NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Covance Central Laboratory Services, Inc. 8211 SciCor Drive Indianapolis, IN 46214 REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-31150	13-26058-01	April 5, 2018

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 violations(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, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

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	Dennis P. O'Dowd	Dennis P O'Dowd	04/05/18
BRANCH CHIEF	Aaron T. McCraw		4/20/18

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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030-31150	13-26058-01	April 5, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
86126	3.01-3.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02410	5	Brian Davidson, RSO	(317) 273-5369

☑ Main Office Inspection Next Inspection Date: April 5, 2023

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a laboratory testing service company authorized for millicurie quantities of iodine-25 (I-125), tritium (H-3), and carbon-14 (C-14), for use in benchtop testing to support medical trials of products for pharmaceutical clients. The licensee was a large company, employing around 1500 employees; however, only approximately 5 laboratory personnel were trained to use licensed material, and of these, only 2 actively used material on a regular basis. Licensed material was used in the Radioimmunoassay (RAI) Area located within a larger lab called the "Central Laboratory." The licensee used I-125 kits exclusively; H-3 had not been used in over 7 years, and as of the inspection date, C-14 had never been possessed or used by the licensee. Each I-125 kit contained about 4-5 μCi of I-125, and approximately 2 kits were utilized per week. The licensee only generated and stored solid waste for decay in storage, and had not used sanitary sewage for disposal since approximately 2012.

PERFORMANCE OBSERVATIONS

The inspector toured the RAI lab area, the waste storage room, and interviewed licensee staff. The inspector observed staff demonstrate package receipt procedures, the licensee's inventory tracking system, proper usage of radioactive material labels and postings, security of radioactive materials (i.e., I-125 kits were secured in a refrigerator designated for radioactive material), and staff demonstration of material handling and survey procedures. The inspector reviewed selected records, including quarterly audits, package receipt records, materials inventory, disposal logs, and weekly wipe tests and survey results.

The licensee was previously cited during a routine inspection conducted on August 14, 2013, (ref. IR 03031150/2013001 (DNMS)) for a violation of a regulatory requirement, specifically, for failure determine the presence or absence of radioactive contamination during and after the use of I-125 RIA kits, as required by the license (i.e., Condition 17 of the license (renumbered as Condition 15 in the current amendment), and application dated July 12, 2010, referenced in Condition 17). Through review of licensee's documentation, discussions with licensee staff, and observations of licensee's staff demonstrations of procedures followed during use of radioactive material, the inspector confirmed that the violation was corrected, and that the licensee's actions to prevent recurrence were effective in ensuring that no further violation of the survey requirement occurred. This violation is therefore considered closed.

No violations of NRC requirements were identified during this inspection.