

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Franciscan Alliance, Inc.
d/b/a Franciscan St. Margaret Health
5454 Hohman Avenue
Hammond, IN 46320

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-01602

4. LICENSE NUMBER(S)

13-02047-02

5. DATE(S) OF INSPECTION

November 18, 2016

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	<i>Zahid Sulaiman</i>	11/18/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>Aaron T. McCraw</i>	11/22/16

Docket File Information

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3. DOCKET NUMBER(S) 030-01602	4. LICENSE NUMBER(S) 13-02047-02	5. DATE(S) OF INSPECTION November 18, 2016	
6. INSPECTION PROCEDURES USED 87130, 87131, 87132	7. INSPECTION FOCUS AREAS 03.01-03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Michael C. Brewer, RSO	4. TELEPHONE NUMBER (219) 932-2300
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- ☒ Main Office Inspection Next Inspection Date: 11/18/2018
- ☒ Field Office Inspection South Campus, 24 Joliet Street, Dyer, IN
- ☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a community hospital located in Hammond and Dyer, Indiana, authorized under NRC license to use byproduct materials for medical uses permitted by 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.600 limited to iridium-192 within a remote afterloading brachytherapy (HDR) unit. The nuclear medicine department was staffed with five full-time nuclear medicine technologists (NMTs) and one PRN who performed approximately 200 diagnostic studies monthly (both sites). The licensee performed the full spectrum of diagnostic studies. The licensee administered approximately 40 iodine-131 (I-131) hyperthyroid and thyroid cancer therapies annually. The licensee received unit doses and I-131 in capsule form from a licensed radiopharmacy. The oncology department was staffed with two oncologists and two authorized medical physicists (AMP). The licensee conducted approximately 120 HDR treatments annually; these treatments were limited to gynecological cancers only. The HDR source was exchanged quarterly, with the most recent source exchange on September 1, 2016. No manual brachytherapy procedures have been performed since the last inspection. The licensee disposed of numerous cesium-137 sealed sources, two barium-133 sealed sources, and a strontium-90 eye applicator to an authorized vendor since the last inspection.

Performance Observations:

The inspection consisted of interviews with select licensee personnel, reviews of select records, and tours of the nuclear medicine department and cancer center facility. The inspector observed an administration of a technetium-99m dose to a patient for a cardiac stress test. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receipt and check-in procedures, the end of the day daily area surveys, and proper handling of radioactive waste and disposal procedures. The inspector observed one HDR treatment to a patient. The inspector had the AMP demonstrate the HDR unit's: (1) security of licensed material; (2) daily spot checks; (3) emergency equipment and procedures; (4) safety procedures and instructions; (5) door interlock system; and (6) radiation monitoring equipment. The inspector reviewed four HDR written directives and treatment plans. The inspector reviewed the following records: radiation safety committee minutes, annual audits, package receipts, waste disposal records, hazmat training, linearity and accuracy checks of the dose calibrator, and sealed source leak tests. The inspector reviewed dosimetry records for 2014, 2015, and till August 30, 2016, indicating the maximum annual doses to be 326 millirem (mrem) whole body and 806 mrem extremity.

No violations of NRC requirements were identified during this inspection.