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 Health: Indianapolis, Mooresville, and Carmel 8111 S Emerson Ave. Indianapolis, IN 46237 REPORT NUMBER(S) 2018001	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
030-09398	13-02128-03	December 11-13, 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	Deborah A. Piskura, Senior Health Physicist	Deborah A Piskura	12/11-13/18
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		12/20/18

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
87130, 87131 & 87132	03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Christopher Njeh, Ph.D., RSO	(317) 528-5141

☑ Main Office Inspection Next Inspection Date: Dec. 13, 2020

☑ Field Office Inspection 5255 E Stop 11 Rd, Indpls, IN (two locations:

☐ Temporary Job Site Inspection surgery center and cardiac departments)

PROGRAM SCOPE

This was a routine inspection of a large medical institution (400+ beds at the main hospital) and conducted licensed activities at four locations in the Indianapolis area. The licensee was authorized for materials in Sections 35.100, 35.200 (including PET), 35.300, 35.400 (current use limited to I-125 eye plaques), 35.500, Ir-192 in an HDR unit, I-125 radioactive seed localization procedures, and Y-90 microspheres. Collectively, the licensee's nuclear medicine departments were staffed with 8 FT technologists and 3 PRNs who performed approximately 500 diagnostic nuclear medicine procedures monthly. The main hospital performed a full spectrum of studies and received unit doses and bulk Tc-99m. Numerous Ra-223 and I-131 dosages (capsules only) for whole body follow up studies, hyperthyroid, and CA treatments were also administered by the main hospital. In addition, the hospital administered 3-5 Y-90 microspheres (SIR-spheres) treatments annually. The licensee retained the services of a consultant who will perform quarterly audits of the radiation safety program; these audits included all locations of use, each performed at separate intervals.

Radiation therapy activities were performed at the main hospital. The radiation oncology department was staffed with 2 AMPs and 4 authorized physician users. The licensee performed 30-40 I-125 ocular implants annually. The licensee administered approximately 20-30 patient treatments annually utilizing its HDR. These treatments were limited to GYN cancer cases. All HDR patient treatments were administered by the attending radiation oncologist, the therapist, and the AMP. Service, maintenance, and source exchanges were performed by the HDR device manufacturer.

This inspection consisted of interviews with selected licensee personnel; a review of selected records, including ocular and HDR written directives and treatment plans; tours of the nuclear medicine, PET and radiation oncology departments; and independent measurements. The inspector observed the licensee staff administer numerous diagnostic dosages and one patient treatment utilizing its HDR unit. The inspector reviewed the patient's written directive and the treatment plan and interviewed the attending physician, therapist (who operated the HDR), and AMP. The inspection included observations of source inventories, dose calibrator QA checks, HDR safety/QA checks, security of byproduct material, use of personnel monitoring, and HDR patient surveys.

No violations of NRC requirements were identified during this inspection.