



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

April 6, 2021

EA-21-036

Mr. Frank Plastini
Corporate Radiation Safety Officer
Ionetix Corporation
101 The Embarcadero, Suite 210
San Francisco, CA 94105

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03039033/2021001(DNMS),
EXERCISE OF ENFORCEMENT DISCRETION, AND NOTICE OF VIOLATION –
IONETIX CORPORATION

Dear Mr. Plastini:

On February 5, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) began an announced, remote (in-office) routine inspection of your cyclotron manufacturing facility in Lansing, Michigan. On February 16, the inspector, Mr. Ryan Craffey, visited the facility as part of the inspection. He subsequently completed his inspection activities remotely. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included an evaluation of records related to the conduct of licensed activities. Mr. Craffey conducted a final exit meeting by virtual teleconference with you and Mr. Eric Mollon of your staff on March 11, 2021, to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated 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 concerned the failure to (1) conduct your radiation safety program in accordance with the statements, representations, and procedures contained in your license application, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3(a) and Condition 16.A of NRC Materials License No. 04-35412-01; and (2) limit your possession of nitrogen-13 (N-13) in a form other than incidentally activated products to 100 millicuries, as required by 10 CFR 30.34(c) and Condition 8.A of your license, when you briefly generated 108.9 millicuries during a cyclotron test on November 2, 2020. The first violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing this violation because the inspector identified it.

In accordance with the Enforcement Policy, the second violation could have been categorized at Severity Level III and considered for escalated enforcement action. However, in accordance with NRC Enforcement Guidance Memorandum (EGM) 20-003, issued July 15, 2020, the NRC is exercising enforcement discretion to categorize this violation as a Severity Level IV violation. The NRC is exercising this discretion because (1) you were already authorized to possess and use nitrogen-13 in this form; (2) you did not significantly exceed your possession limit, such that no additional procedural or programmatic changes would have been required; (3) the failure was not willful, was isolated, and was not repeated from previous inspections; and (4) all other significant safety and security requirements were met with respect to the possession of this material.

Furthermore, the NRC determined that the second violation met the following criteria from Section 2.3.2 of the Policy to be considered a Non-Cited Violation: (1) you identified the violation; (2) you corrected or committed to correct the violation within a reasonable period of time; and (3) the violation was not considered repetitive or willful. Therefore, as a credit to your radiation safety program in identifying and correcting this in a timely fashion, the NRC will not issue a Notice of Violation on the matter.

The inspector determined that the root cause of the first violation was a misunderstanding of regulatory requirements. As near-term corrective action, you stated that Ionetix would either recommission the PSS or request an amendment to its license before operating or testing another cyclotron in a manner that would create a prompt radiation exposure field. Furthermore, you stated that Ionetix would no longer generate incidentally produced radioisotopes or store activated components not attached to a cyclotron in the manufacturing and assembly space as a result of operational and facility changes implemented since the onsite inspection.

The inspector determined that the root cause of the second violation was the unexpected high yield of a production cyclotron during testing at its maximum beam current. As corrective action, you developed and implemented a work instruction to establish operational limits for any cyclotron operation in which N-13 is made to ensure that possession limits are not exceeded. You also committed to train all authorized users on this new work instruction and provided a copy of it to the inspector on March 12, 2021.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

F. Plastini

3

Please feel free to contact Mr. Craffey or my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655 or ryan.craffey@nrc.gov.

Sincerely,

Michael A. Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-39033
License No. 04-35412-01

Enclosure: Notice of Violation

cc w/encl: Eric Mollon, Radiation Safety Officer
State of Michigan

Letter to Frank Plastini from Michael Kunowski, dated April 6, 2021.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03039033/2021001(DNMS),
EXERCISE OF ENFORCEMENT DISCRETION, AND NOTICE OF
VIOLATION – IONETIX CORPORATION

DISTRIBUTION w/encl:

Jack Giessner
Kenneth O'Brien
David Pelton
Joseph Nick
Jamnes Cameron
Kenneth Lambert
Paul Pelke
MIB Inspectors

ADAMS Accession Number: ML21096A169

OFFICE	RIII-DNMS		RIII-DNMS		RIII-EICS			
NAME	RCraffey:brt		MKunowski		JCameron			
DATE	03/29/21		04/06/21		04/06/21			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Ionetix Corporation
San Francisco, CA

License No. 04-35412-01
Docket No. 030-39033
EA-21-036

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from February 5 to March 11, 2021, one violation of NRC requirements was identified by the inspector. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3(a) states, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10 Chapter 1 of the Code of Federal Regulations.

Condition 16.A of U.S. NRC Materials License No. 04-35412-01, Amendment No. 5, dated October 8, 2020, states in part that, except as specifically provided otherwise in this license, Ionetix Corporation shall conduct its program in accordance with the statements, representations, and procedures contained in the application dated February 22, 2017 (ML17061A694). This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's Regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

Section 9 of the application under Personal Safety Systems states, in part, that when operating, the prompt radiation exposure produced by the "Cyclotron Exclusion Zone" is actively monitored by the use of a Personnel Safety System (PSS). The PSS ensures that no cyclotron can be operated in such a way that a Radiation Area is created and that unauthorized entry through the exclusion barriers is prevented during cyclotron operations.

Section 9 of the application under Manufacturing and Assembly Space, states, in part, that only incidentally produced radioisotopes (Item 5A) are produced in this space.

Section 9 of the application under Manufacturing and Assembly Space, states, in part, that no storage of activated components (not attached to a cyclotron) will be permitted in the manufacturing zone.

Contrary to the above, from September 10, 2018 through February 16, 2021, Ionetix Corporation did not conduct its program in accordance with the statements, representations, and procedures contained in Item 9 of its license application dated February 22, 2017. Specifically:

1. Between October 23, 2018 and December 23, 2020, the licensee did not actively monitor the prompt radiation field generated by an operating cyclotron with its Personnel Safety System. Specifically, the licensee decommissioned the PSS and continued to operate cyclotrons without it.

2. Between September 10, 2018 and December 23, 2020, the licensee did not generate only incidentally produced radioisotopes in the manufacturing and assembly space. Specifically, millicurie quantities of nitrogen-13 in a form other than incidentally activated products were routinely produced during the testing of production cyclotrons in the Manufacturing and Assembly Space.
3. As of February 16, 2021, the licensee stored activated borosilicate glass slides in a locked cabinet within the Manufacturing and Assembly Space.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Ionetix Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 6th day of April 2021.