

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Arizona Isotopes Science Research Corp.
dba AZIsotopes Corp.
7796 S Innovation Way
Bunker Hill, IN 46914

REPORT NUMBER(S) 202201

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-39259

4. LICENSE NUMBER(S)

13-35624-02

5. DATE(S) OF INSPECTION

4/26/2022

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 violation(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	Luis Nieves Folch		4/26/2022
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2022.05.16 10:03:45 -05'00'</small>	



Materials Inspection Record

1. Licensee Name: Arizona Isotopes Science Research Corp.		2. Docket Number(s): 030-39259		3. License Number(s) 13-35624-02	
4. Report Number(s): 2022001			5. Date(s) of Inspection: April 26, 2022		
6. Inspector(s): Luis Nieves		7. Program Code(s): 03210		8. Priority: 2	9. Inspection Guidance Used: 37136
10. Licensee Contact Name(s): John Zehner R.Ph., RSO		11. Licensee E-mail Address: jzehner@spectronrx.com		12. Licensee Telephone Number(s): 317-459-8315	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): April 26, 2024 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced, initial inspection of a manufacturing company specializing in developing and producing medical isotopes and research; the licensee possessed a IBA C70 MeV cyclotron at its facility in Bunker Hill, Indiana. The licensee operated Monday to Friday. The licensee was in the pre-production phase of producing radiopharmaceuticals for testing and validation. At the time of the inspection, the licensee's inventory of radioactive material was well below the limits in the license; the licensee had begun testing its Germanium and Iodine targets. The licensee will focus on the production of Strontium-82, Germanium-68, Iodine-123, and Actinium-225. The licensee is still hiring and building its production space.

Performance Observation

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The licensee's staff demonstrated the implementation of procedures for air effluent monitoring, shipping material, spills, waste handling, and bioassay for personnel. Through these observations, demonstrations, and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements. The inspector reviewed a selection of records, inventories, survey meter calibration certificates, hazmat training records, bioassay results, and dosimetry reports, which indicated annual whole-body and extremity doses below regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.