

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Franciscan Alliance, Inc. d/b/a Franciscan
St. Anthony Health - Michigan City
301 West Homer St.
Michigan City, IN 46360

REPORT NUMBER(S) 13-01

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-09928

4. LICENSE NUMBER(S)

13-13144-02

5. DATE(S) OF INSPECTION

February 11, 2013

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:

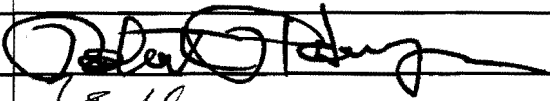

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Robert P. Hays		3/11/13
BRANCH CHIEF	Tamara E. Bloomer		3/18/13

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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6. INSPECTION PROCEDURES USED

87131, 87132

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

2120

2. PRIORITY

3

3. LICENSEE CONTACT

Amy Johns, Nuc. Med. Supv.

4. TELEPHONE NUMBER

(219) 877-1568

- Main Office Inspection Next Inspection Date: 02/11/2016
- Field Office Inspection 8955 W. 400 North, Michigan City, IN
- Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a medical institution located in Michigan City, Indiana, with authorization by the license for diagnostic and therapeutic nuclear medicine procedures and low dose manual brachytherapy procedures. The licensee has two authorized locations of use (ALOU) on their license. One ALOU has been added since the previous inspection and was reviewed during this inspection.

At 8955 W. 400 North, the licensee has conducted only PET studies and averaged of 4-5 patient studies with one primary nuclear medicine technologist (NMT) and other NMTs rotate from the other ALOU as needed. Patient studies are routinely scheduled Monday-Friday, each week. The licensee receives PET doses from an area PET pharmacy. All waste was held for decay-in-storage.

Performance Observations

During the inspections, the licensee's NM Supervisor demonstrated/discussed as applicable: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) wipe test counting; (4) DOT shipping requirements and HAZMAT training; (5) unit dose preparation, safe handling, and assay procedures; (6) waste storage and handling; (7) sealed source inventories and leak tests; (8) security and storage of licensed material; (9) radiation safety program audits; (10) any contamination events (none); and (11) dosimetry < 10% of annual regulatory limit at each facility according to radiation safety committee minutes. Dosimetry records were not available for review at this ALOU, but are maintained at the main facility.

The inspector performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings.