NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Ionetix Corporation	030-39033	04-35412-01

4. Report Number(s):	5. Date(s) of Inspection:
2021-001	February 5 - March 11, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	03210	2	87126

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Eric Mollon - RSO Frank Plastini - CRSO	emollon@ionetix.com fplastini@ionetix.com	517-252-4069 x820 518-357-8645

13. Inspection Type: ☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced

14. Locations Inspected: ☑ Main Office ☐ Field Office ☐ Temporary Job Site ☑ Remote

15. Next Inspection Date (MM/DD/YYYY): 02/16/2023 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a cyclotron manufacturer authorized to generate and possess byproduct material for R&D and testing purposes related to the manufacture of cyclotrons at its facility in Lansing, Michigan. At the time of the inspection, the licensee had manufactured and delivered several production cyclotrons for use at client facilities, generating N-13 and incidentally activated products in the process. The licensee has also generated N-13 and F-18 during the conduct of R&D, and has possessed several Cs-137 sealed calibration sources, all of which have since been transferred to client facilities. The licensee has not yet generated any At-210, nor has it worked at any temporary job sites in NRC jurisdiction.

PERFORMANCE OBSERVATIONS

The inspector toured the facility in Lansing to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys in areas where incidentally activated products were stored, observed the conduct of periodic contamination surveys in these areas, and verified a selection of the licensee's inventory of radioactive material. The inspector discussed the conduct of licensed activities with staff, with emphasis on the licensee's procedures for full-power testing of production cyclotrons, the conduct of R&D, and future plans. The inspector also reviewed a selection of records remotely ahead of the on-site inspection, including the latest version of the licensee's radiation safety manual, area and personnel monitoring results, physical inventory and material accountability documentation, instrument calibration documentation, and recent audits of the radiation safety program. The inspector also reviewed documentation of cyclotron tests including records of N-13 production while on-site.

As a result of the on-site inspection, the inspector identified two violations of regulatory requirements. The first violation involved three examples of the failure to conduct the radiation safety program in accordance with the statements and representations contained in its license application, as required by 10 CFR 30.3(a) and LC 16.A. Specifically, the licensee (1) decommissioned the gamma and neutron monitoring instrumentation of its Personnel Safety System (PSS) in October 2018 after deciding that the low gamma and neutron exposures recorded by the PSS did not justify the cost of its upkeep; (2) routinely generated millicurie quantities of N-13 in the manufacturing area during tests of production cyclotrons to confirm their saturation yield; and (3) routinely stored activated borosilicate glass slides in a locked cabinet at the north end of the manufacturing space. Each of these were contrary to the commitments that the licensee made in Item 9 of its renewal application dated Februrary 22, 2017.

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The second violation involved the failure to limit the possession of N-13 in a form other than incidentally activated products to 100 millicuries, as required by 10 CFR 30.34(c) and LC 8.A. Specifically, on November 2, 2020, the licensee tested a production cyclotron at maximum beam current, and generated 108.9 millicuries of N-13 as a result. For approximately 73.6 seconds thereafter, the licensee possessed an amount of N-13 which exceeded its possession limit.

The inspector determined that the root cause of the first violation was a misunderstanding of regulatory requirements. The licensee mistakenly believed that its June 22, 2017, response to a request for additional information from the NRC relieved them of all commitments in Item 9 of their original license application. As corrective action, the licensee stated that would either recommission the PSS or request an amendment to its license for alternate engineering and procedural controls before operating or testing another cyclotron in a manner that would create a prompt radiation exposure field. Furthermore, the licensee stated that it would no longer generate incidentally produced radioisotopes or store activated components not attached to a cyclotron in the manufacturing and assembly space, and instead would only do so from now on in the R&D area, where a modular shielded vault for cyclotron operation had previously been constructed. The licensee stated that this was the result of planned operational and facility changes implemented since the on-site inspection.

The inspector determined that the root cause of the second violation was an unexpected high yield of a production cyclotron tested at its maximum beam current. As corrective action, the licensee developed and implemented a work instruction ("Engineering & Commissioning Vault Beam Operations Limits") for any cyclotron operation in which N-13 is made to establish operational limits that will ensure the quantities of N-13 produced do not exceed possession limits. The licensee 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.

The first violation was identified by the inspector and therefore was cited as a SLIV violation in accordance with NRC Enforcement Policy example 6.3.D.9. A written response to this violation is required. The second violation was identified by the licensee the day after the test, and was considered a SLIV NCV in accordance with EGM-20-003 and Section 2.3.2 of the NRC Enforcement Policy.