

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Franciscan Health: Indianapolis, Mooresville, and Carmel 8111 South Emerson Avenue Indianapolis, Indiana 46237</p> <p>REPORT NUMBER(S) 2017001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>	
<p>3. DOCKET NUMBER(S)</p> <p>030-09398</p>	<p>4. LICENSE NUMBER(S)</p> <p>13-02128-03</p>	<p>5. DATE(S) OF INSPECTION</p> <p>January 23-25, 2017</p>

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:

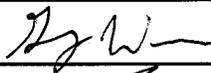
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Geoffrey M. Warren		1/25/17
BRANCH CHIEF	Aaron T. McCraw		2/10/17

Docket File Information

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<p>6. INSPECTION PROCEDURES USED</p> <p>87131, 87132</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01 - 03.09; 03.01 - 03.09</p>
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SUPPLEMENTAL INSPECTION INFORMATION

<p>1. PROGRAM CODE(S)</p> <p>02240</p>	<p>2. PRIORITY</p> <p>2</p>	<p>3. LICENSEE CONTACT</p> <p>Christopher F. Njeh, MSC, Ph.D., RSO</p>	<p>4. TELEPHONE NUMBER</p> <p>(317) 528-5141</p>
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Main Office Inspection Next Inspection Date: January 2019

Field Office Inspection See Part 2

Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a hospital system in the Indianapolis area, with authorization to perform diagnostic and therapeutic nuclear medicine (NM), brachytherapy seed procedures, high dose-rate remote afterloader (HDR) procedures, microspheres procedures, and radioactive seed localization (RSL). The licensee operated two hospitals and three associated facilities under this license.

The main hospital, Franciscan Health Indianapolis, was a 420-bed hospital where the licensee operated a NM facility and a Positron Emission Tomography (PET) clinic. The NM facility employed one full-time and three part-time technologists who administered 200 diagnostic doses monthly, including a wide variety of imaging and uptake studies, five iodine-131 therapy procedures monthly, occasional radium-223 dichloride procedures, and around five microspheres procedures monthly. The PET clinic employed two full-time and one part-time technologists who performed 100 tumor imaging procedures monthly using fluorine-18 doses. Franciscan Health Mooresville was a 84-bed hospital where the licensee operated NM and cardiology clinics, each of which operated two days each week. The NM clinic (Wed/Thu) was staffed with one technologist who performed around 30 diagnostic administrations monthly, including a variety of uptake and imaging procedures. The cardiology clinic (Tue/Thu) was staffed with one technologist who performed around 80 rest and stress procedures monthly. The licensee also operated a cardiology clinic near the main hospital at 5255 East Stop Eleven Road and a facility in Carmel where the licensee had performed occasional sentinel node procedures.

The radiation oncology department at the main hospital was staffed with three physician authorized users and two medical physicists. Each year, the oncology staff performed 50 HDR fractions, primarily gynecological and esophageal cancer therapies; and ten eye plaque procedures using iodine-125 seeds. At this hospital, the licensee had performed ten RSL procedures to date; seeds were received at main NM, implanted at the breast center, removed in tissue samples either at the Franciscan Surgery Center at 5255 East Stop Eleven Road or at the main hospital operating rooms, transferred to pathology within the tissue samples, then returned by pathology staff to NM for storage pending disposal.

(continued on Part 2)

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8111 South Emerson Avenue
Indianapolis, Indiana 46237

REPORT NUMBER(S) 2017001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-09398

4. LICENSE NUMBER(S)

13-02128-03

5. DATE(S) OF INSPECTION

January 23-25, 2017

(Continued)

Performance Observations: The inspector observed three diagnostic and one therapeutic administrations of licensed materials in NM including dose preparation and disposal, one HDR procedure including planning, daily HDR and NM checks, package receipt surveys, and daily contamination surveys. Licensee personnel described additional diagnostic and therapeutic procedures, kit preparation, HDR source exchange, and emergency procedures. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies, HDR therapies, RSL procedures, and eye plaques, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. Radiation Safety Committee minutes indicated good attendance at meetings and discussion of appropriate topics. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

Additional facilities inspected during this inspection included Franciscan Health Mooresville, 1201 Hadley Road, Mooresville IN; and the Franciscan Surgery Center, 5255 East Stop Eleven Road, Indianapolis IN.

No violations were identified during this inspection.