



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

February 15, 2017

Docket No. 03008478

License No. 19-00296-17

Dr. Alfred Johnson
Acting Director, Office of Management
Department of Health and Human Services
National Institutes of Health
21 Wilson Drive MSC 6780
Bethesda, MD 20892-6780

SUBJECT: NRC INSPECTION REPORT NO. 03008478/2016002, DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND AND THE BAYVIEW BUILDING, BALTIMORE, MARYLAND, SITE

Dear Dr. Johnson:

On August 9-10, Randolph Ragland and John Miller of this office commenced an inspection at your Bethesda facility. On September 12, 2016, Mr. Ragland continued the inspection at your Bayview facility in Baltimore, MD. This inspection continued in-office until February 6, 2017. The inspection was limited to a review of your irradiator security program and your implementation of the new 10 CFR 37 requirements. The findings were discussed with you, Catherine Ribaud, Radiation Safety Officer, and others of your organization, by telephone, on February 6, 2017, at the conclusion of the inspection.

We determined that you implemented the 10 CFR 37 requirements and maintained close oversight of your irradiator safety and security programs. However, we also noted that since 2012, you documented in your corrective action program seven security-related violations of NRC requirements.

These violations were evaluated in accordance with the NRC Enforcement Policy. Based on a review of the circumstances, we determined that each of these violations had a low security significance. Because each of these examples shared common causal factors, the seven examples are being characterized as a single, Severity Level IV problem.

Further, consistent with Section 2.3.2 of NRC's Enforcement Policy, this violation (problem) is being treated as a non-cited violation, because: 1) NIH identified the violation and corrected the violation within a reasonable period of time; 2) the violation was neither willful nor repetitive as a result of inadequate corrective action; and 3) the violation was categorized at Severity Level IV.

**Enclosure contains Sensitive Unclassified
Non-Safeguards Information. Upon separation,
this cover letter is decontrolled.**

A. Johnson

2

Because of the security-related nature of the violation, the characterization will not be provided in this letter, but instead in a non-public Enclosure to this letter.

Although you took appropriate and prompt corrective and preventative actions to address each example, we noted that they shared common causal factors. Therefore, the NRC believes that it would be prudent for NIH to conduct an additional review to evaluate the effectiveness of your corrective action program.

During our inspection exit meeting on February 6, 2017, you indicated that you agreed with the NRC's assessment. You emphasized that you have taken corrective and preventative actions to address each example and that NIH is committed to radiation safety and security and to compliance with NRC regulations and licensed conditions. Further, you stated that you believe that you could benefit from conducting a review of the effectiveness of your corrective action program related to security events and that you will plan to complete this review by March 31, 2017.

The NRC has concluded that information regarding the reason for the violation (problem), the corrective actions taken and planned to correct the violation 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 which appears in an Enclosure to this letter, does not accurately reflect your actions or your position.

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 located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agency wide Documents Access and Management System (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosure will not be made available electronically for public inspection in the NRC Public Document Room or from ADAMS. If Security-Related Information is necessary to provide an acceptable response, if you choose to submit one, 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. In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

Current NRC regulations and guidance are included on the NRC's website 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. 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).

A. Johnson

3

Please contact Randolph Ragland at 610-337-5083 if you have any questions regarding this matter.

Sincerely,

/RA/

Blake D. Welling, Chief
Commercial, Industrial, R&D and
Academic Branch
Division of Nuclear Materials Safety

Enclosure:
Determination of Severity Level
and Description of Corrective
Actions

cc w/Encl: State of Maryland

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A. Johnson

3

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DATE	02/08/17		02/08/17		02/15/17			

*see previous concurrence

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