



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

August 30, 2023

NOTICE OF SIGNIFICANT LICENSEE MEETING
PREDECISIONAL ENFORCEMENT CONFERENCE

Licensee: SOFIE CO., d/b/a SOFIE

Date & Time: Thursday, September 14, 2023
1:00 p.m. (EST)

Location: U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road, Room 103
King of Prussia, PA, 19406-1415

Purpose: The purpose of this predecisional enforcement conference (PEC) is to discuss three apparent violations identified during the NRC's reactive inspection performed on January 18-19, 2023, and the routine inspection performed on April 19-20, 2023. These apparent violations involved SOFIE's apparent failure to: (1) ensure an occupational extremity exposure for an employee in calendar year 2022 remained within the NRC's annual limits; (2) ensure an employee wore extremity dosimetry while handling radiopharmaceuticals; and (3) restrict access to an area which exceeded 0.002 rem in any one hour. These apparent violations are discussed in NRC Inspection Report 030-32974/2023-001, dated July 5, 2023 (ADAMS Accession No. ML23158A132).

Category: This is an Observation Meeting. This is a meeting in which attendees will have an opportunity to observe a discussion between NRC staff and SOFIE officials regarding the apparent violations. Following the business portion of the meeting, members of the public will have the opportunity to ask questions of the NRC in person or over a teleconference line. Details on the telephone conference line are below.

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

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

Meeting Contact: Anne DeFrancisco, Chief, MLAB, DRSS, RI
(610) 337-5078
Anne.DeFrancisco@nrc.gov

Teleconference: Interested members of the public can participate in this meeting via a toll-free teleconference. For details, please email Anne DeFrancisco at Anne.DeFrancisco@nrc.gov.

Comments: No regulatory decisions will be made during the meeting. The NRC's Policy Statement, "Enhancing Public Participation in NRC Meetings," effective March 19, 2021, applies to this meeting. The policy statement may be found here <https://www.nrc.gov/docs/ML21209A505> and contains information regarding visitors and security.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in this meeting or need this meeting notice or the transcript or other information from the meeting in another format (e.g., braille, large print), please notify the NRC's meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

MEETING AGENDA

PREDECISIONAL ENFORCEMENT CONFERENCE SOFIE Co., d/b/a SOFIE

**Thursday, September 14, 2023,
1:00 PM (EST)**

**NRC Region I
475 Allendale Road – Suite 102
King of Prussia, PA**

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| I. | Opening Remarks & Introductions | P. Krohn |
| II. | Licensee Opening Remarks | SOFIE |
| III. | Overview of Enforcement Process and Policy | C. Crisden |
| IV. | Summary of Apparent Violations | J. vonEhr |
| V. | Licensee Presentation | SOFIE |
| VI. | NRC Questions | NRC Staff |
| VII. | NRC Caucus/Additional Questions | NRC Staff |
| VIII. | Closing Enforcement Remarks | C. Crisden |
| IX. | Public Questions and Comments | All Conference Participants |
| X. | Closing Remarks | P. Krohn/SOFIE |

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 A DeFrancisco, DRSS
 J vonEhr, DRSS
 J Pfingsten, DRSS
 E Spangler, DRSS

DOCUMENT NAME: <https://usnrc.sharepoint.com/teams/Region-I-MLA/Shared Documents/Sofie PEC/SOFIE PEC Meeting Notice.docx> update

ADAMS ACCESSION NUMBER: ADAMS ACCESSION NO. ML23234A184

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NAME	C Crisden	ADeFrancisco	J Nick	
DATE	08/30/2023	08/30/2023	08/30/2023	

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