

INSPECTION RECORD

Region: III **Inspection Report No.** 2019001

License No. 45-25221-05

Docket No. 030-38113

Licensee: SOFIE Co. d/b/a SOFIE
21000 Atlantic Blvd.
Dulles, VA 20166

Locations Inspected: 8614 NW 107th Terrace, Kansas City, Missouri

Licensee Contact: Todd Heiskell, RSO

Telephone No. 816-801-8544

Program Code: 03210 **Priority:** 2

Type of Inspection: ☐ Initial ☒ Routine ☐ Announced
 ☐ Special ☒ Unannounced

Last Inspection Date: 4/11/17

Date of This Inspection: 4/17/19, with in office review
through 5/14/19

Next Inspection Date: 4/17/21

☒ Normal ☐ Reduced

Summary of Findings and Actions:

- ☐ No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ☐ Non-cited violations (NCVs)
- ☐ Violation(s), Form 591 issued
- ☒ Violation(s), regional letter issued
- ☐ Follow-up on previous violations

Inspector: Kevin Null, Health Physicist

/RA by Aaron McCraw Acting for/
Signature

Date June 7, 2019

Approved: Aaron T. McCraw, Chief, MIB

/RA/
Signature

Date June 7, 2019

PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
10	08/22/2018	Add an authorized user
9	01/17/2017	Change in ownership

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection was conducted on April 11, 2017. No violations of NRC requirements were identified.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

SOFIE Co. was authorized under NRC Materials License No. 45-25221-05 to prepare and distribute radiochemicals to persons authorized by a specific license to receive the material. Licensed material, primarily fluorine-18 (F-18), was produced by a 16 MeV cyclotron. The cyclotron was operated from 12:00 a.m. through about 7:00 a.m., Monday through Friday. Unlabeled F-18 was transferred to six enclosed synthesis units for preparation of radiochemicals.

The radiochemicals were produced under authority of the licensee's NRC Materials License No. 45-25221-05MD. The licensee was staffed by 3 nuclear pharmacists, 1 courier supervisor, 1 production technician, 1 quality control (QC) technician, 1 DOT/packaging technician, and 1 site radiation safety officer/cyclotron engineer. Several cyclotron operators were authorized on the license; however, at the time of the inspection, only one cyclotron operator was present. He was also named on the license as the radiation safety officer (RSO).

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: All

The inspector toured the licensee's main office, including the cyclotron room, the quality control laboratory/hallway where targets were rebuilt, the nuclear pharmacy area where the synthesis units were located, and the exterior of the building where cyclotron effluent was monitored and released. The inspector interviewed the cyclotron operator/RSO and one nuclear pharmacist, and evaluated the facility for security.

The inspector reviewed a selection of records that included licensed material inventory, sealed source leak tests, radiation level surveys and wipe tests of restricted and unrestricted areas, occupational dosimetry, radioactive waste, and effluent monitoring.

Additional in-office inspection activity was conducted through May 14, 2019, to review the license commitments and procedures regarding the control, posting, and surveys of high radiation areas in and around the cyclotron vault.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

During a tour of the facility on April 17, 2019, the inspector performed independent surveys with a RadEye gamma survey meter calibrated on July 30, 2018. The inspector identified radiation levels up to 300 millirem/hour at about 1 foot from a used target source that was being stored behind an L-block shield in the cyclotron hallway. The area was directly adjacent to the cyclotron vault, was posted as a radiation area, and was used to rebuild targets for use in the cyclotron.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector identified two Severity Level IV violations of NRC requirements. The first was a violation of 10 CFR 20.1501(a) for failure to make surveys that are necessary to comply with the regulations in Part 20 and are reasonable to evaluate the magnitude and extent of radiation levels. As noted in item 3 above, the inspector identified that a high radiation level existed in an area adjacent to the cyclotron vault. The elevated radiation levels were from a target that was being stored behind an L-block shield where target rebuilds were performed. The cyclotron engineer had removed a target from the cyclotron vault after midnight on April 17, 2019, and placed it behind the L-block shield for a rebuild. The inspector identified the high radiation levels around 7:30 a.m. on April 17, 2019, while conducting a tour and independent surveys of the facility.

Failure to conduct a survey resulted in a violation of 10 CFR 20.1902(b) for failure to post a high radiation area with a "Caution, High Radiation Area" sign. Based on observations during the tour, the inspector concluded that even though the area was not properly posted there were adequate controls in place to prevent unauthorized access through the presence of trained staff members and secured entry ways into the facility and cyclotron area.

Based on an interview of the engineer, the inspector determined that targets were normally removed from the cyclotron and rebuilt during the day, and then placed back in the vault in a lead storage bunker. Removing the target after midnight on April 17, 2019, was done because the cyclotron engineer was busy during the day on April 16, 2019, performing other duties that included, but were not limited to, providing staff training. The used target could not be placed back in the vault because the cyclotron was running F-18 production after midnight. Due to an oversight, the engineer failed to perform surveys, and therefore did not identify that he had created a high radiation area.

The engineer took immediate corrective action and shielded the target to radiation levels well below 100 millirem/hour. The licensee is evaluating long term corrective actions to prevent recurrence that may include, but not necessarily be limited to, relocating the L-block shield and target rebuild area to the electronics room just outside the cyclotron vault door and posting the area as a high radiation area.

5. PERSONNEL CONTACTED:

- # Todd Heiskell, Cyclotron Engineer/RSO
Mike Roberts, Nuclear Pharmacist
- # Mike Levy, Corporate RSO
- # Attended preliminary exit meeting on April 17, 2019 and final exit meeting on May 14, 2019

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