

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Covenant Medical Center, Inc.  
1447 N. Harrison  
Saginaw, Michigan 48602

REPORT NUMBER(S) 2016001

## 2. NRC/REGIONAL OFFICE

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

## 3. DOCKET NUMBER(S)

030-02012

## 4. LICENSE NUMBER(S)

21-01492-02

## 5. DATE(S) OF INSPECTION

October 6, 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:

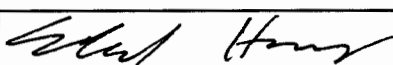
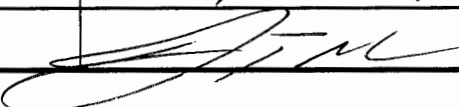
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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			EPH 10/24/16
NRC INSPECTOR	Edward F. Harvey		10/16/16
BRANCH CHIEF	Aaron T. McCraw		10/25/16

**Docket File Information**

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6. INSPECTION PROCEDURES USED

87131, 87132

7. INSPECTION FOCUS AREAS

All

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)

02230

2. PRIORITY

2

3. LICENSEE CONTACT

William K. Wong, M.D.

4. TELEPHONE NUMBER

(989) 583-7000

☒ Main Office Inspection      Next Inspection Date:      October 6, 2018

☒ Field Office Inspection      5400 Mackinaw Road & 700 Cooper Avenue

☐ Temporary Job Site Inspection

**PROGRAM SCOPE**

This was a routine, unannounced inspection of a medical institution licensed to use byproduct materials to conduct diagnostic and therapeutic medical procedures under 10 CFR 35.100, 200, 300, 400, 600, and 1000. The licensee had five locations of use specified on the license. Although authorized, the licensee had not conducted any medical procedure under 35.400 or 35.1000 since the last inspection. The licensee contracted with a health physics consultant to perform quarterly audits of the radiation safety program.

1447 N. Harrison was the address of the main hospital. At this location, the licensee is authorized to use sealed sources for localization of non-palpable lesions. However, the licensee had not yet acquired material for these procedures due to prior issues with finding a vendor.

700 Cooper Avenue was located on the main hospital campus and the licensee was authorized to perform diagnostic and therapeutic procedures under 10 CFR 35.100, 200, and 300 at this location. This facility was staffed Monday-Friday with 4 full-time nuclear medicine technologists performing approximately 50 diagnostic studies per week. This facility also performed approximately 2-3 therapeutic procedures per month for hyperthyroidism and thyroid ablations.

The inspector observed nuclear medicine staff demonstrate package receipt and surveying procedures, daily dose calibrator constancy checks, daily surveys, and waste disposal procedures. In addition, the inspector observed the administration of a dose for a cardiac stress test. The inspector noted that the NMT wore the appropriate personal protective equipment, assayed the doses, and verified patient identity prior to administering the doses. The nuclear medicine staff also demonstrated adequate knowledge of radiation protection principles and emergency procedures in the event of a spill through interviews with the inspector.

At the 5400 Mackinaw Road location, the licensee performed diagnostic and therapeutic procedures authorized under 10 CFR 35.100, 200, 300, and 600. At the time of the inspection, the nuclear medicine department was not performing administrations as they only operate on Tuesdays and Wednesdays.

Continued on Part 2.

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(Continued)

This facility shared full-time staff with the 700 Cooper facility and performed approximately 5-6 diagnostic studies per day. In addition, the nuclear medicine department performed 3-4 therapeutic procedures per year for hyperthyroidism. Although authorized to perform procedures under 10 CFR 35.600, the licensee has ceased operation of their HDR unit as of September, 2016 due to the loss of their authorized user. Prior to discontinuing treatments, the licensee was performing HDR procedures on approximately 2-3 patients per month for skin and gynecological therapy. The licensee has filed an amendment request with the NRC to add a new authorized user and is planning to resume the use of their HDR by January, 2017. The inspector reviewed records of spot checks, source exchanges, treatment plans, and quarterly calibrations with no issues noted.

At both 700 Cooper Avenue and 5400 Mackinaw Road, the inspector reviewed a selection of licensee records, including written directives, program audits, dose calibrator linearity records, dose calibrator accuracy records, dose calibrator geometry records, source inventories, training, survey meter calibration records, package receipt logs, and dosimetry with no issues noted. In addition, the inspector performed independent surveys, which revealed no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

No violations were identified during this inspection.