

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Franciscan Health - Lafayette East
Nuclear Medicine Dept.
1701 S. Creasy Ln.
Lafayette, IN 47905

REPORT NUMBER(S) 2019001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-01642

4. LICENSE NUMBER(S)

13-09788-01

5. DATE(S) OF INSPECTION

8/26-27/19, with in-office
review through 9/5/19

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:

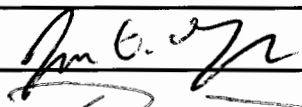
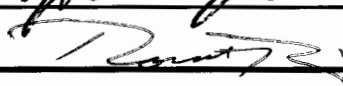
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Jason D. Draper, Health Physicist		9/26/19
BRANCH CHIEF	Aaron T. McCraw Robert Ruiz for		10/01/19

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Franciscan Health - Lafayette East Nuclear Medicine Dept. 1701 S. Creasy Ln. Lafayette, IN 47905 REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-01642		4. LICENSE NUMBER(S) 13-09788-01	
5. DATE(S) OF INSPECTION 8/26-27/19, with in-office review through 9/5/19		6. INSPECTION PROCEDURES USED 87131	
7. INSPECTION FOCUS AREAS 03.01-03.09			

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02120	2. PRIORITY 3	3. LICENSEE CONTACT Robert Mehl, M.D., RSO	4. TELEPHONE NUMBER (765) 502-4722
---------------------------------	----------------------	---	---

☒ Main Office Inspection Next Inspection Date: 08/26/2022

☒ Field Office Inspection Crawfordsville, IN

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a hospital system with multiple locations including in Lafayette and Crawfordsville, Indiana, authorized to use byproduct materials permitted by 10 CFR 35.100, 200, and 300 for diagnostic and therapeutic nuclear medicine procedures. The licensee was also authorized for sealed sources for diagnostic imaging as well as a strontium-90 sealed source, however the licensee no longer used these sources and was storing them incident to disposal. At the time of the inspection, the Lafayette location employed three full-time and three part-time nuclear medicine technologists (NMTs) who performed administrations of unit dosages of radiopharmaceuticals Monday through Friday. The NMTs performed diagnostic administrations for approximately 5-6 patients per day using primarily technetium-99m as well as approximately 10 administrations per week of fluorine-18 FDG for PET studies. The licensee also performed approximately 1 therapeutic iodine-131 administration per month. At the licensee's Crawfordsville location, two NMTs performed diagnostic administrations on approximately 20 patients per week. The licensee's radiation safety program was reviewed quarterly by a medical physics consultant.

PERFORMANCE OBSERVATIONS

At both locations, the inspector toured the nuclear medicine departments to observe material security, postings, and any other potential hazards to the material. The inspector also performed independent surveys of unrestricted areas outside the PET injection and camera rooms at the Lafayette location to verify the licensee's shielding analysis as well as general area and contamination surveys at both locations to verify there was no unidentified contamination. The licensee had completed administrations for the day at the Crawfordsville location, but the inspector observed one PET administration at the Lafayette location and interviewed the NMTs with regard to radiation safety practices, emergency procedures, package receipt, instrument calibrations, and surveys. The inspector found the NMTs to be knowledgeable of radiation safety practices and the licensee's procedures. The inspector also reviewed a sample of records including written directives, inventories, leak tests, equipment calibrations, spill reports, surveys, dosimetry, radiation safety training and periodic program reviews, and did not identify any issues of regulatory concern.

No findings of significance were identified.

Draper, Jason

From: Draper, Jason
Sent: Thursday, October 03, 2019 8:16 AM
To: robert.mehl@radpartners.com
Cc: david.reisman@franciscanalliance.org; daniel.ratcliff@franciscanalliance.org
Subject: NRC Form 591M, Franciscan Health - Lafayette East
Attachments: SKM_C45819100215040.pdf

Dr. Mehl,

As Mr. Ratcliff and I discussed in our telephone call on September 5, 2019, attached is the inspection report for the routine NRC inspection I performed at your facilities in Lafayette and Crawfordsville, Indiana, on August 26-27, 2019. Please review and keep this document for your records. There is no response required, though I would appreciate an email confirming that you have received the document. Let me know if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Jason Draper
Health Physicist (Inspector)
NRC/RIII/DNMS/MIB
(630) 829-9839
jason.draper@nrc.gov