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

July 5, 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: SOFIE CO - NRC INSPECTION REPORT 030-32974/2023-001

Dear Patrick Phelps:

This letter refers to the 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 inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (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. The preliminary inspection findings were discussed with your staff following the conclusion of the onsite portions of the inspection on January 19, 2023, and April 20, 2023. A final exit briefing was conducted telephonically on June 5, 2023, with the following SOFIE representatives: William Crisp, PharmD, Regional Director, Operations, Kimon Jackson, Mid Atlantic Clinical Account Executive, Kelly Lutkewitte, PharmD, Nuclear Pharmacist and Radiation Safety Officer (RSO), Matthew Hadden, Radiation Compliance Consultant, Riley Harbarger, West Virginia Facility Manager, and Timothy Pellegrin, Nuclear Pharmacist and RSO.

Based on the results of this inspection, the NRC identified three apparent violations (AV), which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These AVs involved the apparent failures to: (1) ensure an occupational extremity exposure for one of your employees in calendar year 2022 remained within the NRC's annual limits; (2) wear extremity dosimetry while handling radiopharmaceuticals; and (3) restrict access to an area which exceeded 0.002 rem in any one hour.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these apparent violations at this time. In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection

report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) request a Pre-decisional Enforcement Conference (PEC); or (2) request Alternative Dispute Resolution (ADR). **If you decide to participate in a PEC or pursue ADR, please contact Anne DeFrancisco at (610) 337-5078 or via email at Anne.DeFrancisco@nrc.gov within 10 days of the date of this letter.** A PEC should be held within 30 days of the date of this letter and an ADR session within 45 days of the date of this letter. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509[1]).

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third-party mediator. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at: http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

[1] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this report may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end.
https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

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

Sincerely,

Paul G. Krohn
Digitally signed by Paul G. Krohn
Date: 2023.07.05 14:43:49 -04'00'

Paul Krohn, Director
Division of Radiological Safety and Security

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

Enclosure:
NRC Inspection Report 030-32974/2023-001

cc w/ enclosure:
T. Pellegrin, R.Ph., SOFIE Radiation Safety Officer
K. Jackson, MSMP, MSA, CNMT, SOFIE Mid-Atlantic Clinical Account Executive
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

SOFIE CO - NRC INSPECTION REPORT 030-32974/2023-001 DATED JUNE 5, 2023.

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F Gaskins, SAO-RI
M Ford, SAO-RI
B Klukan, ORA, RI
J Nick, ORA, RI
R1Enforcement.Resource

ADAMS ACCESSION NUMBER: ML23158A132

☒SUNSI Review: ADAMS: ☐ Non-Publicly Available ☒ Non-Sensitive Keyword:
By: JEV ☒ Yes ☐ No ☒ Publicly Available ☐ Sensitive N/A

| OFFICE | RI:DRSS | RI:DRSS | RI:DRSS | RI:ORA | OGC | OE |
|---|---|---|---|---|---|---|
| NAME | JPfingsten | JvonEhr | NPatel | CCherie | RAugustus | DBradley |
| SIGNATURE | JBP | JEV | NSP | CC | RA | DSB |
| DATE | 06/07/23 | 06/09/23 | 06/08/23 | 06/21/23 | 06/28/23 | 06/27/23 |
| OFFICE | RI:DRSS | RI:DRSS | | | | |
| NAME | ADeFrancisco | PKrohn | | | | |
| SIGNATURE | AED | PGK | | | | |
| DATE | 07/03/23 | 07/05/23 | | | | |

**OFFICAL RECORD COPY**

**U.S. NUCLEAR REGULATORY COMMISSION**
**REGION I**

| | |
|---|---|
| Docket: | 030-32974 |
| License: | 45-25221-01MD |
| Report: | 2023-001 |
| EA No.: | EA-23-063 |
| Licensee: | Sofie Co. d/b/a SOFIE |
| Locations Inspected: | 1 Medical Center Drive, Morgantown, WV<br>8614 NW 107th Terrace, Kansas City, MO |
| Inspection Dates: | January 18-19, 2023, April 19-20, 2023, with in-office review through May 30, 2023 |

Inspectors:

*Jason vonEhr* 07/03/2023
Jason vonEhr, Senior Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

*Netra Patel* 07/03/2023
Netra Patel, Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

*Anne DeFrancisco for* 07/03/2023
Jonathan Pfingsten, Senior Health Physicist Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Approved By:

*Anne DeFrancisco* 07/03/2023
Anne DeFrancisco, Chief Date
Medical & Licensing Assistance Branch
Division of Radiological Safety & Security

Attachment: Supplemental Inspection Information

Enclosure

## EXECUTIVE SUMMARY

### Sofie Co. d/b/a SOFIE
### NRC Inspection Report 030-32974/2023-001

An announced reactive and routine inspection was performed of Sofie Co. on January 18-19, 2023, April 19-20, 2023, with in-office review through May 30, 2023. The inspection was an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's rules, regulations, and with the conditions of the NRC 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.

Program Overview

Sofie Co. is authorized by the U.S. Nuclear Regulatory Commission Materials License No. 45-25221-01MD to use a variety of sealed sources and unsealed byproduct material primarily for the preparation, distribution, and redistribution of radioactive drugs to authorized recipients in accordance with Title 10 of the *Code of Federal Regulations* 32.72. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Morgantown, West Virginia and Kansas City, Missouri.

Inspection Findings

Three apparent violations of NRC requirements were identified. These included the apparent failures to: (1) ensure an occupational extremity exposure for a Sofie employee in calendar year 2022 remained within the NRC's annual limits; (2) wear extremity dosimetry while handling radiopharmaceuticals; and (3) restrict access to an area which exceeded 0.002 rem in any one hour.

Corrective Actions

In a letter dated November 22, 2022, the licensee communicated its initial planned or completed corrective actions regarding Apparent Violation No. 1 described above. These actions included: (1) removing the individual from duties involving exposure to radiation on October 12, 2022 (the individual discontinued their employment with the licensee on October 25, 2022); and (2) modifying the As-Low-As-Reasonably-Achievable (ALARA) policy to lower the 'stop-work' triggers in order to try to account for routine dosimetry reporting delays.

## REPORT DETAILS

### 1. Program Overview (Inspection Procedure 87127)

#### 1.1. Program Scope

Sofie Co., doing-business-as SOFIE (SOFIE) is authorized by the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 45-25221-01MD to use a variety of sealed and unsealed byproduct material primarily for the preparation, distribution, and redistribution of radioactive drugs to authorized recipients in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 32.72. Storage and use of NRC-licensed byproduct materials was authorized at the licensee's facilities in Morgantown, West Virginia and Kansas City, Missouri.

The license was amended seven times since the NRC's last routine inspection (started on October 27, 2020). These amendments included:

- Amendment No. 63, issued on November 12, 2020, which authorized the addition of an Authorized Nuclear Pharmacist (ANP);
- Amendment No. 64, issued on May 26, 2021, which authorized the addition of one ANP and removal of several ANPs;
- Amendment No. 65, issued on September 13, 2021, which authorized the addition of an ANP;
- Amendment No. 66, issued on February 14, 2022, which authorized various changes, including a change in corporate Radiation Safety Officer (RSO), change in site RSO, and addition and removal of various ANPs;
- Amendment No. 67, issued on June 1, 2022, which authorized the removal and addition of various ANPs to the license;
- Amendment No. 68, issued on July 20, 2022, which authorized the addition of two ANPs; and
- Amendment No. 69, issued on September 15, 2022, which authorized the removal and addition of various ANPs to the license.

#### 1.2. Inspection Scope

The inspection was an examination of activities conducted under the NRC license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of the SOFIE 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.

The inspection had two distinct components: a reactive inspection focused on a reported occupational overexposure at the Kansas City, Missouri location and the routine inspection of the Morgantown, West Virginia location. A routine inspection (Agencywide Document Access and Management System (ADAMS) Accession No. ML22180A004[2])

[2] NRC Agencywide Documents Access and Management System (ADAMS) Accession Numbers listed in this report may be accessible using the hyperlink below with the associated ADAMS Accession Number inserted in place of the "ML" at the end.
https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML

for the Kansas City, Missouri location had previously been performed in early 2022 under a separate inspection and did not result in any violations identified.

## 2. Reactive Inspection of Extremity Overexposure

### 2.1. Inspection Scope

In a letter dated November 22, 2022 (ADAMS Accession No. ML23118A342), SOFIE reported one extremity overexposure among its employees at its Kansas City, Missouri location for calendar year 2022. The overexposure was related to a nuclear pharmacy technician packaging F-18 dosages for transport to other licensed facilities. The individual was a new employee with prior single-photon emission computed tomography (SPECT) (e.g., Tc-99m) radiopharmaceutical experience. The worker received 55.6 rem to the right hand, while receiving 1.7 rem whole-body. The extremity exposure was received during normal work operations over a period of approximately two and a half months in 2022. SOFIE removed the individual from radiation-related duties on October 12, 2022, when the licensee's administrative trigger levels (i.e., 45 rem extremity dose) alerted them of the employee nearing the 50-rem annual regulatory extremity dose limit based on incoming dosimetry results. Due to dosimetry processing delays, the nuclear pharmacy technician had already surpassed 50 rems of exposure to the individual's right hand by the time the individual was reassigned from radiation-related duties. The licensee provided a written notification to the NRC on November 22, 2022, after the overexposure became apparent through the dosimetry report received by the licensee on October 28, 2022.

An onsite inspection was performed at the licensee's Kansas City, Missouri location on January 18th and 19th, 2023. The inspector met with the corporate RSO who served as the Kansas City site RSO. The circumstances surrounding the event were discussed, the location was toured, independent surveys were performed, and other employees were observed performing the same tasks as the individual who exceeded the occupational extremity dose limit. Additionally, the inspector and corporate RSO discussed the timeline of the subject employee's exposure, training and retraining, and corrective actions taken and planned at that time.

### 2.2. Observations and Findings

The inspection confirmed that the reported exposures were legitimate and associated with the individual's occupational tasks, as opposed to non-occupational exposures, for example exposures resulting from mishandling of the dosimeters. The individual's work practices directly led to the exceedance of occupational exposure limits.

The inspector interviewed and observed others performing the individual's assigned tasks to better understand what could have caused or contributed to the high extremity dose. Examples identified included:

- Positioning the body at the side of dose transfer drawer versus using the drawer to increase the distance between the person's body and the syringe;
- Capping shielded transport containers (vernacular: "pigs") with two hands versus one hand despite the bottom of pigs being fit into anti-rotation base (i.e., not using engineered features to reduce overall exposure);

- Grabbing/carrying pigs from the base versus cap (i.e., hand was positioned closer to the radiopharmaceuticals);
- Slow movements while transferring the pigs from the dose transfer drawer to U.S. Department of Transportation (DOT) package;
- Holding the pigs while reviewing DOT/patient/client labels as opposed to reviewing these labels before grabbing the transport container or after placing the pig in the DOT package;
- Grabbing syringe that missed the target pig with bare hand versus tongs on at least one occasion; and
- Poor dose relabeling practices.

The root cause of the overexposure was determined to be complacent work habits from previous work experience with lower-energy radiopharmaceuticals (e.g., Tc-99m). The employee failed to utilize common or routine exposure reduction techniques and the inspectors noted the increased risk significance of the technician's work in handling position emission tomography (PET) with higher energy gamma emissions compared to radionuclides with lower-energy gamma emissions. Additional contributing causes included inadequate oversight of the individual as a new employee, degraded or incompatible equipment, and failure to consider routine delays in dosimetry processing (e.g., results received 2-4 weeks following the wear period).

As a result of all the above, an apparent violation of 10 CFR 20.1201(a)(2)(ii) was identified (030-32974/2023-001-01):

> 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 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.

2.3. Conclusions

One apparent violation of 10 CFR 20.1201(a)(2)(ii) was identified and is being considered for escalated enforcement associated with the extremity occupational overexposure of an employee.

## 3. Routine Inspection of Morgantown, WV Location

3.1. Inspection Scope

The announced, routine inspection was performed on April 19-20, 2023, at SOFIE's West Virginia facility. The scope of the inspection was to examine licensed activities as they relate to public health and safety and to the NRC's rules and regulations. 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.

3.2. Observations and Findings

During the routine inspection, the inspectors interviewed and observed staff performing licensed activities, including those representative of the activities of the overexposed Missouri employee. No observations were made of similar work practices which might have contributed to the Missouri employee's elevated occupational radiation exposure. In addition, the inspectors did not observe degraded or incompatible equipment at the West Virginia facility as was noted at the Missouri facility.

In general, staff at the West Virginia facility were knowledgeable and competent of NRC requirements, SOFIE practices and procedures, and performed their tasks using industry-standard techniques to reduce occupational radiation exposures. The inspectors reviewed records, procedures, and incidents at the West Virginia facility. The licensee was diligent in their oversight of licensed activities, including response to and documentation of incidents and concerns as identified by licensee staff or management. Two such incidents are described, briefly, below, and did not result in any noncompliances of NRC requirements.

The first incident occurred in June 2021, and involved West Virginia University (WVU) facilities staff (SOFIE's West Virginia facility is located within a WVU building). The staff were escorted into a restricted area to perform non-licensed activities. The licensee identified the WVU staff's shoes as having been contaminated with F-18. The licensee adequately monitored the WVU staff before, during, and after, and thus identified this contamination in a timely manner. The affected articles (the facilities staffs' shoes) were removed and decontaminated, reducing the radiation levels to background levels. The licensee performed extensive investigations through July 2021 to identify and address the source of the contamination. The licensee was able to identify a leak on an H-Pipe fitting adjacent to the exhaust lines under lead shielding and a kinked exhaust line. This pipe fitting and exhaust line were replaced, and further monitoring performed to demonstrate the lack of contamination in future production runs. An estimate by the licensee concluded, and the NRC inspectors concurred, that the WVU staff remained well within NRC regulatory requirements for radiation exposure to members of the public.

The second incident occurred in March 2023, and involved skin contamination of a SOFIE employee as a result of a line, which carries the N-13 product, coming loose. The employee had a drop of the target water under their eye, resulting in skin contamination (but not internal exposure: the drop remained outside of the eye). The employee's skin was decontaminated to near-background levels, and the employee remained in a restricted area until the remaining N-13 (which has a 9.97-minute half-life) had decayed to below background levels. The licensee implemented several actions to reduce the opportunity for recurrence (dealing with the positioning of mobile shielding) and address the lack of a timely internal notification to the RSO. An estimate was performed for the extremity exposure which concluded that the incident resulted in approximately 530 millirem to the individual's skin.

In addition to the above, two further issues were identified during the routine inspection that involved the apparent failures to: (1) wear extremity dosimetry while handling radiopharmaceuticals; and (2) restrict access to an area which exceeded 0.002 rem in any one hour.

The first issue identified was regarding the RSO's abnormal dosimetry results. Specifically, that the individual's recorded extremity exposure was approximately a quarter of the whole-body exposure, which is abnormal in that, particularly with radiopharmaceutical work, the extremities are exposed to radiation at a higher rate than the whole-body as a result of handling the radioactive material in far closer proximity. In discussion with the RSO, the individual had a misunderstanding of the more restrictive commitments within the NRC license as to when SOFIE staff was required to wear extremity monitoring. This likely resulted in an unmonitored extremity exposure on the order of 1-2 rems, based on the whole-body dosimeter result. The failure to wear extremity monitoring while handling the PET products is an apparent violation of the license commitments made during the 2013 application. Specifically, the 2013 application committed to wearing extremity monitoring badges whenever an individual was working with millicurie-quantities of radioactive material, or where personnel are directly handling F-18 and other isotopes/radiation sources.

As a result, an apparent violation of the NRC license was identified (030-32974/2023-001-02):

> 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.

The second issue identified was regarding the effluent exhaust system on the roof of the building housing the SOFIE radiopharmacy. Specifically, SOFIE's exhaust system included a filter bank which nominally captures and holds a high percentage of the facility's exhaust products for radioactive decay. This filter bank results in external exposure rates in-excess of 2 millirem in any one hour. As a result, the licensee was responsible for restricting access to this area, in accordance with 10 CFR 20.1301(a)(2). SOFIE elected to restrict access to the complete roof area via a locked ladder necessary to access the roof from the facility below this area. However, the roof had a parallel and alternative path by way of a large access portal. Only certain WVU facilities staff, who would be considered members of the public, would nominally have access to this alternative pathway. Furthermore, these personnel would not have a reasonable need to

be on the roof near the filter bank, and thus the opportunity and likelihood for a member of the WVU facilities staff to have accessed the radiation field in excess of 2 millirem in any one hour was very limited.

As a result, an apparent violation of 10 CFR 20.1301(a)(2) was identified (030-32974/2023-001-03):

> 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.

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.

### 3.3. Conclusion

Two apparent violations were identified during the routine inspection on April 19-20, 2023, in addition to the apparent violation described in Section 2.2 as a result of the reactive inspection. The two apparent violations involved the apparent failures to: (1) wear extremity dosimetry while handling radiopharmaceuticals; and (2) restrict access to an area which exceeded 0.002 rem in any one hour.

## 4. Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on January 18-19, 2023, at your facilities in Kansas City, Missouri, and on April 19-20, 2023, at your facilities in Morgantown, West Virginia. The licensee acknowledged the findings presented and committed to formulating a corrective action plan. The NRC conducted a final exit briefing via teleconference on June 5, 2023, with the following SOFIE representatives: William Crisp, PharmD, Regional Director, Operations, Kimon Jackson, Mid Atlantic Clinical Account Executive, Kelly Lutkewitte, PharmD, Nuclear Pharmacist and RSO, Matthew Hadden, Radiation Compliance Consultant, Riley Harbarger, West Virginia Facility Manager, and Timothy Pellegrin, Nuclear Pharmacist and Radiation Safety Officer.

## SUPPLEMENTAL INSPECTION INFORMATION

### LIST OF PERSONS CONTACTED

William Crisp, PharmD, Regional Director, Operations,
Kimon Jackson, Mid Atlantic Clinical Account Executive
Timothy Pellegrin, Nuclear Pharmacist and NRC License Radiation Safety Officer
Matthew Hadden, Corporate Radiation Safety Officer (former), Radiation Compliance Consultant
Kelly Lutkewitte, PharmD, Nuclear Pharmacist and RSO, and
Riley Harbarger, West Virginia Facility Manager

### INSPECTION PROCEDURES USED

87127 - Radiopharmacy Programs

### ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

| | | |
|---|---|---|
| 030-32974/2023-001-01 | AV | 10 CFR 20.1201(a)(2)(ii) – apparent failure to limit occupational extremity exposure to below NRC annual limit. |
| 030-32974/2023-001-02 | AV | License Condition 15 – apparent failure to wear extremity monitoring devices. |
| 030-32974/2023-001-03 | AV | 10 CFR 20.1302(a)(2) – apparent failure to restrict access to an area exceeding 2 millirem in any one hour. |

Closed

None

Discussed

None

(Continued on next page)

## LIST OF ACRONYMS AND ABBREVIATIONS USED

| | |
|---|---|
| ADAMS | Agencywide Documents Access and Management System |
| ADR | Alternative Dispute Resolution |
| ALARA | As-Low-As-Reasonably-Achievable |
| ANP | Authorized Nuclear Pharmacist |
| AV | Apparent Violations |
| d/b/a | Doing Business As |
| CFR | *Code of Federal Regulations* |
| DOT | U.S. Department of Transportation |
| ICR | Institute on Conflict Resolution (Cornell University) |
| NMED | Nuclear Materials Event Database |
| NRC | Nuclear Regulatory Commission |
| PEC | Pre-decisional Enforcement Conference |
| PET | Positron Emission Tomography |
| RSO | Radiation Safety Officer |
| SPECT | Single-Photon Emission Computed Tomography |
| TLD | Thermoluminescent Dosimeter |
| WVU | West Virginia University |