

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Sofie Network Inc. d/b/a Sofie 2220 W. Sunset St. Springfield, Missouri 65807 REPORT NUMBER(S) 2021001	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) 030-38460	4. LICENSE NUMBER(S) 24-32827-01MD	5. DATE(S) OF INSPECTION October 14-20, 2021
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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. 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, 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	Geoffrey Warren, Sr. HP	Geoffrey M. Warren <small>Digitally signed by Geoffrey M. Warren Date: 2021.10.21 10:33:40 -05'00'</small>	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.10.21 16:04:52 -05'00'</small>	

Warren, Geoffrey

From: Warren, Geoffrey
Sent: Monday, October 25, 2021 9:34 AM
To: khalil.flowers@sofie.com
Subject: NRC Inspection Report - Sofie Network
Attachments: Sofie Network - 591MsgMK.pdf

Enclosed is the inspection report for the NRC's remote inspection performed October 14-20, 2021, at your nuclear pharmacy in Springfield, Missouri. No violations were identified as the result of the inspection, and the violation from the previous inspection was closed. No response is required to the report or to this email.

Please contact me if you have any questions.

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Geoffrey Warren
Senior Health Physicist (Inspector)
NRC Region III, Lisle, IL
630-829-9742



Materials Inspection Record

1. Licensee Name: Sofie Network Inc. d/b/a Sofie		2. Docket Number(s): 030-38460		3. License Number(s) 24-32827-01MD	
4. Report Number(s): 2021001			5. Date(s) of Inspection: October 14-20, 2021		
6. Inspector(s): Geoffrey Warren, Sr. HP		7. Program Code(s): 02500	8. Priority: 2	9. Inspection Guidance Used: IP 87127	
10. Licensee Contact Name(s): Khalil Flowers, R.Ph., RSO		11. Licensee E-mail Address: khalil.flowers@sofie.com		12. Licensee Telephone Number(s): 417-889-0400	
13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		<input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		10/14/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced routine inspection performed remotely. The licensee employed three pharmacists and five pharmacy technicians/drivers at this nuclear pharmacy facility. The licensee had around ten regular customers located in southwestern Missouri, and distributed approximately 90 doses each weekday. The pharmacy was open weekdays from around 1 am through 4 pm with limited weekend hours. The licensee's first weekday run was shipped starting around 3 am, with deliveries continuing as needed throughout the day. The licensee received two Mo-99/Tc-99m generators each week for preparation and distribution of Tc-99m pharmaceuticals, and occasionally prepared and distributed diagnostic doses containing Tl-201, Cu-64, I-123, In-111, and other isotopes. In addition, Xe-133 gas vials were received and redistributed. The pharmacy compounded I-131 therapy capsules for distribution; all I-131 material was manipulated and stored in a glove box. While the licensee was authorized to possess a Ge/Ga-68 generator, they had not acquired one at the time of the inspection and had no plans to acquire one. The RSO conducted an annual audit of the program to identify areas for improvement. The maximum dose received by licensee personnel in calendar year 2019 was 377 mrem whole body and 14.6 rem extremity, calendar year 2020 was 259 mrem whole body and 17.8 rem extremity, and January through September 2021 was 279 mrem whole body and 14.0 rem extremity.

Performance Observations: Because the inspection was performed remotely, observation of licensed activities was limited. By camera, the inspector toured the facility and observed licensee staff surveying, breaking down, and cleaning returned packages and pigs, and performing exit surveys from the pharmacy area. Licensee staff demonstrated or described package receipt surveys, tracking of generators, generator elution, molybdenum checks, kit preparation, QA testing of kits, drawing and labeling of doses, wipe surveys of pigs and packages, package survey and preparation, shipping paper preparation, blocking and bracing of packages, delivery of doses, decay in storage and disposal of waste materials, production of I-131 capsules, dose calibrator testing and QC, survey meter QC, training, facility security, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Licensee postings were consistent with survey records.

As a result of the last inspection (IR 2018001), the licensee was cited for the failure to develop certain procedures as committed to in the license application. The inspector verified that the licensee had developed and implemented the procedures and that licensee activities were consistent with these procedures. Based on this, the previous violation is closed.

No violations were identified as a result of this inspection.