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, Morresville, and Carmel 8111 S Emerson Ave Indianapolis, IN 46327 REPORT NUMBER(S) 2021001	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	October 26-27, 2021

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.

1 Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 20.1101(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, the licensee did not performed the 2020 annual radiation protection program review. As corrective action, the new RSO will conduct the annual radiation program audit annually.

☐ 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	Terri S Ruff	Terri S Ruff	11/15/21
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman Digitally signed by Zahid M Sulaiman Date: 2021.11.08 15:26:36 -06'00'	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.11.12 06:26:20 -06'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Franciscan Health	030-09398	13-02128-03

4. Report Number(s):	5. Date(s) of Inspection:
2021001	October 26-27, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02230	2	87130, 87131, & 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Howard Salmon, PhD - RSO	Howard.Salmon@franciscanalliance.org	Work: (317) 528-2843 Cell: (352) 870-6412

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	10/26/2023 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a large medical institution, authorized to conduct licensed activities at five locations in the Indianapolis area. The licensee was authorized to use byproduct materials for medical purposes permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 for yttrium-90 (Y-90) microspheres. The main hospital nuclear medicine department was staffed with two full-time and four PRN nuclear medicine technologist (NMTs), who performed approximately 200 diagnostic nuclear medicine procedures monthly, 100 iodine-131 (I-131) hyperthyroid and thyroid ablations, 4-6 radium-223 (Xofigo), and 10-12 Y-90 (Theraspheres) procedures annually. The diagnostic administrations included a variety of imaging procedures using technetium-99m (Tc-99m) primarily for the HIDA, bone scans, GI bleeds, gastric emptying, lung scans using Xe-133, and parathyroid / thyroid uptake and whole body scan using I-131. The main hospital PET clinic employed a full-time NMT who performed 60-70 diagnostic imaging procedures monthly using fluorine-18 unit doses.

The nuclear medicine department at Mooresville, Indiana was staffed with a full-time NMT, who performed approximately 50 diagnostic nuclear medicine procedures monthly. The licensee retained the services of a consultant who performs quarterly audits of the radiation safety program for all locations of use.

The radiation oncology department was staffed with four oncologists, eight therapists, two dosimetrists, and two authorized medical physicists (AMPs) who performed approximately 40 iodine-125 eye plaque implants and 50 high dose rate remote afterloader (HDR) procedures (mostly gynecological cancer treatments) annually. The licensee has not performed any 35.400 seed implants since the last inspection.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the main hospital, the cancer center, and the Mooresville hospital; interviews with select licensee personnel; a review of select records; an observation of security of the materials; and independent measurements. The inspector observed an HDR procedure for gynecological cancer treatment, and administrations of Tc-99m for cardiac stress test to two patients. The inspector had the NMT conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, with no issue noted. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings

Materials Inspection Record (Continued)

The inspector had the AMP demonstrate the HDR unit's: (1) security; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment checks. The inspector reviewed select HDR, I-131, Ra-223, I-125 eye plaques, and Y-90 written directives and treatment plans. Through these demonstrations and other discussion, the inspector found that the licensee personnel was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: annual radiation protection program audits, radiation safety committee minutes, quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed dosimetry records for 2019 through Aug 31, 2021, indicating the maximum annual dose to be 1,485 mrem - DDE, and 5,432 mrem - SDE.

The inspector identified an NCV of 10 CFR 20.1101(c) for failure to review the radiation protection program annually. The licensee had identified that the 2020 annual radiation protection program review was not performed by the previous RSO. As corrective action, the new RSO will ensure that the annual radiation program audit is conducted annually.