

24 July 2023

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

SUBJECT: Additional Information PharmaLogic Michigan, LLC 21-32190-01MD (Docket 030-35125, CN 635954)

Regarding our request to increase our license limits for Ge/Ga-68 generators, we commit to the following provisions of the most recent licensing guidance as published by the NRC.

Item 6: Radiation Protection Program Changes

We request to incorporate a change process similar to 10 CFR 35.26 that will allow minor changes to our radiation safety program. Such a change process can allow some future changes to radiation safety programs without the need to request a license amendment. Examples of acceptable changes include,

- The revision does not require a license amendment under 10 CFR 35.13;
- The revision is based upon NRC's current guidance for use of the Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;
- The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;
- The affected individuals are instructed on the revised program before the change is implemented;
- We shall retain a record of each change for 5 years; and

- The record will include a copy of the current guidance for use of the Ge-68/Ga-68 generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change

Item 7: Notes for Licensing

7.1 Labeling

Syringes and unit dosages will be labeled in accordance with 10 CFR 35.69 for medical licenses and 10 CFR 32.72(a)(4) for commercial nuclear pharmacy licenses.

7.2 Assay of Dosages

PharmaLogic Michigan commits to assay each patient dosage in the dose calibrator (or instrument) before dispensing it (10 CFR 35.63). We will not dispense a dosage if it does not fall within the prescribed dosage range or if it varies more than $\pm 20\%$ from the prescribed dosage, except as approved by an AU.

Item 7.3 Waste Disposal

Item 7.3.1 Eluate Disposal

Due to breakthrough, the generator eluate may contain small amount of Ge-68 activity, which has a half-life of greater than 120 days (the half-life of Ge-68 is 270.8 days). Depending on the activity of Ge-68, composition of the waste, and state, local, and federal regulations, PharmaLogic Michigan commits to:

- Dispose the waste in accordance with 10 CFR 20.2003; or
- Transfer the waste to an authorized recipient.

Item 7.3.2 Returning Generators to Manufacturer/Distributor

Used generators will be returned to the manufacturer / distributor. This permission does not relieve PharmaLogic Michigan from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations. We commit to perform the following actions when returning a Ge-68/Ga-68 generator:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose-rate and removable-contamination measurements; and;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions. Retain records of receipts and transfers in accordance with 10 CFR 30.51, "Records."

If you require any additional information, please do not hesitate to contact me.

Sincerely,

James P. Nunn, MS, CHP, DABR
MS, CHP, DABR

Digitally signed by James
P. Nunn, MS, CHP, DABR
Date: 2023.07.24 12:30:17
-04'00'

James P. Nunn, MS, CHP, DABR
Senior Medical and Health Physicist
Corporate Radiation Safety Officer
PharmaLogic Holdings, Inc.
5301 North Federal Highway, Suite 280
Boca Raton, Florida 33487
(540) 239-0224 (cell)

Martha Pavon

From: Sara Forster
Sent: Monday, July 24, 2023 12:53 PM
To: Martha Pavon
Subject: FW: Additional Information re PharmaLogic Michigan, L.L.C. amendment, NRC License No. 21-32190-01MD, CN 635954
Attachments: Ge generator RFI CN 635954 signed.pdf

Good afternoon, Martha:

Could you please add the referenced item to ADAMS, and let me know the accession number? It is additional information as noted.

Thank you!

Sara

From: James Nunn <jnunn@radiopharmacy.com>
Sent: Monday, July 24, 2023 11:33 AM
To: Sara Forster <Sara.Forster@nrc.gov>
Cc: Dana Suttle <dsuttle@radiopharmacy.com>
Subject: [External_Sender] RE: Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

Sara,

Please see the attached RFI response. I went ahead and detailed everything rather than just a blanket commitment. I apologize for the confusion, but I would have presumed that all of this information would have been covered when the Ge-Ga generators were initially licensed and this was just an increase in licensed activity and a change of the DCE. Either way, here it is all spelled out. Please let me know if you have any additional questions.

Cheers

James



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From: Sara Forster <Sara.Forster@nrc.gov>
Sent: Wednesday, July 19, 2023 1:09 PM
To: James Nunn <jnunn@radiopharmacy.com>
Subject: RE: Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

Great! It is a pretty straightforward request. A one-page letter should be sufficient.

Sara

From: James Nunn <jnunn@radiopharmacy.com>

Sent: Wednesday, July 19, 2023 11:36 AM

To: Sara Forster <Sara.Forster@nrc.gov>

Subject: [External_Sender] Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

Sarah, I think I understand what you want. Although, that should've all been taken care of with their initial application for that material. Although it is quite possible that that was not taken care of.... Hence the "no changes needed."

James

James P. Nunn, MS, CHP, DABR
Medical and Health Physicist
Corporate Radiation Safety Officer
PharmaLogic Holdings, Inc.
(540) 239-0224 cell

From: Sara Forster <Sara.Forster@nrc.gov>

Sent: Wednesday, July 19, 2023 12:33:38 PM

To: James Nunn <jnunn@radiopharmacy.com>

Subject: RE: Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

Hi, Jim...

I am available for a call on Monday 7/24 or Tuesday 7/25. I apologize for the lack of clarity.

The question is responding to a statement in the application that changes to the Ge/Ga radiation protection program would not be needed. However, there is always a possibility that the program will need to be updated at a future date. There are two options to respond. Either:

1. Provide a signed and dated letter confirming the items in pages 6-7 of NRC's Ge-68/Ga-68 licensing guidance, found at <https://www.nrc.gov/docs/ML1910/ML19106A367.pdf>. A copy of the applicable items is attached to this email message; or
2. If you do not wish to build flexibility for updating the program into the license, please submit an alternative signed and dated letter, stating that the Ge-68/Ga-68 radiation protection program will not be updated absent submitting and receiving approval for an amendment to the license.

Once this letter is received we will be able to amend the license. Please note that we will be in touch soon regarding the submitted decommissioning cost estimate and funding plan. Once that is reviewed and found to be adequate, a financial assurance mechanism will be needed for the license.

If you still need to speak with me following this message, please let me know your availability for Monday & Tuesday of next week.

Sincerely,

Sara A. Forster, Health Physicist
U.S. Nuclear Regulatory Commission - Region III

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From: James Nunn <jnunn@radiopharmacy.com>
Sent: Wednesday, July 19, 2023 11:07 AM
To: Sara Forster <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

Sara,

I caught a little Wi-Fi this morning in Antigua. Would it be acceptable if I called you sometime next week to discuss license amendment? Some of your response didn't make any sense and I just wanted to make sure what you actually need for this amendment.

James

James P. Nunn, MS, CHP, DABR
Medical and Health Physicist
Corporate Radiation Safety Officer
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(540) 239-0224 cell

From: Sara Forster <Sara.Forster@nrc.gov>
Sent: Tuesday, July 18, 2023 7:35:01 AM
To: James Nunn <jnunn@radiopharmacy.com>
Subject: RE: Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

From: James Nunn <jnunn@radiopharmacy.com>
Sent: Sunday, July 16, 2023 8:16 AM
To: Sara Forster <Sara.Forster@nrc.gov>
Subject: [External_Sender] Re: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954

From: Sara Forster <Sara.Forster@nrc.gov>
Sent: Thursday, July 13, 2023 4:38:08 PM
To: James Nunn <jnunn@radiopharmacy.com>
Subject: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954