NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Ionetix Corporation 3130 Sovereign Drive Lansing, MI REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-39033	04-35412-01	4/16/18

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	5/1/18
BRANCH CHIEF	Aaron T. McCraw		5/2/18

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Ionetix Corporation 3130 Sovereign Drive Lansing, MI REPORT NUMBER(S) 2018001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-39033	04-35412-01	4/16/18

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126	02.01, 02.02, 02.05, 02.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03210	2	Gary Horner, RSO	(808) 430-0312

☑ Main Office Inspection Next Inspection Date: 04/16/2020

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced initial inspection of a research and development company authorized to possess and store byproduct material incidental to radionuclide production resulting from the manufacture and operation of cyclotrons, and research and development of cyclotron and target performance tests. The licensee's work hours were 7:00am to 5:30pm Mondays through Fridays. Research and development was conducted about one day every two weeks. The licensee employed a radiation safety officer (RSO), an alternate RSO, and five authorized users, including the RSO. As of the inspection, the licensee had not made F-18; however, the licensee plans to make F-18 in October 2018. In December 2017, the licensee made N-13, and it was disposed by decay-in-storage. Most of the licensed material was limited to solid parts (e.g., cyclotron parts) that were activated by neutrons. The licensee stored the licensed material with access limited to authorized users. No principal activities were conducted during the inspection. The licensee had not possessed unsealed licensed material yet. No cyclotrons have been transferred from the licensee's facility.

Performance Observations

The inspector: (1) used a calibrated NRC-owned survey meter to measure selected activated components, and the highest measurement was 3 milliRoentgens per hour at 30 centimeters from the component; (2) observed the RSO conduct a physical inventory of licensed material based on selected items chosen by the inspector; (3) reviewed the dosimeter badge results through December 20, 2017, and the highest whole body and extremity readings were 0 millirem and 14 millirems, respectively; (4) noted that there were no accidents, loss, theft, flooding, or fire involving licensed material; (5) noted that the licensee did not cut, sand, or file activated components; (6) noted that the licensee's accelerator carbon targets were low dose (e.g., 3000 counts per second); (7) observed that the licensee had a survey instrument that is calibrated annually; (8) noted that the licensee transported licensed material from the University of Michigan (U of MI) to its facility; and (9) reviewed HAZMAT training records for the individual who transported licensed material from the U of MI to the licensee's facility.

No violations were identified as a result of this inspection.