

Nieves Folch, Luis

From: Nieves Folch, Luis
Sent: Friday, March 10, 2017 9:16 AM
To: 'Lowden, John'
Subject: NRC report 591
Attachments: image2017-03-10-095210.pdf

Dear Mr. Lowden,

This email is to send you with a copy of the inspection report done for the inspection conducted from February 15, 2017 to February 16, 2017. The results of the inspections was one severity level IV violations as discuss during the exit meeting. You are required to sign the report next to the space that says Licensees Representative as acknowledgment and receipt of this report and send it back to me at this email address, after that no further actions are required on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions, or if there is anything else we at the NRC can do to assist you.

Luis Nieves
Health Physicist
US Nuclear Regulatory Commission
Materials Inspection Branch, Region III
(630) 829-9571

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Goshen Health 200 High Park Ave. Dept. of Nuclear Medicine Goshen, IN 46526 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) 030-14254	4. LICENSE NUMBER(S) 13-18845-01	5. DATE(S) OF INSPECTION February 15, 2017	

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.

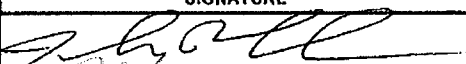
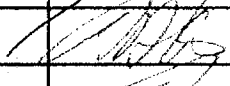

(Violations and Corrective Actions)

Contrary to 10 CFR 20.1802, on February 16, 2017, the licensee failed to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. Specifically, the Nuclear Medicine Technologists (NMT) licensee left one unit dose containing 10 millicuries of fluorine-18 inside the hot lab with the door open, and the NMT could not maintain constant surveillance and control while he was administering a dose to the patient.

The cause of the violation was that the NMT misunderstood what constitutes adequate surveillance. As corrective action, the licensee installed an automatic door closer and placed postings in the area reminding staff to close the hot lab door when leaving.

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	JOHN P. LOWDEN		3/10/17
NRC INSPECTOR	Luis Nieves Poch		3/9/17
BRANCH CHIEF	Aaron T. McCraw		3/9/17

Docket File Information
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6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT John Lowden, M.S., RSO	4. TELEPHONE NUMBER (888) 456-5255
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- Main Office Inspection Next Inspection Date: February 15, 2019
- Field Office Inspection 1135 Professional Drive , Goshen, Indiana
- Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a 126-bed hospital located in Goshen, Indiana, authorized for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 (Ir-192 in an HDR unit), 35.1000 (Y -90 microspheres and I-125 seeds for localization of non-palpable lesions). Although authorized to perform brachytherapy procedures under 35.400, the licensee had not performed any such procedures in several years and had no plans to reactivate the program. The nuclear medicine department was staffed with 5 full-time technologists, who administered 140 diagnostic doses monthly, including the full spectrum of procedures using Tc-99m, In-111, Xe-133, and other isotopes. Therapy procedures included 32 I-131 treatments per year, including thyroid ablation, hyperthyroid treatments, and whole body scans; 1 Sm-153 treatment; and 3 treatments using Ra-223 Xofigo. The licensee's PET area was staffed with one technologist who performed whole body scans using F-18 FDG. The radiation therapy department was staffed with two physician authorized users and two medical physicists. HDR procedures included breast, gynecological, prostate, skin, bronchial, and other procedures. The licensee performed about eight Y -90 SirSphere treatments per year. In addition, the therapy department oversees the Retreat Womens Health Centers use of I-125 seeds for localization of non-palpable lesions, of which more than 100 were performed in 2016.

Performance Observations

The inspector observed the preparation and administration of a cardiac stress test, rest test and a PET scan during the inspection. The technologist described dose calibrator constancy; survey meter and well counter QC; package receipt surveys and wipes; waste handling; and daily and weekly contamination surveys. The inspector noted no concerns with these activities. The inspector observed an HDR source exchange, including HDR daily checks, and reviewed written directives and treatment plans for 11 selected treatments. The inspectors also reviewed written directives for radiopharmaceutical therapies, and microspheres procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of licensee dosimetry and survey records indicated no concerns with exposures to radiation workers or general public. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

One violation of NRC requirements were identified as a result of this inspection, as documented on Part 1.