

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Crittenton Hospital Medical Center
1101 W. University Drive
Rochester, MI 48307

REPORT NUMBER(S) 2012-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-02157

4. LICENSE NUMBER(S)

21-13562-01

5. DATE(S) OF INSPECTION

Feb 17, 2012

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, 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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

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>	<i>2/17/2012</i>
BRANCH CHIEF	Tamara E. Bloomer	<i>[Signature]</i>	<i>2/23/12</i>

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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6. INSPECTION PROCEDURES USED

87132

7. INSPECTION FOCUS AREAS

03.01-07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02230

2. PRIORITY

2

3. LICENSEE CONTACT

V. Elayne Arterbery, M.D., RSO

4. TELEPHONE NUMBER

☐ Main Office InspectionNext Inspection Date: unchanged☒ Field Office Inspection 1901 Star Batt Drive, Rochester, MI☐ Temporary Job Site Inspection**PROGRAM SCOPE**

In accordance with MC 2800, this was a re-inspection of the licensee in follow up to escalated enforcement identified during a reactive inspection on February 22-23, 2011. The violation concerned the licensee's failure to develop written procedures to provide high confidence that each HDR administration is in accordance with the written directive, as required by 10 CFR 35.41(a). Eleven HDR medical events demonstrated that the licensee's procedures did not provide such confidence because the procedures did not require verification of the treatment step size prior to administration.

The inspector determined that the licensee had implemented corrective actions as described in the inspection report 030-02157/2011-001 (DNMS) and the enforcement action (EA-11-165). The licensee revised its policy for HDR treatments to address the manual entry of treatment data and the use of a checklist to check step size, dwell positions and all treatment parameters before actual treatment delivery. The licensee implemented a verbal verification of treatment parameters before each treatment. Additionally, the licensee provided training to its staff about the revised policy, the need for verbal and visual confirmation of treatment parameters before each treatment, and the need for a "time out" to review the checklist before treatment delivery to ensure that the staff is sensitive to the potential for error with manual entry of data.

Based on the results of this inspection, the violation is considered closed.