

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Franciscan Healthcare - Munster

701 Superior Ave
Munster, IN 46321

REPORT NUMBER(S) 2022001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-36594

4. LICENSE NUMBER(S)

13-32519-01

5. DATE(S) OF INSPECTION

August 11, 2022

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 violation(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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman	Digitally signed by Zahid M. Sulaiman Date: 2022.08.16 18:07:56 -05'00'
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Geoffrey M. Warren	Digitally signed by Geoffrey M. Warren Date: 2022.08.18 14:39:52 -05'00'



Materials Inspection Record

1. Licensee Name: Franciscan Healthcare - Munster		2. Docket Number(s): 030-36594		3. License Number(s) 13-32519-01	
4. Report Number(s): 2022001			5. Date(s) of Inspection: August 11, 2022		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02230		8. Priority: 2	9. Inspection Guidance Used: 87131 & 87132
10. Licensee Contact Name(s): Gregory R. Warrell, Ph.D, RSO		11. Licensee E-mail Address: Gregory.warrell@franciscanalliance.org Gregory.warrell@gmail.com		12. Licensee Telephone Number(s): Work: (219) 922-4061 Cell: (574) 309-4202	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 08/11/2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was a routine, unannounced, inspection of a hospital located in Munster, Indiana, with authorization to use byproduct materials under 10 CFR Sections 35.100, 35.200, 35.300, and 35.600 (Iridium-192, high dose rate (HDR) remote afterloader). The nuclear medicine department at the main hospital was staffed with two full-time nuclear medicine technologists (NMTs). The NMTs typically administered approximately 6 diagnostic doses daily using Technetium-99m (Tc-99m), primarily for cardiac, HIDA, bone scan, gastric emptying, and lung scan. The nuclear medicine hot lab moved to a new hot lab around July 2022. Licensee has not performed any 35.300 therapeutic procedures since the last inspection. Licensee still plan to use Xofigo and also discussed about using the yttrium-90 microspheres procedures.

The cancer center was staffed with three oncologists and an authorized medical physicist (AMP), who performed approximately 28 HDR gynecologic treatments annually. The PET clinic located at the cancer center was staffed with a NMT who performed approximately 3 PET doses using F-18 daily.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the nuclear medicine department, cancer center, interviews with select licensee personnel, a review of select records, an observation of security of the materials, and independent measurements. The inspector observed the NMT prepare and administer a diagnostic dose using Tc-99m to a patient. The inspector had an 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.

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; (6) radiation monitoring equipment checks; and (7) full calibration measurement. The last HDR source was exchanged on June 14, 2022. The inspector reviewed select HDR written directives, pre and post treatment plans. Through these observations, demonstrations and other discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, package

Materials Inspection Record (Continued)

receipts, waste disposal records, DOT hazmat training, constancy, linearity, and accuracy tests of the dose calibrator, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed the dosimetry records for 2021 through April 14, 2022, indicating the maximum annual dose to be 111 mrem - DDE, and 538 mrem - SDE.

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