



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

December 11, 2025

EAF-RI-2025-0097

Roland Owens, Ph.D.
Acting Deputy Director for Intramural Research
Department of Health & Human Services
National Institutes of Health
21 Wilson Drive, MSC 6780
Bethesda, MD 20892-6780

**SUBJECT: NOTICE OF VIOLATION - DEPARTMENT OF HEALTH & HUMAN
SERVICES (HHS), NATIONAL INSTITUTES OF HEALTH (NIH) -
INSPECTION REPORT NO. 030-37773/2025001**

Dear Dr. Owens:

This letter refers to our in-office inspection initiated on January 23, 2025, conducted on-site at your Bethesda, Maryland facility on February 7, 2025, and continued with further in-office review until September 4, 2025. The inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC) rules and regulations and with the conditions of your license. Based on the results of this review, the NRC identified one apparent violation (AV) involving NIH's operation of a cyclotron in a manner that was outside of the operating conditions described in the licensee's application, dated September 24, 2014 ([ML14280A513](#)¹).

NRC staff discussed the AV with Dr. Jessica McCormick-Ell, Director, Division of Safety, Commander Alfredo Sancho, Program Manager in Office of Intramural Research, Teresa Fisher, RSO, and others during a telephonic exit meeting on September 4, 2025, and described the AV in NRC Inspection Report No.: 030-37773/2025001 that was issued on September 30, 2025 ([ML25232A164](#)). In the letter transmitting the inspection report and AV, we provided you with the opportunity to address the AV identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated October 22, 2025 ([ML25297A285](#)), you provided a written response in which you acknowledged the details of the AV and described your corrective actions, as further discussed below.

¹ NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this letter may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end: <https://www.nrc.gov/docs/ML>

The NRC staff considered the information you provided in your response, as well as the information developed during the inspection, and determined that a violation of NRC requirements has occurred. The violation is cited in the enclosed Notice of Violation (Notice). The violation involved NIH's failure to comply with license condition 18A of NRC License No. 19-00926-21, Amendment 11, dated January 2, 2024, which requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 24, 2014. The application dated September 24, 2014, describes, in part, the facilities and equipment that are needed to safely work with licensed material. Specifically, Item 9, "Facilities and Equipment," states, in part, that the licensee's cyclotron vaults "are safeguarded with interlocks that prevent operation of the cyclotron while the vault door is open" and that the interlock systems are designed to prevent individuals from experiencing potentially high exposure rates while the cyclotrons are running. However, on January 23, 2025, NIH disabled the vault interlock system and operated the cyclotron with the door open [approximately 24 inches]. The NRC considered this violation to be significant because NIH failed to conduct its program in accordance with the statements, representations, and procedures contained in the application when they disabled the designed interlock system and operated the cyclotron with the vault door open, a significant safety concern that could have had radiological or programmatic significance. Therefore, this violation has been characterized in accordance with the NRC Enforcement Policy at Severity Level III (SL III).

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9,000 is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement action within the last two inspections, the NRC considered whether credit was warranted for *corrective action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC staff determined that credit for corrective action is warranted. Specifically, you ceased the test and restored the interlock, and you revised your cyclotron license renewal application to include explicit language regarding changes to operations including a clear statement that any operation of the cyclotron outside of normal operations requires prior notification and approval by the NRC; provided targeted and mandatory refresher training on the requirement to contact the NRC prior to implementing programmatic or procedure changes that differ from what is stated in your NRC licenses; and developed a work safety plan process to evaluate and document procedures that fall outside of standard operating parameters and determine the approvals required to proceed.

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

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 030-37773/2025001 and in your letter dated October 22, 2025. Therefore, you are not required to respond to this letter unless the description therein 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.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, should you

choose to provide one, 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 website 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, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>

If you have any questions concerning this matter, please contact Monica Ford of my staff at (610) 337-5214 or Monica.Ford@nrc.gov.

Sincerely,



Daniel S. Collins
Acting Regional Administrator

Docket No. 030-37773
License No. 19-00296-21

Enclosure: Notice of Violation

cc w/Encl:
Teresa Fisher, Radiation Safety Officer
Dr. Liza Lidenberg, Chair, NIH Radiation
Safety Committee

SUBJECT: NOTICE OF VIOLATION - DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS), NATIONAL INSTITUTES OF HEALTH (NIH) - INSPECTION REPORT NO. 030-37773/2025001

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NOTICE OF VIOLATION

National Institutes of Health
Bethesda, MD

Docket No.: 030-37773
License No.: 19-00296-21
EAF-RI-2025-0097

During an NRC inspection conducted between January 23, 2025, and September 4, 2025, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License condition 18A of NRC License No. 19-00926-21, Amendment 11, dated January 2, 2024, requires in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 24, 2014. The application dated September 24, 2014, describes in part the facilities and equipment that are needed to safely work with licensed material. Item 9, "Facilities and Equipment," states in part that the licensee's cyclotron vaults "are safeguarded with interlocks that prevent operation of the cyclotron while the vault door is open" and that the interlock systems are designed to prevent individuals from experiencing potentially high exposure rates while the cyclotrons are running.

Contrary to the above, on January 23, 2025, NIH failed to conduct its program in accordance with the statements, representations, and procedures contained in the application dated September 24, 2014. Specifically, although the application represents that the cyclotron was designed and constructed with an interlock system that only allows operation when the vault door is shut, NIH disabled the vault interlock system and operated the cyclotron with the door open [approximately 24 inches].

This is a Severity Level III violation (Enforcement Policy 6.3.c.11)

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 will be achieved, is already adequately addressed on the docket in your letter dated October 22, 2025. Therefore, you are not required to respond to this Notice of Violation (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, (EAF-RI-2025-0097)," 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 Rd., Suite 102, King of Prussia, PA 19406 within 30 days of the date of the letter transmitting this 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. If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 11th day of December, 2025