NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
McLaren Medical Center Bay Region 1900 Columbus Avenue Bay City, MI 48708 REPORT NUMBER(S) 2015-002	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13900	21-18585-01	October 21st, 2015

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 violations(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	Ryan Craffey / Luis Nieves	Ryan Craffey / Luis Nieves	10/21/15
BRANCH CHIEF	Aaron McCraw		11/5/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87132	FE 1, 6, and 7

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Matthew Buczek - AMP	(989) 667-6675

☐ Main Office Inspection Next Inspection Date: No Change

☑ Field Office Inspection 3180 East Midland Road, Bay City, Michigan

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an escalated enforcement follow-up inspection of a regional medical center authorized to use byproduct material for medical purposes at two locations in Bay City, Michigan. The purpose of this inspection was to verify completion and assess the effectiveness of corrective actions for a Severity Level III violation identified during a reactive NRC inspection on February 11-13, 2015. The NRC conducted that inspection (IR 03013900/2015001 (DNMS)) in response to a medical event which occurred on February 6, 2015 during an HDR procedure which used a closed-ended transfer tube catheter that the licensee had inadvertently positioned incorrectly inside the applicator prior to administration. The NRC cited the licensee in a final action dated August 27, 2015 for the failure to develop, implement and maintain a written procedure to provide high confidence that each HDR administration was in accordance with the written directive, as required by 10 CFR 35.41(a)(2).

PERFORMANCE OBSERVATIONS

The inspectors reviewed the circumstances of the medical event with the licensee's staff at the Jeppesen Radiation Oncology Center in Bay City, Michigan, including the root cause, contributing factors, and corrective actions taken in response to the event. As described in the licensee's statement of corrective actions dated August 4, 2015, the staff demonstrated the now-mandatory use of radio-opaque markers to verify the position of closed-ended transfer tube catheters using CT radiographs prior to administration. The inspectors reviewed the licensee's revised procedure for verifying correct catheter position using the markers, as well as revised treatment checklists completed prior to commencing HDR treatments. The inspectors also reviewed written directives, treatment plans, and associated documentation for a selection of HDR treatments which had used closed-end transfer tube catheters since the medical event occurred, and noted through CT radiographs and pretreatment checks that the catheters had been placed in the correct position, and that the licensee had verified this placement with high confidence prior to the administration.

The inspectors identified no additional examples of the previously cited violation, and furthermore determined that the licensee had implemented adequate corrective actions to address the potential for recurrence of a similar violation. Therefore, the NRC considers this violation to be closed. No other violations of NRC requirements were identified as a result of this inspection.