



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

April 6, 2015

Mr. Steve Smith  
Associate Director, Environmental  
Health and Safety  
Covance Laboratories, Inc.  
671 South Meridian Road  
Greenfield, IN 46140

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03037840/2015001(DNMS) AND  
NOTICE OF VIOLATION – COVANCE LABORATORIES, INC.

Dear Mr. Smith:

On January 29 through 30, 2015, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Greenfield, Indiana, with continued in-office review through March 12, 2015. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The purpose of the in-office review was to examine elements of your access authorization and security program not available during the on-site inspection. Ms. Deborah Piskura of my staff conducted a preliminary exit meeting with you and other members of your staff on January 30, 2015, and a final telephonic exit meeting with Mr. Brian Davidson of you staff on March 12, 2015, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspection included a review of your corrective actions to violations cited during our January 19 through 20, 2010 inspection. The NRC considers these violations closed.

Based on the results of this inspection, the NRC has determined that six Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are of a security-related nature; details are available in Enclosure 2 (non-public).

Enclosures 1 and 2 contain Sensitive  
Unclassified Non-Safeguards Information.  
When separated from Enclosures 1 and 2,  
this transmittal letter decontrolled.

S. Smith

-2-

Immediate corrective actions for the violations have since been taken to restore compliance with NRC requirements. The violations are cited in the enclosed non-public Notice of Violation (Notice) (Enclosure 1). The NRC is citing the violations in the Notice because the inspector identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. Enclosures 1 and 2 contain security-related information and their disclosure to unauthorized individuals could present a security vulnerability; therefore, Enclosures 1 and 2 and your response to the Notice will not be made available electronically for public inspection. Please mark the top of each page of your response "Security-Related Information – Withhold under 10 CFR 2.390." To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

*/RA/*

Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-37840  
License No. 13-32713-01

Enclosures:

1. Notice of Violation (Non-public)
2. IR No. 03037840/2015001(DNMS) (Non-public)

cc w/encls: Brian Davidson, Radiation Safety Officer  
cc w/o encls: State of Indiana

~~OFFICIAL USE ONLY – SECURITY RELATED INFORMATION~~

S. Smith

-2-

Immediate corrective actions for the violations have since been taken to restore compliance with NRC requirements. The violations are cited in the enclosed non-public Notice of Violation (Notice) (Enclosure 1). The NRC is citing the violations in the Notice because the inspector identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at: <http://www.nrc.gov/reading-rm/adams.html>. Enclosures 1 and 2 contain security-related information and their disclosure to unauthorized individuals could present a security vulnerability; therefore, Enclosures 1 and 2 and your response to the Notice will not be made available electronically for public inspection. Please mark the top of each page of your response "Security-Related Information – Withhold under 10 CFR 2.390." To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,  
*/RA/*  
Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-37840  
License No. 13-32713-01

Enclosures:

- 1. Notice of Violation (Non-public)
- 2. IR No. 03037840/2015001(DNMS) (Non-public)

cc w/encls: Brian Davidson, Radiation Safety Officer  
cc w/o encls: State of Indiana

DISTRIBUTION:

See next page

ADAMS Accession Number: ML15098A092

Publicly Available       Non-Publicly Available       Sensitive       Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" Copy without attach/encl "E" Copy with attach/encl "N" No copy

OFFICE	RIII DNMS	RIII DNMS				
NAME	DPiskura:rj AM for	AMcCraw AM				
DATE	04/06/2015	04/06/2015				

OFFICIAL RECORD COPY

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~

Letter to Steve Smith from Aaron McCraw, dated April 6, 2015

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03037840/2015001(DNMS) AND  
NOTICE OF VIOLATION – COVANCE LABORATORIES, INC.

DISTRIBUTION w/encl:

Darrell Roberts  
Patrick Loudon  
Julio Lara  
Richard Skokowski  
Paul Pealke  
Carole Ariano  
Jim Clay  
Carmen Olteanu  
MIB Inspectors

~~OFFICIAL USE ONLY – SECURITY-RELATED INFORMATION~~