NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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) 2022001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38113	45-25221-05	3/21/2022 to 4/13/2022

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 violations(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	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2022.04.19 16:49:21 -05'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.04.20 09:41:04 -05'00'	

From: Nieves Folch, Luis
To: James Coder
Subject: SOFIE NRC 591 clear report
Date: Wednesday, April 20, 2022 2:00:00 PM
Attachments: Sofie Cyclotron 591 signMK.pdf

Dear Mr. Coder

Attach is the clear 591 report for the inspection conducted on March 21, 2022. 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

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
SOFIE Co. d/b/a Sofie	030-38113	45-25221-05

4. Report Number(s):	5. Date(s) of Inspection:
2022001	March 21, 2022 to April 13, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Luis Nieves	03210	2	87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
James Coder, Pharm.D., Radiation Safety Officer	james.coder@sofie.com	816-801-8544

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☐ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	March 21, 2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced, routine inspection of a radiopharmacy with a cyclotron located in Kansas City, Missouri. This radiopharmacy employed three pharmacists and three pharmacy technicians; the licensee utilizes a carrier for the delivery of the doses. The licensee uses 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 detection; Cu-64 is received from another licensed entity and repackaged and shipped to clients. The licensee distributed approximately 150 doses daily to 100 regular costumers. The cyclotron was operated from 8:00 pm through 9:00 am, for a total of 6 runs every day approximating 12 Curies of F-18 before synthesis for each run. The licensee had a lot of turn over in staff since the pandemic began.

PERFORMANCE OPSERVATIONS

The licensee demonstrated drawing doses of F-18 products, packaging and surveying of doses, pig and package surveys and wipes, verification of package contents, preparation of labels and shipping papers, waste disposal, and use of syringe shields and long-handled tools. Licensee personnel demonstrated and described daily area surveys and wipes, package receipt surveys, spill procedures, waste disposal, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector reviewed a selection of records, including internal audits, dose calibrator constancy, dose calibrator linearity, dose calibrator accuracy, survey meter calibration certificates, cyclotron maintenance records, waste disposal of activated parts, well counter constancy, area surveys, and dosimetry reports. This inspection was prolonged due to information not available at the time of the onsite inspection.

The inspector reviewed corrective actions for two violations identified in the previous routine inspection. The violations were for failure to perform appropriate surveys of a work area in which a high radiation area had been created by the storage of a highly activated target and for failure to post the area appropriately. The inspector performed independent surveys of similar areas during the current inspection and observed appropriate postings of work areas. These violations are closed.

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