

## SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

## 1. LICENSEE/LOCATION INSPECTED:

Covance Laboratories, Inc.

8211 Scicor Dr.  
Indianapolis, IN 46214

REPORT NUMBER(S) 2019001

## 2. NRC/REGIONAL OFFICE

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

## 3. DOCKET NUMBER(S)

030-37840

## 4. LICENSE NUMBER(S)

13-32713-01

## 5. DATE(S) OF INSPECTION

September 25, 2019

## 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	<i>Zahid Sulaiman</i>	9/25/19
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB <i>Geoffrey Warren for ATN</i>	<i>ATN</i>	10/15/19

**Docket File Information****SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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3. DOCKET NUMBER(S)  030-37840		4. LICENSE NUMBER(S)  13-32713-01	5. DATE(S) OF INSPECTION  September 25, 2019
6. INSPECTION PROCEDURES USED  87126		7. INSPECTION FOCUS AREAS  03.01 - 03.07	

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03611	2. PRIORITY  5	3. LICENSEE CONTACT  Brian Davidson, RSO	4. TELEPHONE NUMBER  (317) 273-5369
<input type="checkbox"/> Main Office Inspection      Next Inspection Date: 09/25/2024			
<input checked="" type="checkbox"/> Field Office Inspection    671 S. Meridian Rd, Greenfield, IN 46140			
<input type="checkbox"/> Temporary Job Site Inspection			

**PROGRAM SCOPE**

This was a routine, unannounced inspection of a Type B research and development license. The main office is located in Indianapolis, Indiana, and the research facility is located at the Greenfield, Indiana location. The radiation safety department was staffed with a full-time radiation safety officer (RSO) and a technologist. The licensee predominately used microcurie quantities of phosphorus-33 (P-33), carbon-14 (C-14), and tritium (H-3) for research and development. The RSO was authorized to approved users and laboratories for in-vitro and in-vivo research studies. The licensee has approximately 38 radioactive materials users. No radioactive materials studies has been performed since November, 2017.

The licensee has removed the self-shielded irradiator from its Greenfield, Indiana, location and transferred it to the manufacturer on December 19, 2017. The licensee also transferred five generally licensed nickel-63 sources in gas chromatographs to Eurofins Food Integrity and Innovation on August 7, 2018. The licensee was acquired by Lab Corp around October, 2015 and maintains the license name as Covance Laboratories, Inc.

**Performance Observations:**

The inspection consisted of interviews with selected licensee personnel, a review of selected records, and tours of research laboratories and waste storage facility. There was no active laboratory work being performed at the time of the inspection. The inspector had the staff demonstrate/discuss byproduct materials ordering, receiving, and check-in procedures, master inventory list and tracking of licensed materials, approval process of principal investigators and radioactive material users, security of materials, program audits, laboratory work with H-3 and C-14, laboratory surveys, and wipe tests performed by the radiation safety and the laboratory staff. The technologist described the radioactive waste collection process from the labs and transport to waste storage facility, and radioactive waste disposal to an authorized vendor. The last waste shipment of C-14 and H-3 was done on March 2019 to Bionomics Inc. The inspector reviewed the self-shield irradiator transfer document, with no issues noted.

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The inspector reviewed the following records: annual program audits, sealed source inventory and leak tests, radioactive materials inventory, radiation safety training, instrument calibration, and waste disposal. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector did not perform the 10 CFR Part 37 inspection. The inspector reviewed the licensee's 10 CFR Part 37 security-related corrective actions described in the licensee's letter dated May 11, 2015 for the violations reported on NRC Inspection Report 03037840/2015-001(DNMS). The licensee implemented its corrective actions as stated. These violations are closed.

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