

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD – SUITE 102 KING OF PRUSSIA, PA 19406-1415

July 14, 2025

Cami Still, Director, Health Physics Cardinal Health P.R. 120, Inc. 7000 Cardinal Place Dublin, OH 43017

SUBJECT: CARDINAL HEALTH P.R. 120, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 647263

Dear Cami Still:

This is in reference to your letter dated June 9, 2025, requesting to amend NRC License No. 34-31473-02MD. In order to continue our review, we need the following additional information:

The supporting documentation submitted to support the authorization for Olga Gonzalez, R.Ph, includes an apparent contradiction. Specifically, the Preceptor Attestation includes a statement regarding the completeness of training identified in 10 CFR 35.55(b)(1). However, the page titled *"Radioisotope Handling Experience"* dated June 9, 2025, does not include any experience noted in Use Category 1, corresponding to *"Ordering, shipping, receiving radioactive materials and performing related radiation surveys."* This use category corresponds to the required supervised practical experience identified in 10 CFR 35.55(b)(1)(ii)(A) (*"Shipping, receiving, and performing related radiation surveys"*).

In response to the above observation, please either: (1) submit additional training documentation showing that the supervised practical experience element in 10 CFR 35.55(b)(1)(ii)(A) has been addressed; (2) submit a corrected copy of the "*Radioisotope Handling Experience*" and provide an explanation for the discrepancy; or (3) withdraw your amendment request. If you withdraw your amendment request, you may re-submit at a later date and refer to Mail Control No. 647263 to address information already provided to the NRC.

We will continue our review upon receipt of this information. Please reply to my attention at:

<u>R1DRSSMail.Resource@nrc.gov</u> Cc: <u>Jason.vonEhr@nrc.gov</u> Reference – Jason vonEhr Mail Control No. 647263

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: <u>www.nrc.gov</u>. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <u>http://www.nrc.gov/materials/miau/med-use-toolkit.html</u>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to the NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all the portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5256 or via electronic mail at <u>Jason.vonEhr@nrc.gov</u>.

Thank you for your cooperation.

Sincerely,

Jason vonEhr, Senior Health Physicist Medical and Licensing Assistance Branch Division of Radiological Safety and Security Region I

License No. 34-31473-02MD Docket No. 030-38569 Mail Control No. 647263

cc: Marco Colberg, R.Ph, Radiation Safety Officer

SUBJECT: CARDINAL HEALTH P.R. 120, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 647263 DATED JULY 14, 2025

SUNSI Review Complete: JEV

After declaring this document "An Official Agency Record" it will be released to the Public.

OFFICE	RI:DRSS		
	Jason vonEhr		
NAME			
	07/14/2025		
DATE			

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