| NRC FORM 591M PART 1 U.S. NUCLEAR REGULATORY COMMISSION (07-2012) 10 CFR 2.201 SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------|------------------------------|--|--|--|--|
| 1. LICENSEE/LOCATIO                                                                                                                                                                                                                                                                                                                                                                                                                                              | ON INSPECTED:                                                                                                                 |                                            | 2. NRC/REGIONAL OFFICE                                                                               |                                                         |                              |  |  |  |  |
| Covance Clinical Research Unit, Inc.<br>Global Clinical Pharmacology<br>617 Oakley Street<br>Evansville, IN 47710                                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                                            | Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 |                                                         |                              |  |  |  |  |
| REPORT NUMBER(S                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 3) 2013-001                                                                                                                   |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
| 3. DOCKET NUMBER(S                                                                                                                                                                                                                                                                                                                                                                                                                                               | )                                                                                                                             | 4. LICENSE NUMBER(S)                       |                                                                                                      | 5. DATE(S) OF INSPECTION                                | N                            |  |  |  |  |
| 030-33820                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 030-33820                                                                                                                     |                                            | 13-26640-01                                                                                          |                                                         |                              |  |  |  |  |
| Regulatory Commiss                                                                                                                                                                                                                                                                                                                                                                                                                                               | n examination of the activities conduct<br>ion (NRC) rules and regulations and th<br>esentative records, interviews with pers | e conditions of you                        | r license. The inspection consist                                                                    | ed of selective examinatio                              | ns of                        |  |  |  |  |
| 1. Based on                                                                                                                                                                                                                                                                                                                                                                                                                                                      | the inspection findings, no violations v                                                                                      | vere identified.                           |                                                                                                      |                                                         |                              |  |  |  |  |
| 2. Previous                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Previous violation(s) closed.                                                                                                 |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
| non-repet                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Non-cited violation(s) were discussed involving the following requirement(s):                                                 |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
| cited in ac<br>with 10 C                                                                                                                                                                                                                                                                                                                                                                                                                                         | s and Corrective Actions)                                                                                                     | as described below<br>cy. This form is a N | OTICE OF VIOLATION, which m                                                                          | n of NRC requirements an<br>ay be subject to posting in | nd are being<br>n accordance |  |  |  |  |
| 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<br>REPRESENTATIVE                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                               |                                            |                                                                                                      |                                                         |                              |  |  |  |  |
| NRC INSPECTOR                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Bill C. Lin                                                                                                                   |                                            | Bill                                                                                                 | <del>-</del>                                            | 8/12/12                      |  |  |  |  |
| BRANCH CHIEF                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Aaron T. McCraw                                                                                                               |                                            | AT M                                                                                                 | /                                                       | 8 12/13                      |  |  |  |  |

NRC FORM 591M PART 1 (07-2012)

| NRC FORM 591M PART 3 U.S. NUCLEAR REGULATORY COMMISSION (07-2012) 10 CFR 2.201  SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION                                                                                                                                                                                                                                                                                                                                                                                         |                               |                     |                                                                                                               |                          |  |  |  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------|--------------------------|--|--|--|--|
| LICENSEE/LOCATION INSPECT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ED:                           |                     | 2. NRC/REGIONAL OFFICE                                                                                        |                          |  |  |  |  |
| Covance Clinical Research Unit, Inc. Global Clinical Pharmacology 617 Oakley Street Evansville, IN 47710  REPORT NUMBER(S) 2013-001                                                                                                                                                                                                                                                                                                                                                                                        |                               |                     | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |                          |  |  |  |  |
| 3. DOCKET NUMBER(S)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                               | 4. LICENSE NUMBER(S | S)                                                                                                            | 5. DATE(S) OF INSPECTION |  |  |  |  |
| 030-33820                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                               | 13-26640-01         |                                                                                                               | 08/02/2013               |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 6. INSPECTION PROCEDURES USED |                     | SAREAS                                                                                                        |                          |  |  |  |  |
| 87130 3.01-3.07 SUPPLEMENTAL INSPECTION INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                               |                     |                                                                                                               |                          |  |  |  |  |
| 1. PROGRAM CODE(S)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2. PRIORITY                   | 3. LICENSEE CONTAC  |                                                                                                               | 4. TELEPHONE NUMBER      |  |  |  |  |
| 03810                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3                             | Robert G. Kochan    |                                                                                                               | (608) 310-8268           |  |  |  |  |
| Field Office Inspection  Temporary Job Site Inspection                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                               |                     |                                                                                                               |                          |  |  |  |  |
| The licensee is a clinical research facility located in Evansville, Indiana. The licensee currently have a possession and storage in standby NRC Materials License only. The licensee currently does not possess any authorized license materials.                                                                                                                                                                                                                                                                         |                               |                     |                                                                                                               |                          |  |  |  |  |
| Inspection Scope                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                               |                     |                                                                                                               |                          |  |  |  |  |
| The inspector took a toured of the facility, interviewed licensee personnel, and took independent radiation surveys. The licensee currently does not possess any radioactive materials and does not planted on having any radioactive materials anytime in the near future. Licensee personnel is knowledgeable about NRC Regulations and the Conditions of NRC Materials License 13-26640-01. The inspector took independent surveys to confirmed that there are no radioactive materials within the licensee's facility. |                               |                     |                                                                                                               |                          |  |  |  |  |
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