

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Abbott Laboratories Abbott Diagnostic Division 200 Abbott Park Road Abbott Park, IL 60064</p> <p>REPORT NUMBER(S) 2018001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-38556</p>	<p>4. LICENSE NUMBER(S)</p> <p>12-24014-01E</p>	<p>5. DATE(S) OF INSPECTION</p> <p>March 28, 2018</p>
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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:


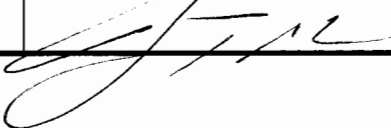
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Luis Nieves Folch		4/4/18
BRANCH CHIEF	Aaron T. McCraw		4/4/18

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03253	2. PRIORITY 5	3. LICENSEE CONTACT John Sarich	4. TELEPHONE NUMBER (224) 667-6100
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Main Office Inspection Next Inspection Date: March 28, 2023
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of an exempt distribution licensee that distributes a device called an Optical Module Validation Tool (OMVT), which is used as a (multi use) QC standard to test the optics of an instrument to test blood for blood borne diseases. There are two carbon-14 sources encapsulated in the matrix of the OMVT, giving an approximate total activity of 10 microcuries per device. On average, the licensee distributes around 6-10 devices each month and transfers no more than 1-2 devices at a time. The OMVTs have been distributed solely from the new Illinois location since July 2012. The OMVT are recieved from their Texas location and redistributed from their Illinois location. The OMVT are shipped to their costumers to be used by Abbott employees for the calibration of the equipment.

Performance Observations

Interviews with staff revealed an adequate level of understanding of the handling, packaging, labeling, and shipping procedures for the devices. The inspectors observed that the labels on the OMVT itself, and on the accompanying documents, contained all the required information. Additionally, the staff explained the ordering process for the devices, as well as their methods for maintaining records of each transfer with no issues identified. Independent measurements taken on the surface of the OMVT packages did not indicate any readings above background.

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

Nieves Folch, Luis

From: Nieves Folch, Luis
Sent: Wednesday, April 04, 2018 8:49 AM
To: 'Sarich, John S'
Subject: NRC Clear Report 591
Attachments: SKM_C45818040409440.pdf

Dear Mr. Sarich,

Attach is the clear 591 report for the inspection conducted on March 28, 2018, no further actions are required at this moment 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 message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
(630) 829-9571