

Laura Cender

From: Western, Evan <evan.western@cardinalhealth.com>
Sent: Friday, May 19, 2023 1:15 PM
To: Laura Cender
Subject: [External_Sender] RE: RE: RFI Response 34-29200-01MD
Attachments: 230519 Response to RFI 230519.pdf

Ms. Cender,

Please see attached for the requested letter addressing Tara Bernal's handling experience.

Please let me know if you have any additional questions.

Thanks,
Evan



Evan T. Western, CHP
Manager, Health Physics
7000 Cardinal Place, SC6
Dublin, OH 43017
614.553.4555 tel / 614.553.9763 fax

Learner | Analytical | Woo | Individualization | Input

Please note: I will be out on PTO from Tuesday, May 23 through Tuesday, May 30.

From: Laura Cender <Laura.Cender@nrc.gov>
Sent: Friday, May 19, 2023 2:02 PM
To: Western, Evan <evan.western@cardinalhealth.com>
Subject: RE: RE: RFI Response 34-29200-01MD

External Email – Please use caution before opening attachments or clicking links

Hello Evan

Thank you for your prompt response, no need to resend the information below as a formal letter. The information submitted to date is sufficient to move forward with authorizing Janet Frigo and Scott Early as users of the RadioGenix system due to their status of as Authorized Nuclear Pharmacists (ANP's) as outlined in Section 5.1.c of [the NRC's 35.1000 Licensing Guidance for the NorthStar RadioGenix System.](#)

This guidance does allow for non-Authorized Nuclear Pharmacists or 35.200 medical Authorized Users to be named as Authorized Users of the NorthStar RadioGenix system on a case by case basis. I have reviewed the December 18, 2006 letter (attached) outlining the training requirements for non-pharmacists Authorized Users.

Could you please provide a signed letter clarifying the following for Tara Bernal's training and experience:

- Provide a description of typical quantities, types, and forms of radioactive material that Tara Bernal has received training in handling and that would typically be encountered during the course of her normal employment to date.
- Please indicate if Tara Bernal has received the additional 380 hours of training under the supervision of an ANP as described in this letter for non-ANP authorized users who handle radioactive materials for radiopharmaceutical use.

Please let me know if you have any questions.

Thank you,
Laura

From: Western, Evan <evan.western@cardinalhealth.com>
Sent: Thursday, May 18, 2023 11:47 AM
To: Laura Cender <Laura.Cender@nrc.gov>
Subject: [External_Sender] RE: RFI Response 34-29200-01MD

Hi Laura,

Please see below. If you need these responses in a formal letter, I'm happy to provide that as well.

1. Tara Bernal is approved by the Cardinal Health Radiation Safety Committee as a non-pharmacist Authorized User. Janet Frigo and Scott Early are both approved Authorized Nuclear Pharmacists.
2. The model installed at the St. Louis, MO pharmacy will be the RadioGenix model 1.2.

Thanks,
Evan



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From: Laura Cender <Laura.Cender@nrc.gov>
Sent: Wednesday, May 17, 2023 11:00 PM
To: Western, Evan <evan.western@cardinalhealth.com>
Subject: RE: RFI Response 34-29200-01MD

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Hello Evan,

I've reviewed the information that you submitted and have a few additional questions.

1. Please confirm that Janet Frigo, R.Ph., Tara Bernal, and Scott Early are identified as Authorized Nuclear Pharmacists on your license.
2. Please provide the model number for the NorthStar RadioGenix System that is requested. Additionally, please provide the model number for the NorthStar RadioGenix System that is currently in use. The NRC will not include the model number on the license, but under 10 CFR 30.33(a)(3) we are required to document the model that will be possessed and used. I apologize for not including this in my initial information request.

Please let me know if you have any questions.

Thank you,
Laura

From: Western, Evan <evan.western@cardinalhealth.com>
Sent: Tuesday, May 16, 2023 12:28 PM
To: Bryan Parker <Bryan.Parker@nrc.gov>
Subject: [External_Sender] RFI Response 34-29200-01MD

Mr. Parker,

Please find attached Cardinal Health's response to the request for additional information regarding the multi-site nuclear pharmacy license 34-29200-01MD. This is in response to a request via phone from Laura Cender under docket number 030-36973.

Please let me know if you have any questions.

Thanks,
Evan



Evan T. Western, CHP
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