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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
Crittenton Hospital Rochester, MI 48307 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
030-02167	21-13562-01	March 1, 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)

The licensee released two patients on Dec. 29, 2006 and Jan 24, 2007, who were administered 100 millicuries of Na I-131 and the licensee did not determine the total effective dose equivalent to any other individuals from exposure to the released individuals was not likely to exceed 0.5 rem as required by 10 CFR 35.75(a). The licensee will develop a worksheets for determining (calculations) the exposures from released patients. The licensee will also provide training to the nuclear medicine techs.

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	William Bell, Jr.	William Bell, Jr.	3/1/07
NRC INSPECTOR	Deborah A. Piskura	D A Piskura	3/1/07

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 **Crittenton Hospital** REPORT NUMBER(S) 2007-001	2. NRC/REGIONAL OFFICE **Region III** **2443 Warrenville Road** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02157	21-13562-01	Mar. 1, 2007

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
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
02230	G 2	Judith Bender, M.D., RSO	248.652.5000

[X] Main Office Inspection — Next Inspection Date: March 2009

[ ] Field

[ ] Temporary Job Site

PROGRAM SCOPE

This large hospital was authorized to use materials permitted in Sections 35.100, 35.200, 35.300, 35.400, 31.11, Gd-153 line transmission sources, and iridium-192 in an HDR unit. The nuclear medicine department was staffed with 4 technologists who performed approximately 300 diagnostic nuclear medicine procedures per month which included a full spectrum of diagnostic imaging studies. The licensee received unit doses and bulk Tc-99m from a licensed nuclear pharmacy. Typically in a year, the hospital treated 10-15 cases of hyperthyroidism, and 2-5 whole body CA follow up studies. Radioiodine was obtained from a licensed nuclear pharmacy in capsule form. The department had not administered any beta-emitting radiopharmaceutical dosages to date. The licensee retained the services of a consulting physicist to audit the nuclear medicine radiation safety activities on a quarterly basis. In Dec. 2006 and Jan. 2007 the licensee administered its first I-131 dosages for thyroid carcinoma; these patients were released under the provisions of Section 35.75 however the department failed to determine the TEDE to any other individuals from these released patients (see below).

The radiation therapy department was staffed with 2 contract medical physicists and 1 dosimetrist, and 2 authorized physician users. The department used I-125 for permanent prostate implants to treat approximately 50 cases per year. The department acquired an HDR unit in August 2006 and administered 3 patient treatments to date; these treatments were for gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist and the medical physicist. 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 nuclear medicine and radiation oncology departments, and independent measurements. The inspection included observations of dose calibrator QA checks, security of byproduct material, use of personnel monitoring, and package receipts and surveys. The inspection also included interviews with licensee staff as required by TI2800/039, "Information Collection: Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material."

One violation of NRC requirements was identified concerning the licensee's failure to determine the TEDE to any other individuals from two released patients. The licensee released two patients on 12/29/2006 and 1/24/2007 who were each administered 100 mCi of I-131. The licensed failed to determine the TEDE (by calculations) to any other individuals from exposure to these released patients was not likely to exceed 0.5 rem as required by Section 35.75(a). The licensee staff were unaware of this requirement. The licensee committed to develop a worksheet for determining/calculating the TEDE from released patients and provide instruction to the nuclear medicine staff on Section 35.75 requirements. Based on the inspector's calculations, the TEDEs for these two released patients was 262 millirem and 283 millirem. Therefore, the release of these patients would not exceed the 500 millirem TEDE limit in Section 35.75.