



Materials Inspection Report

1. Licensee/Location Inspected: CardioNavix, LLC 515 Park Place Circle Mishawaka, IN 46545 Report Number(s) 2023001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. Docket Number(s) 03039322	4. License Number(s) 37-35686-01	5. Date(s) of Inspection 8/25/2023

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
 - A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
 (Non-cited violation(s) was/were discussed involving the following requirement(s))
 - B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2023.08.25 10:09:00 -05'00'</small>
BRANCH CHIEF	Rhex Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2023.09.18 07:17:54 -05'00'</small>



Materials Inspection Record

1. Licensee Name: CardioNavix, LLC		2. Docket Number(s): 03039322		3. License Number(s) 37-35686-01	
4. Report Number(s): 2023001			5. Date(s) of Inspection: 8/25/2023		
6. Inspector(s): Elizabeth Tindle-Engelmann		7. Program Code(s): 02511	8. Priority: 5	9. Inspection Guidance Used: 87125	
10. Licensee Contact Name(s): Lon Wilson, RSO		11. Licensee E-mail Address: lon.wilson@cdlnuclear.com		12. Licensee Telephone Number(s): 724-933-5570	
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 type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 08/25/2028 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 515 Park Place Circle, Mishawaka, IN 46545					
17. Scope and Observations: <p>The licensee was a service provider and distributor of Strontium-82/Rubidium-82 radionuclide generators. On this license they had distribution hubs in Indiana and Idaho. The licensee had authorization for possession, storage, distribution, and redistribution of used and unused Strontium-82/Rubidium-82 radionuclide generators. The licensee's radiation safety officer was a corporate employee who was onsite as needed. The licensee utilized a consultant for program reviews and oversight of the radiation protection program. The licensee's staff performed equipment calibrations and other general radiation safety tasks. The licensee was only onsite when licensed activities were occurring which was approximately twice per month. The licensee's typical scope of work involved receiving a Strontium-82/Rubidium-82 radionuclide generator in a Type A package, installing it in a Bracco Cardiogen-82 system, and transporting it to client facilities in an excepted package for radioactive instruments in accordance with 49 CFR 173.424.</p> <p>The inspector toured one authorized location. The licensee had received and redistributed 7 generators at the time of the inspection from that location. The inspector observed a sealed source inventory and the receipt of a package. The licensee's staff demonstrated decay in storage procedures and the general process for their licensed activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety and security concepts and procedures. The inspector reviewed the following records: area surveys, dosimetry, instrument calibrations, package receipt, package return, program reviews, sealed source leak tests and inventories, select policies and procedures, training, and waste logs.</p> <p>The inspector performed independent and confirmatory radiation measurements using a RadEye G (serial number: 30653, calibration expiration: 05/09/2024).</p> <p>No violations were identified as a result of this inspection.</p>					

Materials Inspection Record (Continued)

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards
Date: 2023.09.18 07:17:29 -05'00'