

Nieves Folch, Luis A

From: Nieves Folch, Luis A
Sent: Friday, November 18, 2016 8:34 AM
To: 'lskillman@majorhospital.org'
Subject: NRC 591 Report
Attachments: New Doc 2.pdf

Mrs. Skillman

Here is the 591 report with a severity level 4 violation for the inspection conducted on October 21, 2016. As discussed on the exit meeting you need to sign where it says Licensee's Representative and send it back to me at this email. After that no further actions are required from the licensee.

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

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1 LICENSEE/LOCATION INSPECTED

Major Hospital
150 West Washington Street
P.O. Box 10
Shelbyville, IN 46176

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)

030-08191

4 LICENSE NUMBER(S)

13-14877-01

5 DATE(S) OF INSPECTION

October 21, 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):


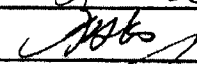
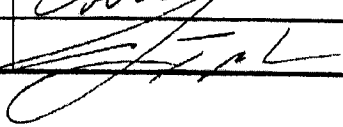
- ☒ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Contrary to Title 10 of the Code of Federal Regulations (CFR) 35.75(c), as of October 21, 2016, the licensee failed to maintain a record of the basis for authorizing the release of an individual in accordance with CFR 32.2075(b). Specifically, the licensee failed to maintain a record of the calculations for the release of three therapy patients on October 27, 2016, September 23, 2016, and July 5, 2016.

The cause of the violation was that the licensee did not to save the electronic file or print the calculations documenting the bases for the release of the three therapy patients. As corrective action, the Radiation Safety Officer reviewed the scenarios with the licensee and retrained licensee staff on required recordkeeping for authorizing the release of an individual.

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	LINDA SKILLMAN, RTRKMD		11/18/16
NRC INSPECTOR	Luis Nieves Folch		10/21/16
BRANCH CHIEF	Aaron T. McCraw		11/17/16

Docket File Information

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1. LICENSEE/LOCATION INSPECTED:

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4. LICENSE NUMBER(S)

13-14877-01

5. DATE(S) OF INSPECTION

October 21, 2016

6. INSPECTION PROCEDURES USED

87131

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02120

2. PRIORITY

3

3. LICENSEE CONTACT

Ty A. Montgomery, M.D., RSO

4. TELEPHONE NUMBER

(317) 421-5657



Main Office Inspection

Next Inspection Date: October 21, 2019



Field Office Inspection



Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a 35-bed hospital authorized by its NRC license to use unsealed byproduct material for diagnostic and therapeutic procedures under 10 CFR 35.100, 35.200, and 35.300 at its facility in Shelbyville, IN. A local radiopharmacy delivered unit doses to the hospital for a variety of diagnostic procedures. The clinic employed two full-time nuclear medicine technologist who staffed the department Monday to Friday. The licensee performed approximately seven diagnostic studies per day and two therapeutic administration per month. The licensee retained the services of a medical physics consultant to perform instrument calibrations, leak tests, and quarterly audits of the radiation safety program.

PERFORMANCE OBSERVATIONS

The inspector toured the nuclear medicine laboratory and observed the nuclear medicine technologist demonstrate package receipt surveys and instrument quality control checks. The inspector observed the preparation and administration of one heart stress study. The inspector performed independent surveys of the hot lab and other areas of the nuclear medicine department and found no contamination or exposures to members of the public distinguishable from background. The nuclear medicine technologist demonstrated adequate knowledge of radiation safety principles and practices through interviews. The inspector reviewed quarterly audit reports, spill reports, and documentation of package receipt, area surveys, instrument quality control, waste disposal, and employee training. The inspector also reviewed monthly dosimetry reports, which indicated annual whole-body and extremity doses below regulatory limits.

The inspector identified one violation during this inspection, concerning record keeping for authorizing the release of an individual. The nuclear medicine technologist was retrained on adequate record keeping for authorizing the release of an individual. Licensee management confirmed these corrective actions.

No other violations of NRC requirements were identified as a result of this inspection.