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
Franciscan Healthcare - Munster 701 Superior Ave. Munster, IN 46321 REPORT NUMBER(S) 2018002	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
030-36594	13-32519-01	October 22, 2018

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	Jason D. Draper, Health Physicist	Jason D. Draper	10/22/18
BRANCH CHIEF	Aaron T. McCraw	for ATM	11/5/18

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	03.01-03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Michael Brewer, RSO	(219) 992-4200

☑ Main Office Inspection Next Inspection Date: no change

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, special inspection of a hospital in Munster, Indiana. At the time of the routine inspection in August 2018, the licensee had not yet received the high dose rate (HDR) remote afterloader device they were authorized to possess and use under 35.600, therefore, the purpose of this special inspection was to focus on the licensee's HDR (Nucletron B.V. Model microSelectron 106.990) receipt and use for gynecological cancer treatments. The licensee's cancer department had two Authorized Users for HDR therapies as well as one Authorized Medical Physicist (AMP). Since the licensee received the HDR in September 2018, the licensee had treated three treatments using tandem and ring or cylinder applicators. The licensee expects to perform approximately 150 treatment fractions per year using the HDR.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's facility to verify it was as described in the licensee's license amendment documentation. The inspector also reviewed the security of the device, area postings, and the availability of emergency equipment. The inspectors performed confirmatory surveys in public areas adjacent to the treatment room and did not identify any dose rates above background. The inspector observed the AMP perform spot checks on the HDR, and interviewed the AMP with regard to topics including: the receipt of the HDR source, installation of the HDR device by the vendor, unit calibration, and emergency procedures. The inspector reviewed written directives and treatment plans associated with two of the treatments and determined that the treatments were performed in accordance with the written directives. Since the licensee had just recently received the HDR, certain common inspection elements (e.g., dosimetry reports, radiation safety program reviews, source shipping documentation) were unable to be reviewed.

No violations of NRC requirements were identified as a result of this inspection.