



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

April 2, 2024

EA-23-142

Michael A. Levy, R.Ph.  
Radiation Safety Officer  
Ionetix Alpha Corporation  
6424 Westland Way  
Lansing, MI 48917

SUBJECT: NOTICE OF VIOLATION; NRC INITIAL INSPECTION REPORT NO.  
03039318/2023001 (DRSS) – IONETIX ALPHA CORPORATION

Dear Michael Levy:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 17, 2023, through January 22, 2024, at your Lansing, Michigan facility. The purpose of the inspection was to review activities performed under your NRC license to ensure activities were being performed in accordance with NRC requirements. During the inspection, two apparent violations of NRC requirements were identified. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during a telephone exit meeting on January 22, 2024. Inspection Report No. 03039318/2023001 (DRSS) was issued on January 31, 2024, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML24024A134. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated February 13, 2024, you provided a written response to the apparent violations (ML24045A049).

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated, February 13, 2024, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The first violation (Violation A) involved, on April 6, 2023, the failure to follow your license, which requires, that safety interlocks and effluent monitoring be in place before operating the cyclotron. The root cause of the violation appears to be your staff's lack of understanding of these license requirements.

Operating the cyclotron without all the safety interlocks installed and operational is a significant safety concern as the safety interlocks are designed to ensure that the unit shuts down to limit radiation exposure to staff entering the vault. No overexposures occurred as a result of this event. In addition, the failure to have effluent monitoring systems installed prevents your staff from monitoring the cyclotron's effluents and ensuring those effluents do not exceed NRC regulatory requirements. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The NRC Enforcement Policy can be found at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions previously, since this was your initial inspection, 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. Corrective actions included: (1) committing to not operating the cyclotron until the facility is fully constructed and commissioned; (2) installing safety interlocks and testing operability in September 2023, and training all cyclotron operations on the system; (3) installing the high-efficiency carbon absorber filter systems in November 2023, and reviewing the system's monitoring checks and maintenance procedure with all authorized users; (4) installing the exhaust flow fan motor and system in November 2023, and training authorized users on the system and reporting requirements for loss of ventilation; (5) installing the continuous air monitoring system in December of 2023; and (6) hiring a full-time site radiation safety officer. Based on the above, *Corrective Action* credit is warranted.

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. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>.

The NRC has also determined that a non-escalated Severity Level IV violation of NRC requirements occurred (Violation B). This violation involved the failure to monitor a package containing radioactive materials within 3 hours of package receipt as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1906(c). This violation was also evaluated in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed Notice and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the inspector.

The NRC has concluded that information regarding: (1) the reason for the violations; (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 Inspection Report No. 03039318/2023001 (DRSS) and your letter dated February 13, 2024. 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 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you chose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's 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 or proprietary 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).

Sincerely,



Signed by Giessner, Jack  
on 04/02/24

John B. Giessner  
Regional Administrator

Docket No. 030-39318  
License No. 04-35412-02

Enclosure: Notice of Violation

cc w/encl: State of Michigan

Letter to M. Levy from J. Giessner dated April 2, 2024.

SUBJECT: NOTICE OF VIOLATION; NRC INITIAL INSPECTION REPORT NO. 03039318/2023001 (DRSS) – IONETIX ALPHA CORPORATION

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## NOTICE OF VIOLATION

Ionetix Alpha Corporation  
Lansing, Michigan

Docket No. 030-39318  
License No. 04-35412-02  
EA-23-142

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 17, 2023, through January 22, 2024, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. License Condition 19 of License No. 04-35412-02 (Corrected Copy), dated March 22, 2023, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in letters dated August 1, 2022, and October 11, 2022.

The letter dated August 1, 2022, describes, in part, the facilities and equipment that are needed to safely work with licensed material. Item 9, titled "Facilities and Equipment" states, in part, that: (1) The entrance into the [cyclotron] vault is provided with a safety interlock that shuts down the machine under conditions of entrance during target bombardment; (2) Effluent from the facility is filtered through a MERV prefilter and high-efficiency gas absorber (HEGA) carbon absorber; (3) The facility has one primary exhaust stack. The emission point for the facility is located on the rooftop of the building; (4) An integrated monitoring solution system is utilized in which effluent is analyzed on a continuous basis with a real time readout.

The letter dated October 11, 2022, Item 14 states, in part, the licensee will install, operate, and maintain the continuous air monitor (CAM) system in accordance with the manufacturer or vendor instructions and recommendations.

Contrary to the above, on April 6, 2023, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the letters dated August 1, 2022, and October 11, 2022. Specifically, the licensee failed to ensure that: (1) the entrance into the [cyclotron] vault had a safety interlock that shut down the machine under conditions of entrance during target bombardment; (2) effluent from the facility was filtered through a MERV prefilter and HEGA carbon absorber; (3) the facility had one primary exhaust stack and that the emission point for the facility was located on the rooftop of the building; (4) an integrated monitoring solution system was utilized in which effluent is analyzed on a continuous basis with a real time readout; and (5) the CAM system was installed and operated in accordance with the manufacturer or vendor instructions and recommendations prior to operating the cyclotron, and manufacturing and handling 6 millicuries of astatine-211.

This is a Severity Level III violation (Enforcement Policy Section 6.3.c.1(a)).

- B. Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1906(b) requires, in part, each licensee to monitor the external surfaces of packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4.

Enclosure

Title 10 CFR 20.1906(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, on June 8, 2023, the licensee received a package labeled with a Radioactive Yellow II label during working hours, the package was not exempt from the monitoring requirement for radioactive contamination, and the licensee did not perform the required monitoring within 3 hours after receipt. Specifically, the package received by the licensee contained approximately 216 microcuries of cesium-137 in normal form, and the licensee did not monitor the package until July 27, 2023.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d.4).

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, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03039318/2023001 (DRSS) and the licensee's letter dated February 13, 2024. 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, EA-23-142" 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 III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 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.

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 or proprietary 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 2<sup>nd</sup> day of April 2024.