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) 2019001	Region III 2443 Warrenville Rd. Lisle, IL 60532 Select a location (Use keyboard arrows to select). . .

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36594	13-32519-01	9/18/19

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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	9/18/19
BRANCH CHIEF	Aaron T. McCraw	Robert Ruiz for A.M.	10/7/19

NRC FORM 591M PART 3
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Docket File Information

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1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Franciscan Healthcare - Munster 701 Superior ave. Munster, IN 46321 REPORT NUMBER(S) 2019001	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	9/18/2019

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87132	03.01 through 03.08

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: 09/18/2021

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a hospital in Munster, Indiana. The licensee conducted high dose rate (HDR) remote after loader device therapy (e.g., using tandem and ring or cylinder applicators). The licensee's cancer department had two Authorized Users for HDR therapies as well as two Authorized Medical Physicist (AMP). In addition, the licensee administered flourine-18 (F-18) flourodeoxyglucose (FDG) to patients for positron emission tomography (PET)/computerized axial tomography (CAT) for diagnostic tests. The licensee did not conduct 35.300 therapies yet, but they plan to use Xofigo. The licensee used technetium-99m medronate (MDP) for conducting bone scans, thallium-201 heart scans, and other diagnostic tests.

Performance Observations

The inspector: (1) noted that there were no HDR treatments during the inspection; (2) observed that the PET facility was as per the diagram; (3) observed a nuclear medicine technologist (NMT) administer F-18 FDG to a patient for a PET/CAT scan, and the NMT wore her whole body dosimeter badge and her extremity dosimeter badge; (4) used an NRC, calibrated survey meter to conduct an independent ambient exposure rate survey at selected surfaces of stored, shielded sealed sources in the PET hot lab, and the results were low background; (5) observed selected licensee survey meters and they were calibrated; (6) conducted a comparative ambient exposure rate survey at the surface of a constancy check source and the inspector used an NRC, calibrated survey meter to conduct the survey and the licensee and the inspector had the same result; (7) observed an NMT demonstrate how licensed material packages were received, including ambient exposure rate surveys and removal contamination surveys for each surface of the packages; (8) observed an NMT demonstrate how to respond to a spill of unsealed licensed material based on a scenario posed by the inspector; (9) observed an NMT use a dose calibrator to verify the radioactivity of a dosage prior to administration to the patient; (10) observed that the HDR remote after loader device was as authorized and properly secured; (11) observed that the HDR remote after loader device facility was as per the facility diagram; (12) used an NRC, calibrated survey meter to conduct an independent ambient exposure rate survey at the hot spot on the HDR remote after loader device and there was no concern; (13) observed an AMP demonstrate how to conduct HDR remote after loader device spot checks; (14) noted that the HDR Oncentra software was Version 4.6.0, such that the software does not any bugs; (15) reviewed selected records for HDR treatments including written directives, images of dose information overlayed with anatomy,

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PROGRAM SCOPE

pre- and post-treatment information to verify that the HDR remote after loader device such that the device conducts the actions to execute the treatment in accordance with the written directive and the treatment plan; (16) noted that the licensee verified the patients' identity by way of name and birth date; (17) observed records showing that HDR patients and the HDR remote after loader device get an ambient exposure rate survey to verify that the sealed source is not in the patient's body prior to releasing the patient; (18) reviewed records of HDR emergency refresher training for all of the staff that conduct HDR treatments; (19) reviewed dosimeter badge results for 2018 through 8/14/2019, and the doses were well below the occupational dose limits; (20) reviewed records of radiation protection program audits; (21) reviewed records of dose calibration calibrations; (22) reviewed records of sealed source inventories and leak tests; (23) reviewed selected ambient exposure rate surveys for facilities containing licensed material; and (24) reviewed selected radiation safety committee meeting minutes.