

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Abbott Laboratories
Abbott Diagnostics Division
200 Abbott Park Road
Abbott Park, IL 60064

REPORT NUMBER(S) 2021001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-39221

4. LICENSE NUMBER(S)

12-24041-02E

5. DATE(S) OF INSPECTION

February 4, 2021

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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2021.02.09 15:21:25 -06'00'</small>	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.02.10 05:49:03 -06'00'</small>	



Materials Inspection Record

1. Licensee Name: Abbott Laboratories		2. Docket Number(s): 030-39221		3. License Number(s) 12-24014-02E	
4. Report Number(s): 2021001			5. Date(s) of Inspection: February 4, 2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 03253		8. Priority: 5	9. Inspection Guidance Used: 87126
10. Licensee Contact Name(s): Steven Ellingson		11. Licensee E-mail Address: Steven.ellingson@abbott.com		12. Licensee Telephone Number(s): (224) 668-0381	
13. Inspection Type: <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 02/04/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced remote initial inspection of an exempt distribution licensee that distributes a device called an Optical Module Validation Tool (OMVT), which is used as a counting standard to validate the operation of the optics system in the Abbott PRISIM system of an in-vitro immunoassay analyzer. Each OMVT tray contains two 5-microcurie carbon-14 sources, encapsulated in a solid scintillation matrix and bound into two separate reaction wells, giving an approximate total activity of 10 microcuries per tray. On average, the licensee distributes around 30 devices annually and transfers no more than 1-2 devices at a time. The OMVTs have been distributed solely from the Abbott Park, Illinois facility. The Irving, Texas facility receives the OMVT from the manufacturer, assigns standard values to each device, processes each device for final packaging and labeling, and ships it to the Illinois facility for distribution.

Performance Observations

This inspection was conducted virtually through Microsoft Teams and consisted of interviews with select licensee personnel, a review of select records, and an observation of security of the materials. The inspector had the staff described the package survey and receipt process. Interviews with staff revealed an adequate level of understanding of the handling, packaging, labeling, and shipping procedures for the devices. The inspector observed that the labels on the OMVT itself, and on the accompanying documents, contained all the required information. Additionally, the staff explained inventory tracking system, the ordering process for the devices, as well as their methods for maintaining records of each transfer with no issues identified. The inspector reviewed the annual materials transfer report dated January 28, 2021, that was submitted to the NRC.

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