



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION I  
475 ALLENDALE RD, SUITE 102  
KING OF PRUSSIA, PA 19406-2713

October 5, 2022

IA-22-026

Dr. William Regits  
HOME ADDRESS DELETED  
UNDER 10 CFR 2.390

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT 1-2022-001 AND NOTICE OF VIOLATION

Dear Dr. Regits:

This letter refers to the investigation initiated on October 6, 2021, by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Investigations (OI) and conducted at the U.S. Department of Commerce – National Institute of Standards and Technology (NIST). The investigation, which was completed on December 22, 2021, was conducted, in part, to evaluate whether you, as a designated Source Custodian under contract with NIST, caused NIST to violate its NRC license by deliberately failing to comply with licensee procedures for responding to a release of radioactivity.

In a letter dated June 27, 2022 (ML22115A167), the NRC provided you with a factual summary of the OI report and offered you the opportunity to address the apparent violation described in the letter by either attending a pre-decisional enforcement conference (PEC) or providing a written response before we made our final enforcement decision. On August 10, 2022, a predecisional enforcement conference (PEC) was conducted with you to discuss the apparent violation, its significance, the root cause, and your corrective actions. During the conference, you stated that you are no longer working at NIST and that you will not again work under a broad scope license.

Based on the information developed during the investigation and shared during the August PEC, the NRC has determined that a deliberate violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1).

The violation involves your deliberate failure to comply with Safety Evaluation SE-0010, "Preparation and Calibration of SRMs Measurement Assurance Program for the Radiopharmaceutical Industry," which is a work instruction for Source Custodians that is required by NIST's NRC license. The section "Emergency Procedures" states, in part, that if there is a release of radioactivity, evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact Gaithersburg Radiation Safety Division (GRSD). Contrary to this requirement, on September 22, 2021, during the preparation of short-lived radioactive standards, you identified a release of radioactive material, but you did not evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact GRSD. Rather, you deliberately attempted to decontaminate yourself, the equipment, and lab facilities.

Your deliberate actions placed NIST in violation of License Condition 10 of NRC License No. SNM-362, Amendment 11, which states, in part, that the authorized use for materials is in accordance with statements, representations, and conditions of the licensee's renewal

application dated June 29, 2007. The renewal application states, in part, that Source Custodians shall maintain control over source utilization and ensure work is done in compliance with appropriate protocols, instructions, and safe handling practices. The NIST procedure Safety Evaluation SE-0010, "Preparation and Calibration of SRMs Measurement Assurance Program for the Radiopharmaceutical Industry," requires that if there is a release of radioactivity, evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact GRSD. Enclosure 2 includes a copy of the letter and Notice of Violation issued to NIST.

Your deliberate actions also placed you in violation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30.10, "Deliberate Misconduct." Given the significance of the underlying issue and the deliberate nature of your actions, your violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In determining the appropriate sanction to be issued in this case, the NRC considered issuing an Order prohibiting your involvement in NRC-licensed activities as a result of your actions. However, after consultation with the Director, Office of Enforcement, and after considering the circumstances of this case, including: (1) the actual safety significance was low; and (2) NIST took action regarding your wrongdoing, including terminating your contract, I have decided to issue the enclosed Notice of Violation (Notice, Enclosure 1). You should be aware that if you are involved in NRC-licensed activities in the future, additional deliberate violations could result in more significant enforcement action or referral to the U.S. Department of Justice for potential criminal prosecution.

Because you are no longer employed by NIST, and in consideration of the information you provided during the August 10, 2022, PEC, you are not required to respond to the Notice of Violation. If you disagree with this enforcement sanction, you may deny the violation within 30 days of the date of this letter as described in the Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and 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>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

All final NRC documents, such as the OI report described above, are official agency records and may be made available to the public under the Freedom of Information Act (FOIA) subject to redaction of information appropriate under the FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, Requests for Records. Additional information is available on the NRC website at <http://www.nrc.gov/reading-rm/foia/foia-privacy.html>.

The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>. In addition, your privacy information related to this letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." This system, which is not publicly accessible, includes all records pertaining to individuals who are being, or have been, considered for enforcement action, whether such action was taken or not. Detailed information about this system of records, including the NRC-3 system notice, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Dr. W. Regits

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Please feel free to contact Marjorie McLaughlin of my staff at 610-337-5240 or [Marjorie.mclaughlin@nrc.gov](mailto:Marjorie.mclaughlin@nrc.gov) if you have any questions.

Sincerely,

David C. Lew  
Regional Administrator

Enclosures:

1. Notice of Violation to Dr. Regits
2. Notice of Violation to NIST

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT 1-2022-001 AND NOTICE OF VIOLATION DATED

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OFFICE					R1/DRSS	RA
NAME					B Welling	D Lew
DATE					9/30/22	10/05/22

ENCLOSURE 1  
NOTICE OF VIOLATION

Dr. William Regits  
[HOME ADDRESS DELETED  
UNDER 10 CFR 2.390]

IA-22-026

During an NRC investigation conducted between October 6, 2021, and December 22, 2021, the NRC identified a violation of NRC requirements. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.10 states, in part, that any employee of a contractor or subcontractor of any licensee, may not engage in deliberate misconduct that causes a licensee to be in violation of any term, condition, or limitation of any license issued by the Commission.

License Condition 10 of Amendment 11 to License Number SNM-362 states, in part, that the authorized use for materials is in accordance with statements, representations, and conditions of the licensee's renewal application dated June 29, 2007.

The renewal application for License Number SNM-362 dated June 29, 2007, states, in part, that Source Custodians shall maintain control over source utilization and ensure work is done in compliance with appropriate protocols, instructions, and safe handling practices.

Safety Evaluation SE-0010, "Preparation and Calibration of SRMs Measurement Assurance Program for the Radiopharmaceutical Industry," is the work instruction for preparation and calibration of short-lived radioactive standards in support of the NIST Radioactivity Measurements Assurance Program (NRMAP). The section "Emergency Procedures" states, in part, that if there is a release of radioactivity, evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact Gaithersburg Radiation Safety Division (GRSD).

Contrary to the above, on September 22, 2021, you engaged in deliberate misconduct that caused the licensee to be in violation of a condition of its license when you did not use materials in accordance with statements, representations, and conditions of the licensee's renewal application dated June 29, 2007. Specifically, as a Source Custodian working under contract to NIST, you did not ensure work was done in compliance with appropriate instructions. During the preparation of short-lived radioactive standards in support of the NRMAP, there was a release of radioactivity, but you did not evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact GRSD. Rather, you deliberately attempted to decontaminate yourself, the equipment, and lab facilities to avoid disruption to your work activities by GRSD.

This is a Severity Level III violation (NRC Enforcement Policy Section 2.2.1.d).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 07000398/2021003, and in the letter forwarding this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that

case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (IA-22-026)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Document Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Your privacy information related to this letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, Enforcement Actions Against Individuals. This system, which is not publicly accessible, includes all records pertaining to individuals who are being or have been considered for enforcement action, whether such action was taken or not. Detailed information about this system of records, including the NRC-3 system notice, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Dated this 5<sup>th</sup> day of October, 2022.

ENCLOSURE 2

NOTICE OF VIOLATION TO NIST