

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Covance Laboratories 671 South Meridian Road Greenfield, Indiana 46140 REPORT NUMBER(S) 2010-01		2. NRC/REGIONAL OFFICE Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-37840		4. LICENSEE NUMBER(S) 13-32713-01	
5. DATE(S) OF INSPECTION January 19-20, 2010			

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, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

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	Geoffrey M. Warren		1/20/10

gms

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6. INSPECTION PROCEDURES USED 87122, 87126		7. INSPECTION FOCUS AREAS 03.01 – 03.07, 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03611	2. PRIORITY 5	3. LICENSEE CONTACT Brian Davidson, RSO, EH&S	4. TELEPHONE NUMBER 317-467-2607
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Main Office Inspection Next Inspection Date: January 2015

Field Office _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an initial inspection of activities performed under this license. The facility was previously authorized under NRC License Nos. 13-01133-02 and -04, but Covance Laboratories, Inc., purchased the facility and a new license for the facility was issued by NRC in January 2009.

Covance Laboratories was a research and development facility, with a Type B broad scope license. The radiation safety officer and a part-time technician provide radiation safety services. There are four authorized users and approximately 35-40 radiation workers at this facility, working in approximately 30 research laboratories approved for use of radioactive materials. Procedures include animal research. In addition, the licensee possesses a research irradiator used for irradiation of small animals. The primary isotopes included tritium, carbon-14, and iodine-125 as radioimmunoassay kits. The licensee disposed of wastes through decay in storage or incineration. When the new license was issued, licensee personnel re-approved all authorized users and radiation workers rather than relying on previous authorizations from the previous owner.

Performance Observations

The inspector observed an experiment using tritium in progress, and licensee personnel demonstrated package receipt surveys, laboratory surveys, and irradiator use. Licensee personnel described animal research protocols, tracking of radioactive materials and waste, incinerator use, and training procedures. The inspector noted no concerns with these practices. 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.