



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 7, 2019

Mr. Michael Levy
Corporate Radiation Safety Officer
SOFIE Co. d/b/a SOFIE
21000 Atlantic Boulevard
Dulles, VA 20166

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038113/2019001(DNMS) AND
NOTICE OF VIOLATION – SOFIE CO. D/B/A SOFIE

Dear Mr. Levy:

On April 17, 2019, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Kansas City, Missouri facility, with continued in-office review through May 14, 2019. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of procedures and commitments tied down in your NRC license. Mr. Kevin Null of my staff conducted a final exit meeting by telephone with you on May 14, 2019, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations concerned the licensee's failure to perform surveys necessary to comply with NRC regulations, and to evaluate the magnitude and extent of radiation levels, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1501(a). This resulted in the licensee's failure to post a high radiation area, as required by 10 CFR Part 20, Section 20.1902(b). The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the enclosed Notice because the inspector identified them. Because the violations are closely related and share a common root cause, the NRC is citing the violations as one Severity Level IV problem.

The inspector determined that the violations resulted from a one-time change in work process involving target removal and rebuild. Target rebuild was conducted after midnight on April 17, 2019, instead of during the day on April 16, 2019, because of other duties that were being performed by the cyclotron engineer during the day. When targets are processed during the day they are immediately returned to a lead bunker in the cyclotron vault for storage. After midnight on April 17, 2019, the cyclotron was running and the target could not be returned to the vault. Instead, the target was stored behind an L-block shield in the cyclotron work room which created a high radiation area in and around the L-block shield.

To restore compliance, the cyclotron engineer took immediate corrective action to add additional shielding to reduce the radiation levels, and later relocated the target to a more secured, shielded area. During the preliminary exit meeting on April 17, 2019, the cyclotron engineer stated that long-term corrective actions to prevent recurrence would be developed and may include relocating the L-block shield and target rebuild area to the electronics room located directly outside the cyclotron vault door.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made 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>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Null if you have any questions regarding this inspection. Mr. Null can be reached at 630-829-9854.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-38113
License No. 45-25221-05

Enclosure: Notice of Violation

cc w/encl:

1. State of Missouri
2. Todd Heiskell, Site Radiation Safety Officer

Letter to Michael Levy from Aaron McCraw, dated June 7, 2019.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038113/2019001(DNMS) AND
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| OFFICE | RIII-DNMS | C | RIII-DNMS | C | | | | |
| NAME | KNull:brt (via email) | | AMcCraw | | | | | |
| DATE | 6/5/2019 | | 6/7/2019 | | | | | |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

SOFIE Co. d/b/a SOFIE
Dulles, Virginia

License No. 45-25221-05
Docket No. 030-38113

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 17, 2019, with continued in-office review through May 14, 2019, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Pursuant to Title 10 of the *Code of Federal Regulations* (CFR) 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Title 10 CFR 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Contrary to the above, on April 17, 2019, the licensee failed to make surveys necessary for the licensee to comply with 10 CFR 20.1902(b), which required the posting of high radiation areas in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates. Specifically, the licensee did not make radiation level surveys in the area surrounding an L-block shield where a target was being stored. The L-block shield was located on the target rebuild benchtop in the cyclotron hallway.

- B. Title 10 CFR 20.1902(b) states that the licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

Contrary to the above, on April 17, 2019, the area surrounding an L-block shield on the target rebuild bench top in the cyclotron hallway, a high radiation area with a radiation dose rate of approximately 300 millirem in one hour at about 30 centimeters from a radiation source, was not posted with a sign bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

This is a Severity Level IV problem (Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, SOFIE Co. d/b/a SOFIE, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an

Enclosure

adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made 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>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available 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 7th day of June 2019.