



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 22, 2023

EA-23-045

COL Chad Koenig, Commander
Walter Reed Army Institute of Research
503 Robert Grant Avenue
Silver Spring, Maryland 20910

SUBJECT: WALTER REED ARMY INSTITUTE OF RESEARCH (WRAIR) - NRC
INSPECTION REPORT NO. 030-38997/2023001

Dear COL Koenig:

This letter refers to the Nuclear Regulatory Commission's (NRC) inspection conducted on February 27, 2023, at the Walter Reed Army Institute of Research (WRAIR) facility in Silver Spring, Maryland. This inspection examined activities as they relate to public health and safety and to confirm compliance with the NRC's rules and regulations. Within these areas, the inspection consisted of a selected examination of representative records, interviews with personnel, and direct observations. The inspection included in-office reviews through June 2, 2023. A final telephonic exit briefing was conducted with you on June 2, 2023.

Based on the results of the inspection, apparent violations were identified that are being considered for escalated enforcement action 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; therefore, details of the violations as well as corrective actions that have since been taken to restore compliance with regulatory requirements, are discussed in the non-public Enclosure 2.

The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during the inspection exit meeting on June 2, 2023. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we request that you discuss the apparent violations addressed in this inspection report at a Pre-decisional Enforcement Conference (PEC). The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. Rather, due to the complex nature and number of apparent violations, a PEC is warranted to obtain information to assist the NRC in making an enforcement decision. Topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference will include an opportunity for you to provide your

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perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. Following the PEC, you will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations, other than to arrange the PEC, is required at this time.

In lieu of the PEC, you may choose to request Alternate Dispute Resolution (ADR) mediation with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of receipt of this letter if you are interested in pursuing resolution of this issue through ADR.**

A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter. The PEC or the ADR session will be closed to public observation because they would involve Security-Related Information. However, the time and date of the PEC or ADR session will be publicly announced. Please contact Christopher Cahill at (610) 337-5108 or via email at Christopher.Cahill@nrc.gov within **10 days** of the date of this letter to schedule the PEC or request ADR. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information as described above. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

C. Koenig

3

If you have any questions concerning this matter, please contact Randolph Ragland of my staff at (610) 337-5083, or via electronic mail at Randolph.Ragland@nrc.gov.

Thank you for your cooperation.

Sincerely,

Paul G. Krohn, Director
Division of Radiological Safety and Security

Docket No. 03038997
License No. 19-35377-01

Enclosures:

1. Safety Inspection No. 03038997/2023001 (Publicly Available)
2. Security Inspection Addendum with attachment (Non-Publicly Available)
3. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action" (Attached to Security Enclosure)

C. Koenig

SUBJECT: WALTER REED ARMY INSTITUTE OF RESEARCH (WRAIR) - NRC
INSPECTION REPORT NO. 030-38997/2023001 DATED JUNE 22, 2023

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Enforcement Coordinators

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Non-Public Designation Category: MD 3.4 Non-Public A.3

Public: ADAMS ACCESSION NO. ML23172A068

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EXECUTIVE SUMMARY

Walter Reed Army Institute of Research
NRC Inspection Report No. 03038997/2020001

The Walter Reed Army Institute of Research (WRAIR) is authorized to perform research using unsealed tritium and carbon-14 radioactive materials, sealed calibration reference sources, and two self-shielded irradiators: one containing cesium-137 and one containing cobalt-60. Research using unsealed materials has dropped significantly and currently they do not have any active research using unsealed materials. WRAIR uses the self-shielded irradiators several times per month.

As a result of the inspection, no violations of safety requirements were identified. However, apparent violations of security requirements were identified and are being considered for escalated enforcement action. The circumstances of these violations, as well as preliminary and proposed corrective actions are discussed in the non-public Security Addendum to this report.

ENCLOSURE 1: INSPECTION REPORT

REPORT DETAILS

1. **Organization and Scope of the Program**

a. Inspection Scope

The inspectors reviewed the organization and scope of the licensee's research and development (R&D) program. Information was collected through a tour of the facility, surveys of laboratories, interviews with individuals involved in the radiation safety program, and a review of records.

b. Observations and Findings

The WRAIR is authorized to possess and use two self-shielded irradiators as well as unsealed radioactive materials for R&D purposes. It is also approved to use sealed radioactive material for equipment calibration. Research using unsealed materials declined significantly with no active research occurring at the time of the inspection. The licensee received a clear NRC inspection in November 2017. Licensed activities are scheduled to be overtaken by the Defense Health Agency in October 2023.

Prior to the inspection, the WRAIR Radiation Safety Officer (RSO) notified the inspector that he was leaving his position at WRAIR to start a new position as the RSO at the Naval Surface Warfare, Carderock; which is part of the Navy's Master Materials License (MML), issued by the NRC. However, he committed to oversee licensed activities at WRAIR as long as his current management will allow. The RSO was present onsite to facilitate the inspection. He continues to be available to the licensee and NRC, despite officially leaving employment on February 12, 2023.

2. **Material Receipt, Use, Transfer, and Control**

a. Inspection Scope

The inspectors reviewed material receipt, use, transfer, and control activities under the licensee's radiation safety program. Parameters were evaluated based upon observations made during the facility tour, interviews, and records review.

b. Observations and Findings

Research activities using unsealed material experienced a marked decline since the 2017 inspection due to primary investigator retirements and a lack of interest in initiating new research using unsealed isotopes. Radiation surveys conducted during the inspection revealed no areas of contamination in laboratories or the waste storage area.

Self-shielded irradiator use continues several times per month for research involving small animals and viruses. Both irradiators were well-maintained and functioning

properly at the time of inspection. Postings in this area were appropriate and displayed in a conspicuous manner.

Record Review

Program oversight is provided by the RSO and was supplemented by a third party independent audit of the overall program. Physical inventories, leak tests, program audits, survey meter calibration, safety training and laboratory surveys were completed at required frequencies and adequate documentation is maintained for inspection. WRAIR no longer monitors personnel for radiation exposure per the established history of low doses to workers in its prospective evaluation.

c. Conclusions

No violations of the NRC regulations were identified during the health and safety inspection.

3. Exit Meeting

On February 27, 2023, the inspectors conducted a debrief with WRAIR at the conclusion of the onsite inspection. Preliminary inspection findings were discussed and acknowledged by the licensee. Subsequent meetings were held to discuss additional concerns and violations documented in the security addendum listed below, on March 13, 2023, and April 7, 2023, respectively. A final inspection exit meeting was conducted by telephone on June 2, 2023.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

* Individuals present at onsite inspection debrief February 27, 2023

+ Individuals present for telephonic exit meeting on June 2, 2023

- *+ COL Chad Koenig, Commander
- *+ Jacob Oberstein, Radiation Safety Officer
- + Justin Garcia, Director of Operations and Security
- + Kenneth Walters
- Yun Fan, Director, Resource Management
- * Joshua Soderberg

INSPECTION PROCEDURES USED

IP 87141, Limited Scope Academic & Research & Development Programs

IP 87137, 10 CFR Part 37 Materials Security Programs

LIST OF ACRONYMS USED

ADR	Alternate Dispute Resolution
AFRRI	Armed Forces Radiobiology Research Institute
CFR	Code of Federal Regulations
LLEA	Local Law Enforcement Agency
MML	Master Materials License
NMRC	Naval Medical Research Command
NRC	Nuclear Regulatory Commission
OPM	Office of Personnel Management
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer
R&D	Research and Development
RO	Reviewing Official
WRAIR	Walter Reed Army Institute of Research
T&R	Trustworthy and Reliable