UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE RD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

November 9, 2023

EA-23-063
NMED 230208

Patrick Phelps
President & CEO
Sofie Co. d/b/a SOFIE
21000 Atlantic Boulevard
Suite 730
Dulles, VA 20166

SUBJECT: NOTICE OF VIOLATION – SOFIE CO - NRC INSPECTION REPORT NO. 030-32974/2023-001

Dear Patrick Phelps:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) announced, reactive inspection conducted on January 18-19, 2023, at your facilities in Kansas City, Missouri, in response to your report of an occupational overexposure event (NMED No. 230208) that occurred on October 31, 2022, and a routine inspection on April 19-20, 2023, at your facility in Morgantown, West Virginia, with continued in-office review through May 30, 2023. The inspections were an examination of activities conducted under your license as they relate to public health and safety to confirm compliance with the NRC rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. Based on the results of the inspections, the NRC identified three apparent violations (AV) of NRC requirements. The NRC discussed the AVs with SOFIE representatives during a telephonic exit meeting on June 5, 2023. The AVs were described in the NRC inspection report sent to you with a letter dated July 5, 2023 (ML23158A132).[1]

In our July 5, 2023, letter transmitting the inspection report, we informed you that the AVs were being considered for escalated enforcement action. On September 14, 2023, a public pre-decisional enforcement conference (PEC) was conducted at the NRC's Region I Office in King of Prussia, PA with members of your staff to discuss the AVs, their significance, their root causes, and your corrective actions. Details of the PEC are found in Enclosure 1

Based on the information developed during the inspection and the information provided during the PEC, the NRC determined that three violations of NRC requirements occurred. These violations involved SOFIE's failure to: (1) ensure that the occupational extremity exposure for one of your employees in calendar year 2022 remained within the NRC's annual limits; (2) ensure that extremity dosimetry was worn while handling radiopharmaceuticals; and (3) restrict

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

access to an area which exceeded 0.002 rem in any one hour. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The NRC considers Violation #1 to be significant because it resulted in an actual consequence when a former employee received dose to an extremity above regulatory limits. Exceeding regulatory limits placed the employee at risk of acute radiation injury. Therefore, this violation is categorized in accordance with the NRC Enforcement Policy as a Severity Level III (SL III) violation. The NRC Enforcement Policy can be found on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $8,750 is considered for a SL III violation. Because SOFIE has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. According to information developed during the inspection, immediate corrective actions taken to address Violation #1 included removing the individual from radiation-related duties, committing to revise the ALARA policy to account for dosimetry reporting delays, and lowering the stop-work trigger levels.

In addition to the immediate corrective action described above, during the PEC, SOFIE described the long-term corrective actions taken and planned to address the issues that resulted in the violations and to prevent reoccurrence. To address Violation #1, SOFIE described changes to its oversight and management of new and existing employees with regards to radiation safety and occupational exposure monitoring. These changes include: increasing resources for corporate oversight; increasing communication and collaboration among site Radiation Safety Officers; engineering changes and a roll-out of a system for requesting engineering changes that assist in reducing employee radiation exposure; enhancements to new employee training and qualifications; and revising the approach and process for dosimetry evaluation and assessment. To address Violation #2, SOFIE described corrective actions related to dosimetry compliance. These actions included: repositioning the mobile shielding; completing an estimate of extremity exposure for the Radiation Safety Officer; developing signage for staff reminders and awareness; incorporating specific elements into staff training; implementing dosimetry verification checks for staff; and building an enhanced safety culture. To address Violation #3, SOFIE, as described in the inspection report, installed a locking metal door.

Finally, after the PEC, in a letter dated September 26, 2023 (non-public document), SOFIE confirmed additional corrective actions related to Violations #1 and #2. Specifically, in response to Violation #1, SOFIE confirmed that on-the-job training and Task Performance Evaluation would be implemented at Kansas City, MO and Morgantown, WV by December 1, 2023, and a computerized maintenance management system would be implemented for Kansas City, MO and Morgantown, WV by December 1, 2023. In response to Violation #2, SOFIE completed a review of the extremity exposure to the individual.

The NRC determined that corrective action credit is warranted. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-32974/2023-001, and in a letter from SOFIE dated September 26, 2023. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if one is provided, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/.

If you have any questions concerning this matter, please contact Anne DeFrancisco of my staff at 610-337-5078 or Anne.DeFrancisco@nrc.gov.

Sincerely,

Daniel S. Collins

Digitally signed by Daniel S. Collins
Date: 2023.11.09 10:13:12 -05'00'

Raymond K. Lorson
Regional Administrator

Enclosures:
1. Summary of September 14, 2023, Pre-Decisional Enforcement Conference and Description of Corrective Actions
2. Notice of Violation

Docket No. 030-32974
License No. 45-25221-01MD

cc (w/Enclosure):
W. Crisp, Operation Regional Director
T. Pellegrin, Nuclear Pharmacist & Morgantown Pharmacy RSO, License RSO
K. Jackson, Radiation Compliance and Environmental Health and Safety Director, Corporate Radiation Safety Officer (RSO)
J. Langston, Bureau Administrator
Missouri Radiation Control Program
Bureau of Diagnostic Services
Department of Health and Senior Services
920 Wildwood Drive, P.O. Box 570
Jefferson City, MO 65102-0570
T. Patton, Director
Radiation, Toxics, Indoor Air
Radiological Health Program
Office of Environmental Health Services
350 Capitol Street, Suite 313
Charleston, WV 25301-1798

SUBJECT: NOTICE OF VIOLATION – SOFIE CO, NRC INSPECTION REPORT NO. 030-32974/2023-001: DATED NOVEMBER 9, 2023

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D Bradley, OE	
J Lubinski, NMSS	RIDSNMSSOD RESOURCE
R Lewis, NMSS	
K Williams, NMSS	
M Burgess, NMSS	
Enforcement Coordinators RII, RIII, RIV (M Kowal; D Betancourt-Roldan; J Groom)	
M Zobler, OGC	RIDSOGCMAILCENTER
P Moulding, OGC	
L Baer, OGC	
H Harrington, OPA	RIDSOPAMAILCENTER
R Feitel, OIG	RIDSOIGMAILCENTER
D D'Abate, OCFO	RIDSOCFOMAILCENTER
P Krohn, DRSS, RI	R1DRSSMAILRESOURCE
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A DeFrancisco, DRSS, RI	
J VonEhr, DRSS, RI	
J Pfingsten, DRSS, RI	
E Spangler, DRSS	
D Screnci, PAO-RI / N Sheehan, PAO-RI	
M Ford, SAO-RI / F Gaskins, SAO-RI	
B Klukan, ORA, RI	
J Nick, ORA, RI	

ADAMS Document Accession NO.: ML23310A007

DOCUMENT NAME: C:\Users\CXS5\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\CGJYEXYL\Sofie NOV-III_SI-IV EA-23-063_rev2 - krohn comments.docx

X SUNSI Review/CJC		X Non-Sensitive ☐ Sensitive			X Publicly Available ☐ Non-Publicly Available	
OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	OE	NMSS
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DATE	10/31/2023				11/03/2023	11/06/2023

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ENCLOSURE 1

SUMMARY OF SEPTEMBER 14, 2023, PRE-DECISIONAL ENFORCEMENT CONFERENCE AND DESCRIPTION OF CORRECTIVE ACTIONS

Licensee: Sofie Co., d/b/a SOFIE

License No. 45-25221-01MD

Docket No. 030-32974

EA No. 23-063

On September 14, 2023, representatives of Sofie Co. (SOFIE) met with NRC personnel in the Region I office located in King of Prussia, Pennsylvania, to discuss the apparent violations identified in NRC Inspection Report Number 030-32974/2023-001 (ML23158A132)[2]. The conference was held at the request of NRC Region I.

The licensee's representatives did not contest any of the apparent violations (AVs). The licensee presented a summary of their perspective on the causes for the AVs and corrective actions. Regarding the overexposure (AV1), the licensee described changes to its oversight and management of new and existing employees with regards to radiation safety and specifically occupational exposure monitoring. Specifically, the licensee described:

- increasing resources for corporate oversight;
- increasing communication and collaboration among site Radiation Safety Officers across all SOFIE facilities;
- engineering changes and a roll-out of a system for requesting engineering changes that assist in reducing employee radiation exposure;
- enhancements to new employee training and qualifications; and
- revising the approach and process for dosimetry evaluation and assessment.

The licensee's representatives also described the extent to which actions were taken in response to the other AVs across the SOFIE network, both within and outside of NRC jurisdiction.

While some of the items described above also addressed AV2 regarding the failure by an individual to wear dosimetry, the licensee also provided additional actions that were more specifically focused on dosimetry compliance, including:

- signage for staff reminders and awareness;
- specific elements incorporated into staff training;
- dosimetry verification checks for staff; and
- building an enhanced safety culture.

The licensee further described the isolated nature and specific actions taken to address AV3,

[2] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

much of which was already known to the NRC and described in the NRC's July 5, 2023, inspection report.

The PEC attendance list, the licensee's and NRC's PEC presentations are attached to this summary.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this summary and its attachments will be made available to the public.

Attachments:
1. Attendance List
2. Licensee Presentation
3. NRC Presentation

Attachment 1 - Attendance List

NRC

Region I:
Paul Krohn, Director, Division of Radiological Safety & Security (DRSS)
Brett Klukan, Regional Counsel, Office of the Regional Administrator (ORA)
Anne DeFrancisco, Chief, Medical and Licensing Assistance Branch (MLAB), DRSS
Jason vonEhr, Senior Health Physicist, MLAB, DRSS
Jonathan Pfingsten, Senior Health Physicist, MLAB, DRSS
Cherie Crisden, Allegations and Enforcement Specialist, Office of the Regional Administrator

Office of Enforcement:
Dan Bradley, Enforcement Specialist

Office of Nuclear Materials Safety and Safeguards:
Michele Burgess, Senior Enforcement Specialist

SOFIE
Kimon Jackson, Radiation Compliance and Environmental Health and
Safety Director, Corporate Radiation Safety Officer (RSO)
William Crisp, Operation Regional Director
Timothy Pellegrin, Nuclear Pharmacist & Morgantown Pharmacy RSO, License RSO
Michael Levy, Consultant

Attachment 2 – Licensee Presentation

SOFIE
From start to clinic

Pre-decisional Enforcement Conference (PEC) - Sofie Co. dba SOFIE

License: 45-25221-01MD

September 14, 2023

SOFIE CO - NRC INSPECTION REPORT 030-32974/2023-001

Reactive Inspection, January 18-19, 2023, Kansas City, Missouri

Occupational overexposure event (NMED No. 230208), October 31, 2022

Routine inspection, April 19-20, 2023, Morgantown, West Virginia

In-office review through May 30, 2023

Presentation Agenda

SOFIE OVERVIEW – WILLIAM CRISP

KANSAS CITY, MO OVERVIEW – WILLIAM CRISP

MORGANTOWN, WV OVERVIEW – WILLIAM CRISP

INSPECTION FINDINGS – KIMON JACKSON

CORRECTIVE & PREVENTIVE ACTIONS FOR INSPECTION FINDNGS – KIMON JACKSON

RADIATION COMPLIANCE PROGRAM IMPROVEMENTS – KIMON JACKSON

QUESTIONS

www.SOFIE.com

SOFIE From start to clinic

ATTENDEES LIST & INTRODUCTION OF SPEAKERS

William Crisp, PharmD, BCNP

Regional Director, Operations

Kimon Jackson MSMP, MSA, CNMT

Director, Radiation Compliance and Environmental Health & Safety

Corporate Radiation Safety Officer

Tim Pellegrin

Nuclear Pharmacist II, Radiation Safety Officer, Pharmacists-in-Charge

Michael A. Levy

Radiation Compliance Consultant

MAGN RESULTS, LLC

INTRODUCTION OF SOFIE BIOSCIENCES (SOFIE)

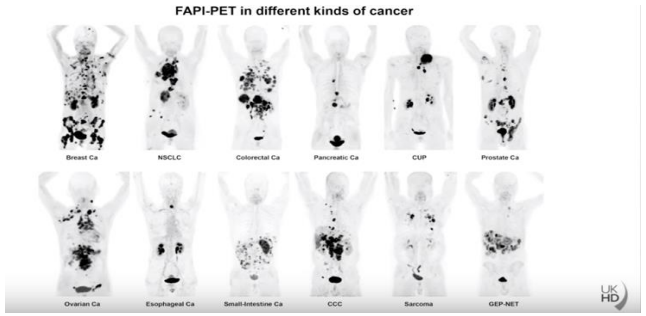
SOFIE's mission is to improve patient outcomes by developing & delivering molecular diagnostics & therapeutics

~260 employees (start of 2021)
~315 employees (start of 2022)
~396 employees (start of 2023)

~1440 imaging centers (2022)
~1254 imaging centers (2023)

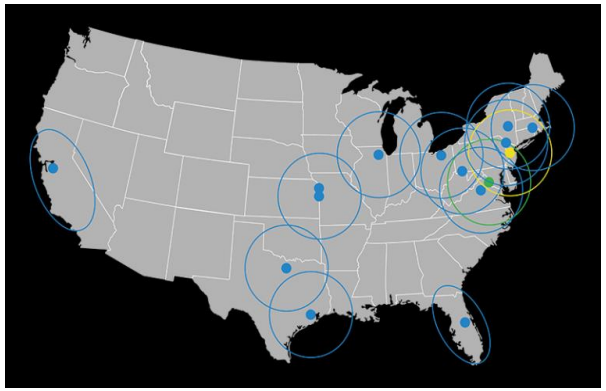
~410,000 doses dispensed (2021)
~499,990 doses dispensed (2022)
>550,000 doses forecasted (2023)

Pipeline of Radiopharmaceuticals



Contract Manufacturing through Theranostic Center of Excellence

Radiopharmacy Network



PET Products Currently Available	
F-18 FDG	F-18 NAF
Neuraceq®	N-13 Ammonia
PYLARIFY®	DetectNet™

Some products are available in select markets only.

INTRODUCTION OF SOFIE's KANSAS CITY, MO RADIOPHARMACY

Facility Overview

Location: Kansas City, MO

Established: 06 Oct 2006

Size: 7,000 sq. ft.

Size of classified areas: 600 sq. ft

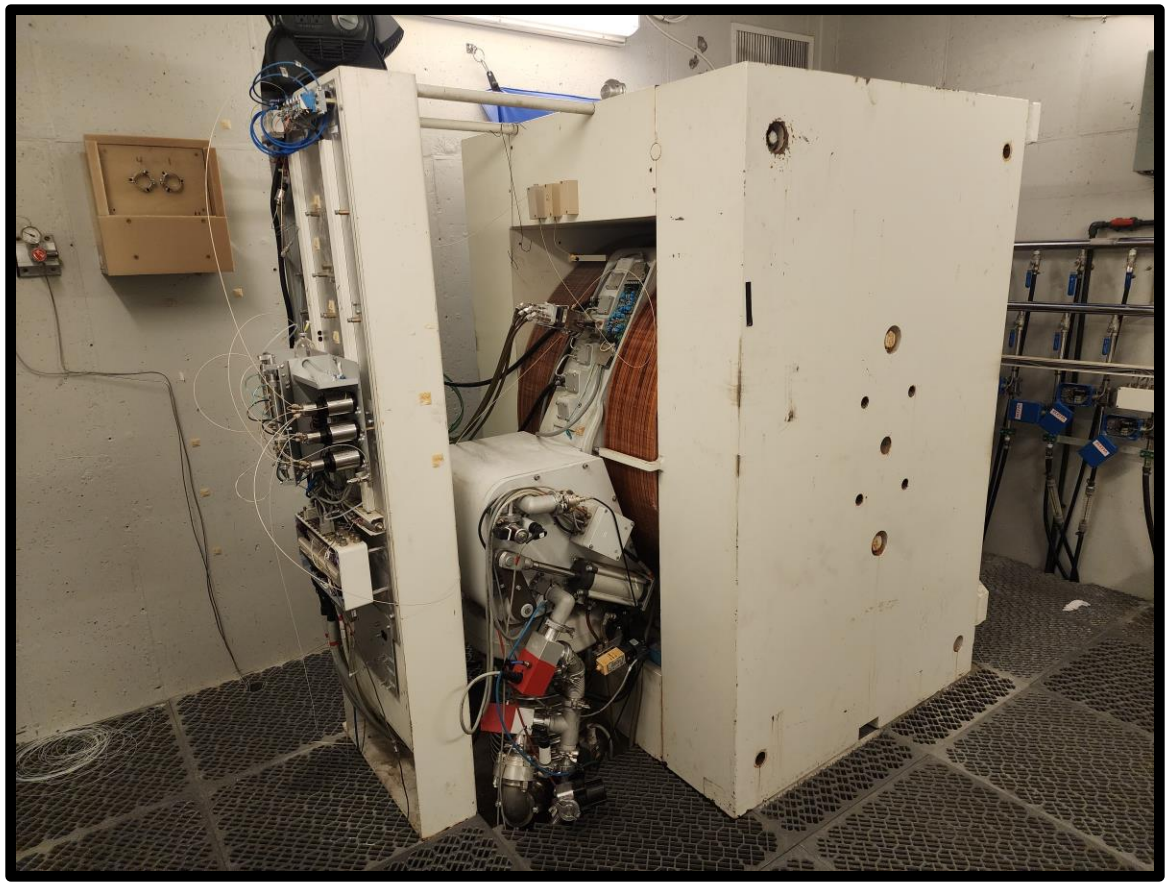
Number of cyclotrons:

GE PET Trace 800

Dual BTI target

Operating Hours:
Sunday to Friday 2100 – 1600
Saturday 0100 – 0500

Number of employees: 18



Products made: 18F-FDG, 18F-FBB, 18F-DCFPyL

Service area: Missouri, Kansas, Nebraska, Iowa, Illinois, Arkansas

Number of doses (annually): ~30,000 (FDG), ~5,500(PyL), ~40 (FBB), ~540 Detectnet

INTRODUCTION OF SOFIE's MORGANTOWN, WV RADIOPHARMACY

Facility Overview

Location: Morgantown, WV

Established: 2014

Size: 2700 sq. ft.

Size of classified areas: 200 sq. ft

Number of cyclotrons: 1 GE Cyclotron

Operating Hours: Monday to Friday 2200 – 1700

Number of employees: 20

Products made: [18F]-Fluro-deoxyglucose (FDG), Ammonia N 13 Injection [13N] (NH3),PYLARIFY [18F]-DCFPyL (PYL), Neuraceq® [18F]-Florbetaben (FBB)

Service area: West Virginia, Pennsylvania, Maryland, Virginia, Ohio

Number of doses (annually): ~22,230 (FDG), 335 (NH3), 743 (PYL), 12 (FBB)

Inspection Findings & Corrective & Preventive Actions

Inspection Finding 1

Regulation	Inspection Findings	Corrective Actions
10 CFR 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.	In 2022, the licensee did not control the occupational dose to the skin or to any extremity of an individual adult to an annual dose limit of 50 rems shallow-dose equivalent. Specifically, one nuclear pharmacy technician received 55.6 rems shallow-dose equivalent to their hand during calendar year 2022.	• On-the-Job Training and Task Performance Evaluation • Radiation Safety Officer Network Consultation • Dosimetry Assessment • Communications & Escalations • Timelier Identification of Issue • Dosimetry / Exposure Review • Limit Changes • Engineering Changes

Inspection Finding 2

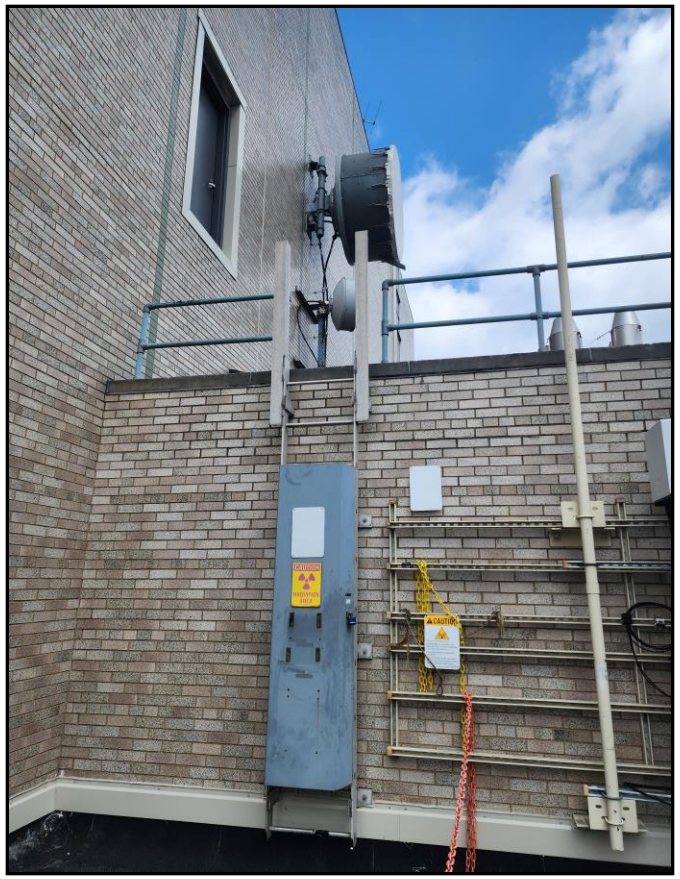
License / Application Commitment	Inspection Findings	Corrective Actions
The licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, in the application dated June 28, 2013. • The application dated June 28, 2013, in Section 8.10.4, Subsection (b)(1)(b) "Rings for Extremity Monitoring;" requires, in part, that the thermoluminescent dosimeter(TLD ring) is a device used for measuring the total exposure by beta, gamma, and/or neutron radiation to the extremities [and] the thermoluminescent dosimeter will be issued in all cases where personnel are eluting Technetium generators or directly handling F-18 and other isotopes/radiation sources. • "Use of Personnel Monitoring Devices;" and requires, in part, that extremity monitoring badges should be worn whenever working with millicurie quantities of material.	On numerous occasions between October 28, 2020, and April 19, 2023, the licensee failed to ensure that extremity monitoring badges were worn whenever working with millicurie quantities of material. Specifically, the radiation safety officer stated that he did not wear his extremity monitoring badges at times when working with greater-than-millicurie quantities of F-18 and N-13.	• Disciplinary Action • Signage • Training • Verification Checks • Safety Culture

Inspection Finding 3

Regulation	Inspection Findings	Corrective Actions
• 10 CFR 20.1301(a)(2) requires, in part, that each licensee shall conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. • 10 CFR 20.1003 defines an unrestricted area as: "an area, access to which is neither limited nor controlled by the licensee."	On April 20, 2023, the licensee failed to conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. Specifically, the licensee's filter bank and exhaust point on the roof of the WVU Health Sciences building produced, at times, at least 5 mR/hr at 30 cm from the filter bank. While the licensee secured this area with a ladder cage, a large access portal allowed parallel access to the roof and filter bank from the building to members of the public, bypassing the licensee's locked ladder cage.	• In response to the unexpected access pathway, the licensee worked with WVU to have the portal in question be closed via a temporary structure installed on April 21, 2023, within a day of the onsite inspection concluding. WVU, on behalf of the licensee, further committed to a longer-term solution, such as a locking metal door.

Corrective & Preventive Actions to Inspection Finding 3

- **Security**
  - Installation of a locked door controlled by SOFE has been completed. This barrier prevents unauthorized personnel from entering a restricted area unless accompanied by SOFIE personnel.



SOFIE Radiation Compliance Program Improvements

Staffing & Resources

Radiation Compliance Program

- A new corporate Director, Radiation Compliance & Environmental, Health, & Safety (EHS), Kimon Jackson, has been hired by SOFIE and officially started on July 3, 2023, to provide additional oversight of facility radiation safety program.
- New Resources to Radiation Compliance Department:
  - Associate Director, Radiation Compliance – Morgan Denman, starts September 18, 2023
  - Manager, Environmental, Health, & Safety (EHS) – Esther Epps, started August 28, 2023
    - These positions will provide additional dedicated support to the SOFIE Radiation Safety Program and to the local site RSOs as well as work to continuously improve policies and procedures, enhance Radiation Safety Training, provide additional oversight to employee exposures and emissions, explore additional engineering controls, and enforce SOFIE's safety culture.
- SOFIE has also contracted an expert Radiation Safety Consultant, Michael Levy, through December 31, 2023, to evaluate SOFIE's Radiation Safety Program and assist in implementation of any improvements necessary.

Training

Radiation Compliance Program

- SOFIE current Radiation Compliance program includes:
  - Nuclear Education Online (NEO) training course
  - Onboarding and annual training
- SOFIE will be expanding:
  - Onboarding and annual Radiation Compliance training,
  - Adding site and job specific radiation safety training
  - Adding on-the-job training and performance evaluation

SOFIE Commitment to a Safety Culture

Radiation Compliance Program

- Monthly SOFIE network Radiation Compliance & EHS meeting for all site RSOs
  - Agenda items will include:
    - Dosimetry Review
    - ALARA Reporting
    - SOPs & Training items
    - Safety moment/Lessons learned
- Monthly reporting of Radiation Compliance & EHS items during network Operations Meeting
- Emphasis on Radiation Safety & EHS at onboarding and ongoing re-enforcement
- Encouraging a safe radiation work environment through self-checks and team awareness

THANK YOU FOR YOUR TIME

Questions?

Attachment 3 – NRC Presentation

PRE-DECISIONAL ENFORCEMENT CONFERENCE

September 14, 2023

1:00 p.m.

LOGISTICS

- Public Meeting that will be transcribed
  - Recording feature of TEAMS
  - Transcript will be non-public, but available through FOIA
- Please turn on camera when speaking
  - State name and affiliation prior to speaking
  - When not speaking, turn off camera and mute microphone

AGENDA

Opening Remarks & Attendee Introductions	P. Krohn
Licensee Opening Remarks	Sofie Representatives
Overview of Enforcement Process	C. Crisden
Summary of Apparent Violations	J. vonEhr
Licensee Presentation	Sofie Representatives
NRC Caucus	NRC Staff
Closing PEC Remarks	P. Krohn/Sofie Representatives
Public Questions and Comments	Public

NRC OPENING REMARKS

- Today's Pre-Decisional Enforcement Conference (PEC) with Sofie Co. (SOFIE) is being conducted to discuss 3 apparent violations (AVs) of NRC requirements.
  - The AVs are related to annual occupational exposure limits, use of extremity dosimetry, and access control to areas where radiation is present.
- Please Note:
  - The NRC has not made a final enforcement decision on this matter.
  - This PEC is your opportunity to provide us information you want the NRC to consider in making a final decision.
- Introductions

SOFIE, CO.
OPENING REMARKS

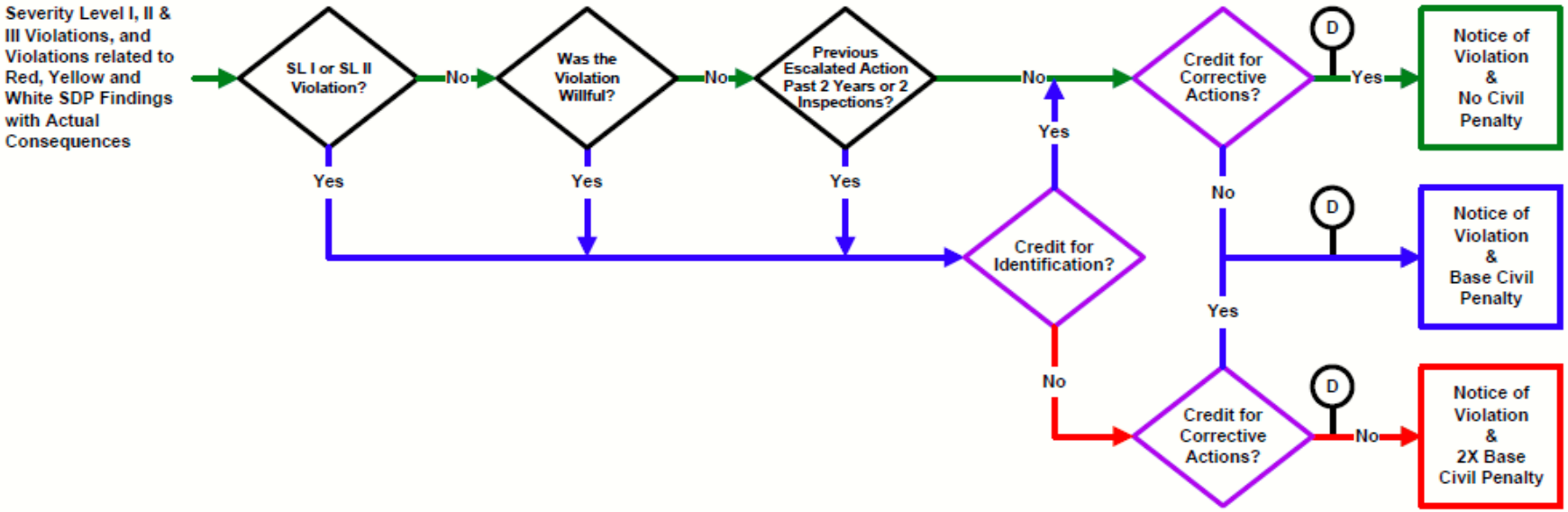
ESCALATED ENFORCEMENT PROCESS

- NRC Enforcement Policy available at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html

- The significance of violations is assessed using Severity Levels.
  - SL I is the most significant and SL IV is the least.
  - SL I, SL II, and SL III violations are considered for escalated enforcement action.

- Factors used in determining Severity Level:
  - Actual Consequences
  - Potential Consequences
  - Impact to the Regulatory Process
  - Willfulness

ESCALATED ENFORCEMENT PROCESS



ENFORCEMENT PROCESS – ROLE OF PEC

- Following this PEC, the NRC will issue the final enforcement outcome.
- A PEC is not a forum for negotiating the enforcement action. It is an opportunity for you to present additional information you want the NRC to consider.
- The NRC staff's final position will not be communicated today. Rather, the NRC staff at this conference will consider the information you present, in conjunction with the information from the inspection, to reach a final decision.

SUMMARY OF APPARENT VIOLATIONS

- A reactive inspection was performed on January 18-19, 2023, and a routine inspection was performed on April 19-20, 2023. The reactive inspection was in response to SOFIE's notification to the NRC regarding the extremity overexposure.
- Three apparent violations were identified; one as a result of the reactive inspection (AV 1) and two as a result of the routine inspection (AV 2 and 3).

APPARENT VIOLATION NO. 1 (REACTIVE)

10 CFR 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.

Contrary to the above, in 2022, the licensee failed to control the occupational dose to the skin or to any extremity of an individual adult to an annual dose limit of 50 rems shallow-dose equivalent. Specifically, one nuclear pharmacy technician received 55.6 rems shallow-dose equivalent to their hand during calendar year 2022.

APPARENT VIOLATION NO. 2 (ROUTINE)

License Condition 19.A of NRC License No. 45-25221-01MD, Amendment No. 69, dated September 15, 2022, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, in the application dated June 28, 2013.

The application dated June 28, 2013, in Section 8.10.4, Subsection (b)(1)(b) "Rings for Extremity Monitoring;" requires, in part, that the thermoluminescent dosimeter (TLD ring) is a device used for measuring the total exposure by beta, gamma, and/or neutron radiation to the extremities [and] the thermoluminescent dosimeter will be issued in all cases where personnel are eluting Technetium generators or directly handling F-18 and other isotopes/radiation sources.

Section 8.10.4 continues in Subsection (b)(3) "Use of Personnel Monitoring Devices;" and requires, in part, that extremity monitoring badges should be worn whenever working with millicurie quantities of material.

Contrary to the above, on numerous occasions between October 28, 2020, and April 19, 2023, the licensee failed to ensure that extremity monitoring badges were worn whenever working with millicurie quantities of material. Specifically, the radiation safety officer stated that he did not wear his extremity monitoring badges at times when working with greater-than-millicurie quantities of F-18 and N-13.

APPARENT VIOLATION NO. 3 (ROUTINE)

10 CFR 20.1301(a)(2) requires, in part, that each licensee shall conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

10 CFR 20.1003 defines an unrestricted area as: "an area, access to which is neither limited nor controlled by the licensee."

Contrary to the above, on April 20, 2023, the licensee failed to conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. Specifically, the licensee's filter bank and exhaust point on the roof of the WVU Health Sciences building produced, at times, at least 5 mR/hr at 30 cm from the filter bank. While the licensee secured this area with a ladder cage, a large access portal allowed parallel access to the roof and filter bank from the building to members of the public, bypassing the licensee's locked ladder cage.

SOFIE, CO. PRESENTATION

NRC CLARIFYING QUESTIONS & ANSWERS

BREAK / NRC CAUCUS

NRC QUESTIONS & ANSWERS

CLOSING REMARKS

PUBLIC QUESTIONS & ANSWERS

ENCLOSURE 2

NOTICE OF VIOLATION

Sofie Co. d/b/a SOFIE
Dulles, Viriginia

Docket No.: 030-32974
License No.: 45-25221-01MD
EA-23-063

During an NRC reactive inspection conducted on January 18-19, 2023, and a routine inspection conducted on April 19-20, 2023, with continued in-office review through May 30, 2023, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

I. ESCALATED VIOLATION

1. 10 CFR 20.1201(a)(2)(ii) requires, in part, that the licensee control the occupational dose to the skin of the whole body or to the skin of any extremity of individual adults to an annual dose limit of 50 rems shallow-dose equivalent.

   Contrary to the above, in 2022, the licensee failed to control the occupational dose to the skin of the whole body or to the skin of any extremity of an individual adult to an annual dose limit of 50 rems shallow-dose equivalent. Specifically, one nuclear pharmacy technician received 55.6 rems shallow-dose equivalent to their hand during calendar year 2022.

This is a Severity Level III violation (Enforcement Policy Section 6.7)

II. NON-ESCALATED VIOLATIONS

2. License Condition 19.A of NRC License No. 45-25221-01MD, Amendment No. 69, dated September 15, 2022, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, in the application dated June 28, 2013.

   In the application dated June 28, 2013, Section 8.10.4 “Dosimetry,” Subsection b(1)(b) “Rings for Extremity Monitoring” requires, in part, that the thermoluminescent dosimeter (TLD ring) (a device used for measuring the total exposure by beta, gamma, and/or neutron radiation to the extremities) will be issued in all cases where personnel are eluting Technetium generators or directly handling F-18 and other isotopes/radiation sources.

   Section 8.10.4, Subsection b(3) “Use of Personnel Monitoring Devices” further requires, in part, that extremity monitoring badges (rings) should be worn whenever working with millicurie quantities of material.

   Contrary to the above, on numerous occasions between October 28, 2020, and April 19, 2023, the licensee failed to ensure that extremity monitoring badges were worn whenever working with millicurie quantities of material. Specifically, the Radiation Safety Officer did not wear their extremity monitoring badges at times when working with greater-than-millicurie quantities of F-18 and N-13.

This is a Severity Level IV violation (Enforcement Policy Section 6.3)

3. 10 CFR 20.1301(a)(2) requires, in part, that each licensee shall conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

   10 CFR 20.1003 defines an unrestricted area as: "an area, access to which is neither limited nor controlled by the licensee."

   Contrary to the above, on April 20, 2023, the licensee failed to conduct operations so that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour. Specifically, the licensee's filter bank and exhaust point on the roof of the West Virginia University Health Sciences building was secured with a ladder cage from access below this roof, but a large access portal bypassed the licensee's locked ladder cage, allowing parallel access to the roof and filter bank from the building to members of the public. The licensee's filter bank and exhaust point produce, at times, at least 5 mR/hr at 30 cm from the filter bank.

This is a Severity Level IV violation (Enforcement Policy Section 6.7)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-32974/2023-001 (ML23158A132)[3], and in a letter from SOFIE dated September 26, 2023 (non-public document). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-23-063)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 9th day of November, 2023.

[3] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.