



05/02/2023

U.S. Nuclear Regulatory Commission- Region III  
Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: Question Regarding our Amendment Request for NRC Materials License No. 24-32462-01MD  
RLS (USA), Inc., 1623 Lotsie Blvd., Overland, MO 63132

Dear Magdalena,

Please allow this letter to serve as my response to your emails received on May 2, 2023, which is attached herewith as Appendix A.

I write to confirm that:

1. The Radiation Safety Officer will receive training on the manufacturer's procedures and the RSO's duties pertaining to the Ge-68/Ga-68 generator use.
2. The Ge-68/Ga-68 generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.
3. The unused generators will be redistributed without opening or altering the manufacturer's packaging.
4. RLS will not open, breach, or physically modify any of the Ge-68/Ga-68 generators in any way.
5. RLS will elute the Ge-68/Ga-68 generators in accordance with the manufacturer's stated frequency and procedures to minimize the concentration of Ge-68 in the eluate.
6. RLS will follow the manufacturer's procedures including Ge-68 breakthrough testing and frequency when in use.
7. In accordance with manufacturers recommendation and RLS's quality policy, the breakthrough of the generator will be measured at least once every 7 calendar days when in use. The first eluate will be discarded if the generator has not been eluted within 48 hours. This is done with the goal not to exceed the manufacturers 0.001 percent of breakthrough limit.

Should you have any additional questions or require additional information, please feel free to contact me personally at (314)-427-6888.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin F. Grant", is positioned above a blue horizontal line.

Kevin F. Grant, R.Ph.

Radiation Safety Officer

RLS (USA), Inc. – Overland, MO Radiopharmacy

Enc. Appendix A : (A) Copy of Email from Magdalena Gryglak

RLS (USA) Inc.  
1623 Lotsie Blvd,  
Overland, MO 63132

# **Appendix A**

Copy of Email from Magdalena Gryglak

**From:** Magdalena Gryglak <[Magdalena.Gryglak@nrc.gov](mailto:Magdalena.Gryglak@nrc.gov)>  
**Sent:** Tuesday, May 2, 2023 1:03 PM  
**To:** Kevin Grant <[kevin.grant@rls.bio](mailto:kevin.grant@rls.bio)>  
**Subject:** Amendment to NRC license no. 24-32462-01MD

Good afternoon Mr. Grant,

I have reviewed the licensee's request dated April 4, 2023 to authorize the Ge68/Ga68 generators.

In a signed and dated letter, please provide the following information:

1. Please confirm that the Radiation Safety Officer will receive training on the manufacturer's procedures and the RSO's duties pertaining to the Ge-68/Ga-68 generator use.
2. Please confirm that the Ge-68/Ga-68 generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.
3. Please confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.
4. Please confirm that you will not open, breach, or physically modify any of the Ge-68/Ga-68 generators in any way. In your letter dated April 4, 2023, you provided the statement specific to only one of the generators.
5. Please confirm that you will elute the Ge-68/Ga-68 generators in accordance with the manufacturer's stated frequency and procedures to minimize the concentration of Ge-68 in the eluate.
6. Please confirm that you will follow the manufacturer's procedures including Ge-68 breakthrough testing and frequency when in use. In your letter dated April 4, 2023, you stated that the breakthrough of the generator will be measured at least once every 7 calendar days when in use. Further, you stated that the first eluate will be discarded if the generator has not been eluted within 48 hours. Please explain whether these limitations are the manufacturer's recommendations or the statements are more restrictive than the manufacturer's recommendations.

Please acknowledge receipt of this email. Please respond by May 22, 2023.

Thank you

**Magdalena R. Gryglak**

**Health Physicist**

**Materials Licensing Branch**

**U.S. NRC Region III**

**630-829-975**

## Martha Pavon

---

**From:** Magdalena Gryglak  
**Sent:** Monday, May 8, 2023 9:18 AM  
**To:** Martha Pavon; Sandy Pavon  
**Subject:** FW: RE: RE: Amendment to NRC license no. 24-32462-01MD  
**Attachments:** MO1 -NRC Response to AddGe-68\_encrypted\_.pdf; 635279 Additional Information dtd 5 2 23 665.pdf

Good morning,

Please place in ADAMS.

Thank you

Magdalena

---

**From:** Kevin Grant <kevin.grant@rls.bio>  
**Sent:** Monday, May 8, 2023 6:46 AM  
**To:** Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>  
**Cc:** RArequest <RArequest@rls.bio>; Pete Mullady <pete.mullady@rls.bio>  
**Subject:** [External\_Sender] RE: RE: Amendment to NRC license no. 24-32462-01MD

Hello Mrs. Gryglak,

Attached is a signed and dated letter to the questions you posed on May 2<sup>nd</sup>. Also attached is a clearer copy of the facility diagram showing the receipt, storage, and use of the Ga68/Ge68 generator.

I have forwarded the email regarding the financial assurance instrument to our regulatory team and will get back to you shortly with a response.

Let me know if you need any further information.

Thank you!



**Kevin Grant, PharmD**  
Radiation Safety Officer

**RLS**

1623 Lotsie Blvd.  
Overland, MO 63132  
United States

**p:** +1 314-427-6888

**e:** [kevin.grant@rls.bio](mailto:kevin.grant@rls.bio)

**w:** rls.bio