Enclosure 6 – Inspection Record

Region Inspection Report No. 2010-001 License No. 13-26640-01

Docket No. 030-33820

Licensee (Name and Address): Covance Clinical Research Unit, Inc.
Global Clinical Pharmacology
Covance – Evansville
617 Oakley Street
Evansville, IN 47710

Location (Authorized Site) Being Inspected: One Waterfront Plaza
500 Ala Moana Boulevard, Suite 400
Honolulu, Hawaii

Licensee Contact: Robert Kochan, RSO Telephone No. 608-310-8268 Priority: 5

Program Code: 02201

Date of Last Inspection: 5/1/06 Date of This Inspection: 11/19/10

Type of Inspection: ( ) Initial ( ) Announced ( ) Unannounced (x) Routine ( ) Special

Next Inspection Date: 11/19/15 (x) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:
( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(x) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) (Name) Michelle M. Hammond Date 4/4/11
(Signature) Robert G. Hatton for

Inspector(s) (Name) Anthony D. Gaines Date 4/4/11
(Signature) Robert G. Hatton for

Approved (Name) Tamara E. Bloomer Date 4/11/11
(Signature) T E Bloomer

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT #	DATE	SUBJECT
10	5/2/07	Added location of use and authorized user
11	11/6/07	Added authorized user
12	5/1/08	Added 35.100, limited to C-14 & H-3, new location & user
13	7/18/08	Removed location of use
14	5/18/10	Added authorized users

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

No violations were identified during the last and only other inspection of the licensee.

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The licensee was authorized for uptake, dilution, and excretion studies using C-14 and H-3. The other NRC licensed location was in Evansville, Indiana. There was 1 authorized user in Honolulu, Hawaii.

The licensee was a contract research organization. Pharmaceutical companies hire the licensee to conduct clinical research trials on newly developed medications and new formulations of long-established medications. Authorized NRC activities include the use of unique populations to study metabolic functions using a capsule with a radiopharmaceutical (typically 1.35 µCi of C-14). The licensee maintained a very detailed and adequate radiation protection program to be in a state of readiness at the Evansville and Honolulu locations to accommodate clients requesting its service.

In 2010, a pharmaceutical company requested a study in Honolulu using a unique population. The RSO prepared the site for conducting the study, confirmed the client's authorization for shipping and receiving licensed material, and appropriate safety measures were in place. The training on radiation safety was up to date and included lectures, video and an i-learn module. Receipt of the licensed material was reviewed and found to be adequate.

Contrary to 10 CFR 30.36(d), between approximately January 2006 and August 2010, a period greater than 24 months, the licensee did not receive licensed material and it did not provide notification to the NRC in writing within 60 days of when no principal activities under the license had been conducted for a period of 24 months. The violation of 10 CFR 30.36(d) was categorized as minor. The cause of the violation is that the licensee was unaware of the requirement.

The planned study was cancelled. The licensee stored the licensed material without using it until early November 2010, when it accessed the stored material for disposal prior to the onsite inspection. Therefore, principal activities occurred in November 2010. As corrective action to prevent a similar violation, on March 29, 2011, the Radiation Safety Officer (RSO) committed to develop a procedure to ensure that actions are taken to comply with the requirements in 10 CFR 30.36(d) or request an extension of the notification time pursuant to 10 CFR 30.36(f).

The inspection consisted of a review of records and interviews of personnel including the authorized user, the site director, and the pharmacist. The licensee demonstrated knowledge in radiation protection, ALARA, occupational dose limits, training, survey techniques, and contamination thresholds.

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)
Inspection Procedure(s) Used: 87126
Focus Areas Evaluated: 02.01-02.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

None

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

See Item 1 above.

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Ted Broering, Vice President
Theresa Cummings, Site Director
Robert Kochan, RSO
Derek Kuniyoshi, Clinical Pharmacist
Thomas Murtaugh, M.D., Medical Director and Authorized User
Herman Scholtz, General Manager and Vice President of Clinical Pharmacology Services

Use the following identification symbols:
* Individual(s) who participated in the telephonic exit meeting on March 29, 2011