NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Covance Clinical Research Unit, Inc d/b/a Covance GFI Research 800 St. Mary's Drive Evansville, IN 47714 REPORT 2006-001	**UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352**

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-33820	13-26640-01	May 17, 2006

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		**Robert P. Hays**		5/17/06

NRC FORM 591M PART 3
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Covance Clinical Research Unit, Inc. REPORT NUMBER(S) **2006-001**	**Region III**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03033820	**13-26640-01**	**May 17, 2006**

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126	**03.01 - 03.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02410	**5**	**Kathleen Boehm, Sr. Mgr.**	**812/479-4255**

[X] Main Office Inspection — Next Inspection Date: **May 2011**

[ ] Field Office _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

The licensee is a clinical research entity authorized for any byproduct material identified in 10 CFR 35.100, limited to 150 millicuries of hydrogen-3 and carbon-14 for medical use in human research studies. The research involves the administration of carbon-14 and hydrogen-3 labeled investigative study drugs to research volunteers to determine the absorption, distribution, metabolism and excretion of the studied drug in humans. No licensed activities had been conducted since the previous inspection. Other medical research is ongoing as principle activites.

Performance Observations

During the inspection, the staff discussed protocols for: (1) surveys; (2) removable contamination surveys; (3) package receipt and handling; (4) waste handling; and (5) security of licensed material.