



05/03/2023

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. 21-26707-01MD
RLS (USA), Inc., 4380 Brockton SE., Suite 3, Kentwood, MI 49512

Dear Magdalena,

Please allow this letter to serve as my response to your emails received on May 3, 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 (616) 554-5717.

Sincerely,

[Timothy Burke \(May 5, 2023 04:27 EDT\)](#)

Timothy B. Burke, R.Ph.
Radiation Safety Officer
RLS (USA), Inc. – Kentwood, MI Radiopharmacy

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

RLS (USA) Inc.
4380 Brockton SE., Suite 3
Kentwood, MI 49512

Appendix A

Copy of Email from Magdalena Gryglak

From: Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>
Sent: Wednesday, May 3, 2023 2:53 PM
To: Timothy Burke <Timothy.Burke@rls.bio>
Subject: Amendment to NRC license no. 21-26707-01MD

Good afternoon Mr. Burke,

I have reviewed the licensee's request dated April 12, 2023 to authorize the Ge-68/Ga-68 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 12, 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 12, 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






GRR-NRC Response to AddGe-68

Final Audit Report

2023-05-05

Created:	2023-05-04
By:	innocent tsorxe (innocent.tsorxe@rls.bio)
Status:	Signed
Transaction ID:	CBJCHBCAABAAw5cLf5dUGjylIFcPcE-YHr5fN0ukV2k0

"GRR-NRC Response to AddGe-68" History

-  Document created by innocent tsorxe (innocent.tsorxe@rls.bio)
2023-05-04 - 4:17:44 PM GMT
-  Document emailed to Timothy Burke (timothy.burke@rls.bio) for signature
2023-05-04 - 4:18:58 PM GMT
-  Email viewed by Timothy Burke (timothy.burke@rls.bio)
2023-05-05 - 8:27:05 AM GMT
-  Document e-signed by Timothy Burke (timothy.burke@rls.bio)
Signature Date: 2023-05-05 - 8:27:33 AM GMT - Time Source: server
-  Agreement completed.
2023-05-05 - 8:27:33 AM GMT

Martha Pavon

From: Magdalena Gryglak
Sent: Monday, May 8, 2023 10:14 AM
To: Sandy Pavon; Martha Pavon
Subject: FW: Amendment to NRC license no. 21-26707-01MD
Attachments: GRR-NRC Response to AddGe-68 - signed.pdf; 635336 Additional Information 665.pdf

Good morning,

Please place in ADAMS.

Thank you

From: Timothy Burke <timothy.burke@rls.bio>
Sent: Friday, May 5, 2023 3:36 AM
To: Magdalena Gryglak <Magdalena.Gryglak@nrc.gov>
Cc: RArequest <RArequest@rls.bio>
Subject: [External_Sender] Amendment to NRC license no. 21-26707-01MD

Good morning,

Attached is the signed document pertaining to the information listed in your email addressing our amendment for Ge-68/Ga-68 generators.

If you need any more information please don't hesitate to ask. Thank you!



Tim Burke
Nuclear Pharmacist/Radiation Safety Officer

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United States

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