



Materials Inspection Report

1. Licensee/Location Inspected: Sofie Co. d/b/a SOFIE 21000 Atlantic Blvd. Ste. 730 Dulles, VA 20166 Location Inspected: 8614 NW 107th Terrace, Kansas City, Missouri 64153 Report Number(s) 2024001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 030-32974	4. License Number(s) 45-25221-01MD	5. Date(s) of Inspection July 26, 2024
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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)

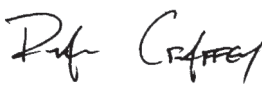
Statement of Corrective Actions

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	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2024.08.22 10:04:12 -05'00'</small>
BRANCH CHIEF	Rhex Edwards, Chief, MIB	<i>Rhex Edwards</i> <small>Digitally signed by RYAN CRAFFEY Date: 2024.08.22 10:18:56 -05'00'</small>



Materials Inspection Record

1. Licensee Name: Sofie Co. d/b/a SOFIE		2. Docket Number(s): 030-32974		3. License Number(s) 45-25221-01MD	
4. Report Number(s): 2024001			5. Date(s) of Inspection: July 26, 2024		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: 87127	
10. Licensee Contact Name(s): William Crisp, Site RSO Casey Melby, PharmD, Facility Manager		11. Licensee E-mail Address: william.crisp@sofie.com		12. Licensee Telephone Number(s): Work: 816-801-8544	
13. Inspection Type: <input type="checkbox"/> Initial <input type="checkbox"/> Routine <input type="checkbox"/> Announced <input checked="" type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Hybrid <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): 09/12/2025 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	
16. Location(s) Inspected List: Field office: 8614 NW 107th Terrace, Kansas City, Missouri 64153					
17. Scope and Observations: This was a non-routine, unannounced escalated enforcement follow-up inspection from the previous routine inspection. SOFIE is a radiopharmacy licensee authorized to prepare and distribute radiopharmaceuticals, including positron emission tomography (PET) products from Kansas City, Missouri facility. A SLIII violation was issued in 2023 (EA-23-063, NMED 230208) for failure to ensure that the occupational extremity exposure remained within the NRC's annual limits as required by Title 10 of the Code of Federal Regulations (10 CFR) Part 20.1201(a)(2)(ii). This inspection reviewed the licensee's corrective actions associated with the Notice of Violation in Report Number 030-32974/2023-001 dated November 9, 2023. The licensee provided corrective actions in an initial written report of overexposure dated November 22, 2022 (ML23118A342) and in supplemental correspondence dated September 26, 2023 (ML23285A056). The inspector interviewed the RSO about each corrective action and (1) verified that the licensee updated its corporate SOP to include On the Job Training (OJT) on proper pig capping procedure and task performance evaluation; the inspector also confirmed that the first OJT training and task evaluation was conducted on February 1, 2024; (2) reviewed and verified that the licensee had created equipment maintenance communication and equipment status escalation systems (a computerized maintenance management system (CMMS)) to report any safety concerns; (3) verified that a new oversight position was added at the corporate office: the associated director of radiation compliance and EHS manager; (4) verified that the licensee created a new reduced ALARA limit and performed timely review of dosimetry report and badge exchanges, and that if any individual exceeds ALARA limit, the site and corporate RSO would be notified; and (5) verified that licensee had developed and implemented a company-wide dosimetry wearing policy (RC-007-A118) on proper wearing of dosimetry badges in restricted areas. No additional examples or other violations were identified. Tthe SLIII violation from the previous inspection is closed.					
Signature and Date - Branch Chief					
			Digitally signed by RYAN CRAFFEY Date: 2024.08.22 10:18:22 -05'00'		