

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Corvame Central Laboratory Services, Inc.
Indianapolis, IN
REPORT NUMBER(S) *2008-001*

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

030-31150

4. LICENSEE NUMBER(S)

13-26058-01

5. DATE(S) OF INSPECTION

Dec. 11, 2008

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

Deborah A. Piskura

Deborah A. Piskura

12/11/2008

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Covance Central Laboratory Services, Inc. REPORT NUMBER(S) 2008-001		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road Lisle, IL 60532					
3. DOCKET NUMBER(S) 030-31150		4. LICENSE NUMBER(S) 13-26058-01		5. DATE(S) OF INSPECTION Dec. 11, 2008			
6. INSPECTION PROCEDURES USED 87126		7. INSPECTION FOCUS AREAS 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, and 03.07					
SUPPLEMENTAL INSPECTION INFORMATION							
1. PROGRAM 02410		2. PRIORITY E 5		3. LICENSEE CONTACT Daniel J. Hall, M.T., RSO		4. TELEPHONE NUMBER 317-271-1200	
<input checked="" type="checkbox"/> Main Office Inspection						Next Inspection Date: Dec. 2013	
<input type="checkbox"/> Field Office _____							
<input type="checkbox"/> Temporary Job Site _____							

PROGRAM SCOPE

Covance was a large testing service company involved clinical trials of medical products for pharmaceutical and biotechnology clients. The Indianapolis site employed 1,200 individuals, as well as 200 contractors; 10-15 individuals used RAM on a routine basis under the supervision of 6 authorized users. All licensed materials were used daily in two dedicated labs. RAM use was limited to in vitro studies using H-3 and I-125. The licensee retained the services of a consultant for health physics support, personnel training, program audits, etc.

This inspection consisted of a tour of the research labs, the radioactive waste storage areas and the material storage areas; review of selected records; interviews with licensee staff; observations of experiment set-ups and in-vitro testing in progress. NOTE to the next inspector: please refer to the attached policies to be followed at this site.

Covance Nature of Business and Associated Hazards

Covance is a biomedical laboratory that contains chemical, biological and radiation hazards. Under normal circumstances, the chemical and radiation hazards should not pose a problem. In the event of a chemical release of other emergency event, the host employee escorting you will inform you of what to do and where to go. Biological hazards are controlled through the use of universal precautions. If entering the universal precautions area (areas marked with a biohazard sign) you must adhere to all procedures as stated below and wear all appropriate protective equipment as described.

If you have further questions regarding the hazards associated with this facility, please contact the Environmental, Health and Safety Department through the security desk at ext. 7033.

General Safety Instructions:

1. All visitors must be escorted at all times by a Covance employee.
2. If an alarm sounds while in the building, exit the building following the exit signs and report to accumulation point 1 in the parking lot outside the front entrance. Security will account for visitors. Wait at accumulation point 1 until given further instructions by Covance emergency personnel.
3. Dial 4444 on an in house phone to report any emergency situation.

The following Universal Precautions guidelines have been adopted by Covance for the protection of visitors entering the laboratory or other areas where there may be exposure to potentially hazardous and/or infectious materials.

1. A fully buttoned laboratory coat will be worn while in any Universal Precautions area.
2. Visitors to the Universal Precautions area must wear safety glasses. They must also have closed toe footwear or wear protective shoe covers.
3. If there is any possibility of contact with specimens, instruments, reagents, etc. disposable gloves will be worn while conducting such activities.
4. No eating, drinking, smoking, applying of cosmetics, or personal items (bags, coats, etc.) will be permitted in the Universal Precautions area.
5. Instruments or objects will not be touched without permission obtained from the escorting employee.
6. Proper disposal of gloves and laboratory coats will be performed by the escorting employee.
7. Hands will be washed immediately after exiting the Universal Precautions area.

Covance strictly prohibits unauthorized photography and audio/video recording on its premises. Authority to take photographs or make recordings can only be granted by the Site Director. The possession of devices capable of photography and/or audio/video recording is prohibited in the Laboratories, Production, Computer Room, Warehouse, Archiving, and Auditing Conference Rooms. You are expected to check these prohibited items prior to entry into these restricted areas. Entry into these restricted areas provides Covance implied consent to scan you for these prohibited devices and to examine such devices if found. Prohibited items found will be confiscated and returned upon departure from the facility.

Date: 12/11/2008 Signature: [Signature] Company Name: USNRC

Title: Health Physicist Company Phone Number: (630) 829-9867

