

Docket File Information
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
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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
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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03611	2. PRIORITY 5	3. LICENSEE CONTACT Brian Davidson, RSO	4. TELEPHONE NUMBER (317) 273-5369
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Main Office Inspection Next Inspection Date: 09/25/2024

Field Office Inspection 671 S. Meridian Rd, Greenfield, IN 46140

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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2. NRC/REGIONAL OFFICE

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

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5. DATE(S) OF INSPECTION

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(Continued)

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.