



June 8, 2020

Sara A. Forster, Health Physicist
Materials Licensing Branch, Division of Nuclear Materials
U.S. NRC, Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Amendment to License 13-32637-01MD, Response to Information Request

Dear Ms. Forster,

We appreciate your review of May 21, 2020 of our amendment application dated March 11, 2020 pertaining to upgrades of our RadioGenix System manufactured by NorthStar Medical Radioisotopes, LLC. We are responding to your request for information as follows:

1. Item 1 of your letter states that NRC cannot accept our request to possess NorthStar Mo-99/Tc-99m activities of 19 curies per source vessel, up to 80 curies total, with our maximum possession activity limited to the approved RadioGenix Safety Evaluation Report (SER).

Response. In place of our request, amend Item 8.L of our license to indicate "Four source vessels not to exceed 10 curies per vessel; 50 curies total."

2. Item 2 of your letter recognizes that NRC specified RadioGenix Model 1.1 in Item 9.L of our current license. The RadioGenix licensing guide states the model should be part of a tie condition and section 10.3.1 of the guide does not indicate the RadioGenix model number.

Response. Upon approval of our amendment request, we plan to upgrade our Model 1.1 system to 1.2, notify NRC within 30 days of the change, and train our staff for the model change, as specified in Item 6 of our application.

3. Item 3 of your letter denies our request to make program changes based on the current, approved RadioGenix SER.

Response. Rephrase Item 3(b) of our request to be consistent to section 7.1(2) of the licensing guide stating, "The revision is based on the current guidance for RadioGenix® System medical use under 10 CFR 35.1000, commercial nuclear pharmacy use posted on the NRC website, or the current operators manual and additional safety recommendations from NorthStar.

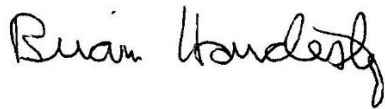
4. Item 4 of your letter mandates conformance with Sections 7 and 8 of the licensing guide.

Response. We are removing any request that is not consistent with the licensing guide. As such:

- We withdraw Item 4 of our application that requests authorization to notify NRC within 30 days of a source vessel activity increase when the change has been approved in a RadioGenix SER.
- We withdraw Item 7 of our application that requests authorization to notify NRC within 30 days when an ANP on our license completes Authorized Individual training.
- We withdraw Item 8 of our application. We will follow Section 8.1 of the NorthStar Medical Radioisotopes, LLC RadioGenix® Molybdenum-99/Technetium-99m Generator System Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies (Jan 2020).

Thank-you for the opportunity to clarify our application to meet NRC expectations. Please let me know if you have any further questions.

Sincerely,

A handwritten signature in black ink that reads "Brian Hardesty". The signature is written in a cursive, flowing style.

Brian Hardesty, RPh, MBA
Vice President / Radiation Safety Officer
Guardian Pharmacy of Indianapolis – Nuclear, LLC
6538 Corporate Drive
Indianapolis, IN 46278

Song, Taehoon

From: Forster, Sara
Sent: Monday, June 08, 2020 1:54 PM
To: Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: RE: Additional Information to Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320
Attachments: ROI NRC RFI-Response Jun 08 2020.pdf

Please Scan the attached document into ADAMS. It is additional information to the referenced action.

Thank you,

Sara

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Monday, June 08, 2020 10:19 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Sara,

Please see my response to your letter dated May 21, 2020.

I look forward to hearing from you.

Thanks,

Brian Hardesty, RPh, MBA
Radiopharmacy of Indianapolis
6538 Corporate Drive
Indianapolis, IN 46278
P: 317-347-0102
F: 317-347-0802

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Saturday, June 6, 2020 10:35 AM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Dear Mr. Hardesty:

Could you please provide an update on the status of your response? We were hoping to finalize this action early this week.

Thank you,

Sara Forster
U.S. NRC

From: Forster, Sara
Sent: Thursday, May 21, 2020 3:08 PM
To: 'Brian Hardesty' <Brian.Hardesty@rpofindy.com>
Subject: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Dear Mr. Hardesty:

Please find attached the documented Request for Information reflecting our May 7, 2020 conversation. Please do not hesitate to contact me if you have any questions concerning this request.

Sincerely yours,

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

sara.forster@nrc.gov

Direct: (630) 829-9892

Facsimile: (630) 515-1078



From: Forster, Sara
Sent: Friday, May 15, 2020 8:48 AM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: RE: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Good morning, Mr. Hardesty. I will send that later today. I apologize for the delay. Thank you for checking in.

Sara Forster

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Friday, May 15, 2020 8:37 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Greetings Sara,

I was wondering if you had sent the written summary you mentioned below. I just want to make sure I did not miss something.

Thank you and have a great weekend.

Brian Hardesty, RPh, MBA
Radiopharmacy of Indianapolis
6538 Corporate Drive
Indianapolis, IN 46278
P: 317-347-0102
F: 317-347-0802

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Saturday, May 9, 2020 10:29 AM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Dear Mr. Hardesty:

Thank you for meeting with me and Cassandra Frazier last Thursday. I will be sending you the written summary of the items we requested via email on Tuesday May 12th or on Wednesday May 13th. Thank you very much.

Sincerely,

Sara Forster
U.S. NRC

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Thursday, May 07, 2020 8:08 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Good morning, Sara. I am ready for your call and can be flexible if you are running late.

Thanks,

Brian Hardesty, RPh, MBA
Radiopharmacy of Indianapolis
6538 Corporate Drive
Indianapolis, IN 46278
P: 317-347-0102
F: 317-347-0802

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Tuesday, May 5, 2020 3:58 PM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: RE: RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Dear Mr. Hardesty:

9 am eastern on Thursday will work. We will call you then.

Thank you for the quick reply,

Sara Forster
U.S. NRC

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Tuesday, May 05, 2020 2:41 PM
To: Forster, Sara <Sara.Forster@nrc.gov>

Subject: [External_Sender] RE: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Sara,

Thanks for the message. Please let me know if 9:00am EST this Thursday still works for your schedule. I can be reached at the pharmacy.

Regards,

Brian Hardesty, RPh, MBA
Radiopharmacy of Indianapolis
6538 Corporate Drive
Indianapolis, IN 46278
P: 317-347-0102
F: 317-347-0802

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Tuesday, May 5, 2020 2:01 PM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: Additional Information Request re Guardian dba ROI, NRC Lic. No. 13-32637-01, CN618320

Dear Mr. Hardesty:

The NRC has reviewed your request for changes to your Northstar Radiogenix program, and has some questions for you. Those questions may require clarification or additional information from you. Accordingly, we would like to set up a phone conference with you to discuss additional information needed to complete our review.

If you could provide your availability for a call for Thursday 5/7 between 6:30 and 8:30 am or after 3:30 pm (central; between 7:30 and 9:30 am eastern or after 4:30 pm eastern), that would be appreciated. If Friday 5/8 would work better for you, please let us know.

Thank you,

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