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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 30, 2018

Segaran Pillai, Ph.D.
Director, Office of Laboratory Science
and Safety
Office of the Commissioner,
Department of Health and Human Services
U.S. Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

SUBJECT: NRC INSPECTION REPORT NO. 03031689/2018001, U.S. FOOD AND DRUG
ADMINISTRATION, SILVER SPRING, MARYLAND, AND NOTICE OF
VIOLATION

Dear Dr. Pillai:

On February 27 and 28, 2018, inspectors from the Nuclear Regulatory Commission (NRC) commenced a safety and security inspection at the above address and at the U.S. Food and Drug Administration located at the White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, Maryland. The inspection was an examination of your licensed activities as they relate to radiation safety, security, and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection on February 28, 2018.

Based on the results of this inspection, the NRC has determined that two violations of NRC requirements occurred. Because of the security-related nature of these violations, specific details of the violations will not be provided in this letter, but instead are provided in non-public enclosures. The violations were evaluated in accordance with the NRC Enforcement Policy which can be found at the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html> The Notice of Violation (Notice), is provided as Enclosure 1 to this letter. The violations are cited because the violations were identified by the NRC. Enclosure 2 provides a determination of severity level and description of the corrective actions taken by U.S. Food and Drug Administration to address the violations.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed in our records. Therefore, you are not required to respond to this letter unless the description of your corrective actions in enclosure 2 does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

The enclosures contain Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is DECONTROLLED.

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S. Pillai

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The Enclosed Notice contains Security-Related Information under 10 CFR 2.390(d)(1), and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agency-wide Document Access and Management System (ADAMS), accessible from the NRC Web site at <http://nrc.gov/reading-rm/adams.html>.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's Web Site at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

If you have any questions regarding this matter, please contact James Cassata of my staff at (610) 337-5303 or via electronic mail at james.cassata@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Arthur L. Burritt, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03031689
License No. 19-07538-05

Enclosures:

1. Notice of Violation (Non-Public)
2. Determination of Severity Level
and Description of Corrective
Actions (Non-Public)

cc w/encls: CAPT Michael A. Noska, RSO

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