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May 4, 2010

EA-10-010

Mr. Mark S. Rund
Associate Director of Environmental, Health and Safety
Covance Laboratories, Inc.
671 South Meridian Road
Greenfield, IN 46140-5006

SUBJECT: NOTICE OF VIOLATION – COVANCE LABORATORIES, INC.
NRC INSPECTION REPORT NO. 03037840/2010-002(DNMS)

Dear Mr. Rund:

This refers to the inspection conducted on January 19 and 20, 2010, at the Covance Laboratories, Inc., facility in Greenfield, Indiana. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements. During the inspection, an apparent security violation of NRC requirements was identified by the NRC inspector. Details regarding the apparent violation were provided in NRC Inspection Report No. 03037840/2010-002(DNMS) dated February 18, 2010.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. In a letter dated March 15, 2010, you provided a response to the apparent violation and the other cited violations. You disagreed with the apparent violation, and you disputed two of the three cited violations. We are evaluating the information you provided and we will address the disputed violations when we complete our evaluation.

Based on the information developed during the inspection and the information that you provided in your March 15, 2010, response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding it are described in detail in our inspection report dated February 18, 2010. In determining this violation, we evaluated the information that you provided in your March 15, 2010, letter and have provided that evaluation in Enclosure 2.

The violation is of concern to the NRC for the reasons stated in Enclosure 2. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is normally considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions, the NRC considered whether credit

The Enclosures Contain Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is decontrolled.
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M. Rund

-2-

was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy. In your letter dated March 15, 2010, you outlined the corrective action that your staff had taken to correct the violation, which is also described in Enclosure 2. Based on your corrective action, the NRC has determined that *Corrective Action* credit is warranted.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective action taken and planned to correct the violation and to prevent recurrence, and the date when full compliance was achieved, was adequately addressed on the docket in the inspection report dated February 18, 2010, and in your reply dated March 15, 2010. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective action or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. Additionally, if you choose to respond, please mark your entire response “Security-Related Information – Withhold from Public Disclosure under 10 CFR 2.390.” In accordance with Title 10 of the Code of Federal Regulations (10 CFR) 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for any response to this letter. However, to the extent possible, a response should not include any personal privacy, proprietary, or safeguards information.

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 Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, because of the Security-Related Information contained in the enclosures, and in accordance with 10 CFR 2.390, copies of this letter's enclosures will not be available for public inspection.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

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

Enclosures:

1. Notice of Violation (Non-Public)
2. Final Determination of Significance (Non-Public)

cc w/encls: State of Indiana

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*See previous concurrence

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NAME	Gryglak*	Bloomer*	Reynolds	Day for Zimmerman ¹	Orth	Pederson for Satorius
DATE	04/27/10	04/28/10	04/30/10	04/26/10	05/03/10	05/04/10

OFFICIAL RECORD COPY

¹. OE concurrence received via e-mail from K. Day on April 26, 2010.

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Letter to Mark S. Rund from Mark A. Satorius dated May 4, 2010

SUBJECT: NOTICE OF VIOLATION – COVANCE LABORATORIES, INC.;
NRC INSPECTION REPORT NO. 03037840/2010-002(DNMS)

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