5, 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	Geoffrey M. Warren		4/5/06

NRC FORM 591M PART 1 (10-2003)

NMED # 060123

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
Saint Mary's Health Care REPORT NUMBER(S) 2006-001	**Region III**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-08291	21-01078-01	April 5, 2006

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.07, 03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Dale J. Schippers, M.S., RSO	616-752-6744

[X] Main Office Inspection — Next Inspection Date: **April 2008**

[X] Field Office 310 Lafayette Ave. SE, 250 Cherry St. SE

[ ] Temporary Job Site

PROGRAM SCOPE

The licensee was a 300-bed hospital located in Grand Rapids, Michigan. Licensee had authorization to use byproduct materials under Sections 35.100, 35.200, 35.300, 35.400, and 35.500, as well as for a high dose rate (HDR) remote afterloader system. Licensed activities were conducted only at the locations indicated on the license.

The licensee had two nuclear medicine areas. The cardiac nuclear medicine area was staffed with one nuclear medicine technologist, who performed approximately 200 studies monthly, limited to cardiovascular studies. The main nuclear medicine area was staffed with five full-time nuclear medicine technologists, who typically administered 500 diagnostic doses monthly. Doses were primarily technetium-99m for bone, gastric, cardiac, and other studies. In addition, the licensee performed occasional studies using other isotopes. Doses were received as unit doses from a licensed radiopharmacy or prepared from bulk technetium. Licensee performed around 20 iodine-131 treatments monthly, including whole-body scans, hyperthyroid treatments, and thyroid ablations with the iodine-131 in capsule form. The licensee performed occasional radiopharmaceutical therapies using other isotopes. All waste was held for decay in storage or returned to the radiopharmacy.

The radiation therapy staff consisted of three physicists, two dosimetrists, and three oncologists. The staff performed around 7-10 HDR fractions monthly, around 20 temporary implants annually using cesium-137 seeds, and around 55 permanent seed implants annually using iodine-125 seeds.

Performance Observations

The inspector was unable to observe any diagnostic administrations of licensed material. Licensee personnel demonstrated package dose preparation, administration, and disposal, as well as package receipt surveys, dose calibrator constancy tests, survey meter daily checks, daily contamination surveys, and daily HDR system checks. The inspector found no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies and permanent and temporary seed implants and found no issues. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures. Radiation surveys indicated radiation levels consistent with licensee postings.

The inspector reviewed NMED Item No. 060123, in which a package with surface contamination was delivered to the nuclear medicine area. The package survey was performed, contamination was detected, and proper notifications were made. The licensee stated that it was possible that the package was contaminated at the hospital, but that the contamination most likely occurred at the radiopharmacy. The highest contamination levels were on the inside of the package. The package was securely stored for decay and returned to the radiopharmacy. This closes the NMED item.

The inspector closed a violation from the previous inspection. The licensee was cited for releasing a patient with the possibility of exposing a member of the general public over 500 mrem from the released patient, contrary to 10 CFR 35.75 (a). To correct this, the licensee prepared a spreadsheet which calculated the dose to a member of the general public based on uptake, dosage, and an assigned occupancy factor. This occupancy factor was adjusted to keep the dose under 500 mrem, and the patient instructions automatically adjusted for that occupancy factor. If the dose was over 500 mrem, the phrase "Dose too high" appeared in large letters on the patient instructions and on the written directive. In that case, either the doctor would reduce the dosage or the procedure would be performed as an inpatient procedure. This closes the previous violation.