



U.S. NRC Region III
Materials Licensing Branch
2443 Warrenville Road Suite 210
Lisle, IL 60532

September 24, 2019

**RE: Response to NRC Form 699 – Conversation Record dated 23-Sep-2019
Addition of Germanium-68/Gallium-68 Generator
Sofie Network, Inc. d/b/a SOFIE – U.S. NRC RAM license Number 24-32827-01MD**

Licensee name and address:
Sofie Network, Inc. d/b/a Sofie
21000 Atlantic Blvd, Suite 730
Dulles, VA 20166

To Sara Forster:

Sofie Network, Inc. currently licensed under NRC License Number 24-32827-01MD respectfully remits the following information in response to the NRC Form 699 – Conversation record dated 23-Sep-2019:

3. Item 10: Radiation Safety Program

Sofie commits to the following change process for use of the Ge-68/Ga-68 generator:

- After installation, Sofie shall perform the conditioning procedure following the manufacturer's instructions properly disposing of the conditioning eluates prior to the first use of eluate for testing or human use.
- During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be distributed or administered to a patient or human research subject.
- Sofie shall send a written report to the appropriate NRC Regional Office within 30 days after discovery of a generator that is unable to meet the manufacturer's stated breakthrough limits of Ge-68 on multiple occasions rendering the generator unusable in human patients and research subjects.
- Shall shall conduct surveys of all areas of license material use, including the generator storage and kit preparation area, for contamination each day of use.



SOFIE

From start to clinic

We appreciate your assistance with this transaction. If you have any questions about this RAM license application, please contact me at (412) 716-6900 or additionally, please direct all regulatory correspondence to michael.levy@sofie.com

Thank you for your assistance in this process.

Attachments
None

Sincerely,

Michael Levy
Director, Radiation Compliance & Environmental Health & Safety
Sofie Network, Inc.
412-716-6900
Michael.levy@sofie.com

Song, Taehoon

From: Forster, Sara
Sent: Tuesday, September 24, 2019 12:44 PM
To: Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: Amendment Request Addendum RAM Lic #24-32827-01MD
Attachments: Ltr to Reg 3 - 24-Sep-19 (Resp to NRC 699 23-Sep-2019; Adding Ge-68-Ga-68).pdf

Could you please scan in the attached letter and return to me? It is additional information to the license and CN as noted below.

Thank you!

Sara

From: Michael Levy <Michael.Levy@sofie.com>
Sent: Tuesday, September 24, 2019 11:22 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] Amendment Request Addendum RAM Lic #24-32827-01MD

To Sara Forster,

Please see addendum in response to the NRC Form 699 (date 23-Sep-2019, mail control number 615342).

Thank you.

Michael Levy

Director, Environmental Health & Safety

SOFIE

Cell: (412) 716-6900