Nieves Folch, Luis A

From: Nieves Folch, Luis A
Sent: Thursday, November 17, 2016 2:36 PM
To: 'Shanon Murphy'
Subject: FW: New Doc 1
Attachments: New Doc 1.pdf

Mrs. Murphy

Here is the 591 report with an NCV (non cited violation) and a severity level 4 violation for the inspection conducted on October 19, 2016. As discus on the exit meeting you need to give this to your management and have them 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

NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1 LICENSEE/LOCATION INSPECTED	2 NRC REGIONAL OFFICE
The Heart and Vascular Clinic 3251 S. Shawnee Drive Bedford, Indiana 47421-5277 REPORT NUMBER(S) 2016001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3 DOCKET NUMBER(S)	4 LICENSE NUMBER(S)	5 DATE(S) OF INSPECTION
030-38425	13-32820-01	October 19, 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 violations(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.

1 Non-cited violation(s) were discussed involving the following requirement(s):

Contrary to Condition 15.A of NRC Materials License 13-32820-01, as of October 19, 2016, the licensee did not conduct its program in accordance with its Hot Lab Equipment Quality Control procedure, which states in part that, the dose calibrator is to be tested for linearity upon installation and at least quarterly thereafter. Specifically, the licensee consultant failed to perform the quarterly linearity test, since January 2016 a period greater than quarterly.

The cause of the violation was the licensee's consultant forgot to do the linearity test for the dose calibrator during the visit on April 4, 2016. As a corrective action, the licensee consultant performed the linearity test of the next visit in July 2016.

☑ 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 Condition 15.A of NRC Materials License 13-32820-01, on October 19, 2016, the licensee did not conduct its program in accordance with its Safe Use of Radioactive Materials Policy procedure Item 17, which states no food, drink or personal effects will be stored in radioactive material preparation, usage, storage or waste area or any restricted area as defined by the RSO. Specifically, on October 19, 2016, the licensee stored candy in the hot lab where radioactive material is prepared and used.

The cause of the violation was licensee oversight. Specifically, the radiopharmacy driver left candy in the hot lab. As corrective actions, all licensee staff has been retrained and the licensee called the radiopharmacy to ask them not to leave any type of food in the hot lab.

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	Stephanie Holdcroft RN	Stephanie Holdcroft RN	11/18/16
NRC INSPECTOR	Luis Nieves Folch		11/14/16
BRANCH CHIEF	Aaron T. McCraw		11/17/16

NRC FORM 591M PART 1 (07-2012)

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
The Heart and Vascular Clinic 3251 S. Shawnee Drive Bedford, Indiana 47421-5277 REPORT NUMBER(S) 2016001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38425	13-32820-01	October 19, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02121	5	Robert T. Anger, Jr	(877) 321-2207

☑ Main Office Inspection Next Inspection Date: March 25, 2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a nuclear medicine clinic authorized by its NRC license to use unsealed byproduct material for diagnostic procedures under 10 CFR 35.100 and 35.200 at its facility in Bedford, IN. A local radiopharmacy delivered unit doses to the clinic for only heart diagnostic procedures. The clinic employed one full-time nuclear medicine technologist who staffed the department on Tuesdays, Wednesdays, and Thursdays. The licensee performed approximately 30 diagnostic studies per month. The clinic 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 department and hot lab to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The licensee demonstrated procedures for administering the material, surveys, spill cleanup, and receiving packages, as there were no patient injections to observe at the time of the inspection. 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 the storage of candy in the hot lab, as documented on Part 1 of this form.