



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

March 16, 2020

Michael Levy  
Director, Radiation Compliance & Environmental  
Health & Safety and Corporate Radiation Safety  
Officer

SOFIE Co. d/b/a Sofie  
21000 Atlantic Blvd.  
Ste. 730  
Dulles, VA 20166

E-mail to: Michael.levy@sofie.com

SUBJECT: SOFIE CO. REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL  
NO. 616031

Dear Mr. Levy:

This letter is in reference to your letter and application dated September 26, 2019, requesting to renew NRC License No. 45-25221-05. In order to continue our review, we need (1) responses to all of the following items on or before March 23, 2020, or, (2) if you are unable to respond to all items by next Monday, March 23, 2020, responses to as many of the following items as possible AND a statement from you confirming that such responses will be provided within not more than 60 days of this letter (on or before May 15, 2020):

**RADIOACTIVE MATERIAL, INCLUDING PURPOSES FOR WHICH LICENSED MATERIAL  
WILL BE USED:**

1. For any form materials with radionuclides atomic numbers 1 – 83 including nitrogen-13 and fluorine-18, please indicate whether this includes volatile material.
2. For any form materials, limited to incidentally activated products, with atomic numbers 1-83, please indicate whether this includes volatile material.
3. Please provide a maximum per-radionuclide possession limit for each atomic number 1-83 (any form and any, incidentally activated products, form) to be listed on the license.
4. For the authorized use described as "preparation," please confirm that this is actually "production" of a radiochemical. In addition, please describe specifically which radionuclides are being produced, besides nitrogen-13 and fluorine-18, at this time. If needed, you may clarify that additional radionuclides may be produced, in accordance with the request, at a later date.
5. In accordance with NUREG 1556, Volume 21, rev. 1, Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Production

of Radioactive Material Using an Accelerator," dated May 2018, please confirm the statement:

*Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office or assign the records to the appropriate NRC regional office before the license is terminated.*

NUREG 1556, Vol. 21, rev. 1, may be accessed at the NRC's website at <https://www.nrc.gov/docs/ML1814/ML18143A670.pdf>.

6. We are still reviewing your Decommissioning Cost Estimate for financial assurance and will contact you via e-mail when that review is complete. No additional information associated with Financial Assurance is required at this time.

#### **INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**

7. Please provide a Delegation of Authority/Memorandum of Understanding (DOA/MOU) designating Michael Roberts as the Radiation Safety Officer (RSO) and Mr. Roberts' understanding and acceptance of that designation. A model DOA/MOU may be found in NUREG 1556, Vol. 21, rev. 1, p. C-3.
8. Please confirm that Authorized Nuclear Pharmacists (ANPs) to be listed on the license are limited to Jacob M. Goddard, Michael G. Roberts, and Mersed Kermic. (i.e. – please confirm removal of the other ANPs listed on Amendment No. 11 to the referenced license.)
9. To add Mersed Kermic as an ANP, please provide training and experience as outlined in Title 10 of the *Code of Federal Regulations* (CFR) Section 35.55, "Training for an Authorized Nuclear Pharmacist." If the proposed ANP is already listed on another NRC license, please provide the license number. If the proposed ANP is already listed on an Agreement State license, please provide a copy of that license.

Title 10 CFR may be found at the NRC's website:  
<https://www.nrc.gov/reading-rm/doc-collections/cfr/>.

10. Please provide a list of cyclotron operators to be listed on the license. For any cyclotron operators not currently listed on the license, please provide training and experience as requested in NUREG 1556, Vol. 21, rev. 1, Section 8.7.2, "Individuals Authorized to Handle Licensed Material," pp. 8-18 to 8-19.

#### **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**

11. Regarding Instrument Calibration to be conducted by the licensee, please confirm that individuals performing calibrations of radiation survey instruments will complete training including:
  - Classroom and laboratory training in the form of lecture, video, computer-based, or self-study, covering the subject areas: (i) principles and practices of radiation protection; (ii)

radioactivity measurements, monitoring techniques, and the use of radiation detection instruments; (iii) mathematics related to the use and measurement of radioactivity; and (iv) biological effects of radiation; and

- On-the-job training consisting of: (i) observing authorized personnel performing radiation survey instrument calibration; and (ii) conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations.

12. Regarding housekeeping, please describe training that will be provided, as needed.

## **FACILITIES AND EQUIPMENT**

13. Submitted facility diagrams are illegible, unclear, and or lacking sufficient detail for NRC to evaluate the adequacy of shielding, safety equipment, air effluent release, waste storage, and transfer lines. In accordance with NUREG 1556, Vol. 21, rev. 1, Section 8.9 "Item 9: Facilities and Equipment," pp. 8-21 – 8-22, please resubmit or otherwise the following, taking care to expand diagrams to the full 8.5" x 11" paper, sufficient to show details requested:

- A description of the areas assigned for the production, transfer, storage, preparation, shipping, security, and measurement of radioactive materials. Submitted diagrams should show how access is controlled for all restricted areas where radioactive materials will be used or stored or where radiation levels may exceed Public Dose Limits outlined in 10 CFR Part 20. Include a description of where waste storage containers may be held for decay, the types of waste to be stored, and estimated expected volume to be stored. Please also explain how long-lived waste, if any, will be handled.
- A description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. For a sample diagram, please refer to Figure 8-4, "Facility Diagram for a Radioactive Materials Production Facility," in NUREG 1556, Volume 21, rev. 1, p. 8-23. The diagram should show or clarify maximum radiation levels above, below and adjacent to the restricted areas of the facility, whether by calculation or by monitoring data. Include any assumptions with your evaluation. Also indicate whether areas are restricted or unrestricted, in your facility diagram.
- A description and diagram of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne.
- Clarify how lines are monitored for radiation levels including at the exhaust point. In addition, verify that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions under 10 CFR 20.1101(d). Include a description of the instruments that will be used to quantitatively measure the radioactivity in the products, process, and effluents. Also include a description of method(s) that may be used to determine the concentration of

radioactive air effluents that are released in order to demonstrate compliance with the 10 CFR 20.1101(d) constraint on air emissions. For real time monitoring of radioactive air effluents, provide a description of the detector and the methodology that will be used to calculate the air effluent release concentrations. Include the calibration procedures that will be followed to ensure the accuracy of those measurements.

Your verification should include a calculation, sampling data, and/or related methodology to quantitatively demonstrate the adequacy of the ventilation systems for staying within both the dose limits and air emission constraint levels.

*NOTE: For compliance methods for air emissions acceptable to the NRC, see Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors."*

Regulatory Guide 4.20 may be found at the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/reg-guides/environmental-siting/rq/>.

## **RADIATION SAFETY PROGRAM**

14. For radiation-monitoring, instrument specifications, and model survey instrument and air sampler calibration program, please confirm the statement:

*"We will use instruments that meet the radiation-monitoring instrument specifications published in Appendix F of NUREG-1556, Vol. 21, rev. 1, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator.'"*

In the alternative, please describe the facilities where instruments will be used and calibrated, and provide additional details of equal detail as those provided in NUREG 1556, Vol. 21, rev. 1, Appendix F.

15. Regarding occupational dose, please provide:

- the criteria for issuing extremity dosimeters, self-reading dosimeters, and alarming dosimeters.
- A description of how internal doses would be evaluated in a timely fashion if an accidental airborne release were to occur.
- A confirmation of one of the following two statements:

*"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a)." OR*

*"We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by an NVLAP-accredited processor."*

In lieu of these statements, provide a description of an alternative method for demonstrating compliance with the referenced regulations.

16. Regarding surveys and leak tests, please note that references to NUREG 1556, Vol. 21, are no longer current as the volume was updated in 2018 and Appendix numbers have changed. Accordingly, please provide updated statements as referenced in NUREG 1556, Vol. 21, rev. 1, as they relate to surveys and leak tests:

*We will survey our facility and maintain contamination levels in accordance with the radiation survey frequencies and contamination levels published in Appendix J of NUREG-1556, Vol. 21, 'Consolidated Guidance About Material Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator.' AND*

*"We will perform contamination checks on all manufactured sealed sources before distribution. Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Alternatively, we may perform leak tests using a leak-test kit and the kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services. As an alternative to either of these leak test implementation methods, we will implement the model leak-test program published in Appendix K of NUREG 1556, Vol. 21, 'Consolidated Guidance About Material Licenses: Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator.'"*

We will continue our review upon receipt of this information. Please submit your reply to my attention as soon as possible. For fastest processing, please submit your response as a pdf file of a signed and dated letter attached to an email at [sara.forster@nrc.gov](mailto:sara.forster@nrc.gov) or as a signed and dated facsimile letter at 630-515-1078.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document and Management System (ADAMS). ADAMS is accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding this request for additional information, please contact me at 630-829-9892 or [sara.forster@nrc.gov](mailto:sara.forster@nrc.gov).

Sincerely,



Digitally signed by Sara A.  
Forster  
Date: 2020.03.16 16:18:46  
-05'00'

Sara A. Forster, Health Physicist  
Materials Licensing Branch  
Division of Nuclear Materials Safety  
Region III

License No. 45-25221-05  
Docket No. 030-38113  
Mail Control No. 616031

## Song, Taehoon

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**From:** Forster, Sara  
**Sent:** Monday, March 16, 2020 4:30 PM  
**To:** Song, Taehoon; Pavon, Sandy  
**Cc:** Tomczak, Tammy  
**Subject:** FW: Additional Information Needed for SOFIE Co. d/b/a Sofie renewal, NRC License No. 45-25221-01, CN616031  
**Attachments:** 03210.616031.45-25221-05 Request for Additional Information 20200316signed.pdf  
  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi Tae and Sandy,

Could you please put the attached letter into ADAMS? It is a request for additional information for the referenced action.

Thank you!

Sara

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**From:** Forster, Sara  
**Sent:** Monday, March 16, 2020 4:29 PM  
**To:** 'Michael Levy' <Michael.Levy@sofie.com>  
**Subject:** Additional Information Needed for SOFIE Co. d/b/a Sofie renewal, NRC License No. 45-25221-01, CN616031

Dear Mr. Levy:

Thank you for the inquiry.

We have reviewed your renewal application dated September 26, 2019, and have found that additional information is needed in accordance with the attached letter. Please confirm receipt of this request, review the items as requested, and let me know if you have any questions. If you are unable to respond in full, within the next 5 business days, please respond with a signed and dated letter, confirming the date or time period (e.g. 60 days) by which you will provide responses to items outlined in the request.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer  
U.S. Nuclear Regulatory Commission - Region III  
Division of Nuclear Materials Safety  
2443 Warrenville Rd. - Ste. 210  
Lisle, IL 60532-4352  
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