



Materials Inspection Report

1. Licensee/Location Inspected:

Sofie Co. dba SOFIE
21000 Atlantic Blvd.
Ste. 730
Dulles, VA 20166

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)

030-38113

4. License Number(s)

45-25221-05

5. Date(s) of Inspection

9/12/2023

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	Luis Nieves	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2023.10.10 14:51:11 -05'00'
BRANCH CHIEF	Rhex Edwards	 Digitally signed by Rhex A. Edwards Date: 2023.10.10 16:57:34 -05'00'



Materials Inspection Record

1. Licensee Name: Sofie Co. dba SOFIE		2. Docket Number(s): 030-38113		3. License Number(s) 45-25221-05	
4. Report Number(s): 2023001			5. Date(s) of Inspection: 9/12/2023		
6. Inspector(s): Luis Nieves Folch		7. Program Code(s): 03210		8. Priority: 2	9. Inspection Guidance Used: 87127
10. Licensee Contact Name(s): Casey Melby, PharmD, Facility Manager		11. Licensee E-mail Address: casey.melby@sofie.com		12. Licensee Telephone Number(s): 816-801-8544	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Field Office <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 9/12/2025 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input checked="" type="checkbox"/> No change	
16. Location(s) Inspected List: 8614 NW 107th Terrace, Kansas City, Missouri, 64153.					
17. Scope and Observations: <p>This was a routine, unannounced inspection of a cyclotron inside a radiopharmacy in Kansas City, Missouri. The licensee used a GE cyclotron to produce only F-18 products, including fluorodeoxyglucose (FDG), Fibroblast Activation Protein Inhibitor (FAPI) used to detect prostate cancer, and florbetaben for Alzheimer's detection; Cu-64 is received from another licensed entity and repackaged and shipped to clients. The licensee distributed approximately 130 doses daily to 230 regular customers. The cyclotron was operated from 9:00 p.m. to 9:00 a.m. for five daily runs. The licensee had three RSO changes since the last inspection.</p> <p>Licensed personnel interviewed indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements, which showed results consistent with licensee survey records and postings. The inspector reviewed a selection of documents, including internal audits, survey meter calibration certificates, cyclotron maintenance records, area surveys, and dosimetry reports.</p> <p>No violations of NRC requirements were identified as a result of this inspection.</p>					

Signature and Date - Branch Chief

Digitally signed by Rhex A. Edwards
Date: 2023.10.10 16:56:35 -05'00'

From: [Luis Nieves Folch](#)
To: casey.melby@sofie.com
Subject: NRC 591 Sofie Co.
Date: Wednesday, October 11, 2023 8:10:00 AM
Attachments: [591M- Sofie sign_RAE1.pdf](#)

Dear Casey

Attach is the clear 591 report for the inspection conducted on 9/12/2023. At this point there is no further actions on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Office: (630) 829-9571
Fax: (630) 515-1259