



**RADIOPHARMACY
OF INDIANAPOLIS**

July 11, 2019

US Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Subject: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C.,
Lic. 13-32637-01MD, CN612644

Dear Ms Forster:

In response to your e-mail dated July 9, 2019 (Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN612644) and after re-reviewing the attestations previously submitted by Dr. Weatherman, PharmD, BCNP and Mr. Shamby, RPh, ANP, I have confirmed that Dr. Chad A. Fowler, PharmD has satisfactorily completed the 700-hour structured educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Furthermore, Dr. Fowler is authorized for the types and quantities of material listed on our license.

Thank you for your attention to this matter. Should you have any questions concerning this request, do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Brian Hardesty".

Brian Hardesty, MBA, RPh, ANP
Guardian Pharmacy of Indianapolis, Nuclear LLC (d.b.a. Radiopharmacy of Indianapolis)
Radiations Safety Officer

Song, Taehoon

From: Forster, Sara
Sent: Thursday, July 11, 2019 6:47 AM
To: Song, Taehoon; Sandrik, Lauren; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: RE: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN612644
Attachments: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear LLC Lic 13-3263701MD CN612644 (07112019 BKH).pdf

Please scan in the attached letter. It is additional information to the Guardian Pharmacy of Indianapolis Nuclear, L.L.C., open amendment action, CN612644, Lic. 13-32637-01, Dkt. 030-37428. Thank you!!!

Sara Forster

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Thursday, July 11, 2019 5:28 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN612644

Ms. Forster,

Thanks for the quick and detailed response. Please see the attached per your request..

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, July 9, 2019 12:51 PM
To: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Subject: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN612644

Dear Mr. Hardesty:

We have reviewed your amendment request letter dated June 30, 2019, in accordance with Title 10 of the Code of Federal Regulations Section 35.55, and have found additional information is needed to complete our review, in accordance with requirements specified in 10 CFR 35.55(b), to confirm that the proposed Authorized Nuclear Pharmacist (ANP):

(1) *Has completed 700 hours in a structured educational program consisting of both:*

(i) *200 hours of classroom and laboratory training in the following areas—*

- (A) *Radiation physics and instrumentation;*
- (B) *Radiation protection;*
- (C) *Mathematics pertaining to the use and measurement of radioactivity;*
- (D) *Chemistry of byproduct material for medical use; and*
- (E) *Radiation biology; and*

(ii) *Supervised practical experience in a nuclear pharmacy involving—*

- (A) *Shipping, receiving, and performing related radiation surveys;*
- (B) *Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;*
- (C) *Calculating, assaying, and safely preparing dosages for patients or human research subjects;*
- (D) *Using administrative controls to avoid medical events in the administration of byproduct material; and*
- (E) *Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and*

(2) *Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.*

Although the referenced letter contains details regarding both Mr. Fowler's classroom & laboratory training and practical experience, the submitted preceptor attestation does not meet the requirements in 10 CFR 35.55(b)(2). Accordingly, please submit a preceptor attestation for Mr. Fowler in accordance with that regulatory requirement. The preceptor attestation should confirm that:

"Chad A. Fowler has satisfactorily completed the 700-hour structured educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist."

The attestation must be signed by an ANP, authorized for the types and quantities of material for which you are requesting that Mr. Fowler be authorized for use. Please also include a suffix (Pharm.D., R.Ph.) for Mr. Fowler, as applicable. Please provide your response under a signed and dated letter. You may attach a pdf file version of the scanned-in letter to an email message, and e-mail it directly to me. Upon receipt, we will continue our review. Do not hesitate to call or email me with any additional questions you might have.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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