UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

October 20, 2021

Evan T. Western, CHP, Manager, Health Physics
Nuclear & Precision Health Solutions
Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: CARDINAL HEALTH 414, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 627167

Dear Mr. Western:

This is in reference to your application dated June 23, 2021, and subsequent supplemental letter dated July 2, 2021, requesting to renew NRC License No. 34-32780-01. In order to continue our review, we need the following additional information:

1. Your application contained numerous references to “State” regulations, rather than referencing the NRC or using more generic references such as “NRC/State regulations.” Please either revise to your application to reference either the NRC or generalize (e.g. “NRC/State regulations” or “applicable regulatory requirements”).

2. In accordance with Section 8.7., “Individuals(s) Responsible for Radiation Safety Program, and Their Training and Experience” of NUREG-1556, “Consolidated guidance About Materials License, Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator,” volume 21, Revision 1 (NUREG-1556, Vol. 21), submit an organizational chart describing the management structure, reporting paths and flow of authority between executive management and the RSO.

3. In accordance with Section 8.8, “Training for Individuals Working in or Frequenting Restricted Areas,” of NUREG-1556, Vol. 21,

    a. Confirm that authorized users:
        i. Will have a college degree or equivalent experience; and
        ii. A minimum of 6 months of experience with similar types, forms, quantities and uses or radioactive materials before the individual is qualified to be an authorized user. We note that Item 7 of your application states that 120 hours of experience handling curie quantities is required, and 280 hours of cyclotron operation experience. If all authorized users are ALSO cyclotron operators, the total 400 hours of experience is still only 10 weeks, which is less than 6 months of experience.

b. Provide the following:

i. A description of the training for workers other than cyclotron operators and authorized users. Your application Item 7 “Radiation Program Personnel” did not address the training program for ancillary personnel who: (1) are not Authorized Users or cyclotron operators; (2) who may not meet the exposure criteria provided in your application Item 10 “Radiation Safety Program” subitem 3 “Training for Individuals Working In or Frequenting Restricted Areas (Instructions to Workers”); and (3) who may need to work in the vicinity of or with radioactive materials. Such a program must be commensurate with the duties and responsibilities of the group(s) of workers;
ii. A description of how you assess the effectiveness of training;
iii. Qualifications of the instructors; and
iv. The frequency of training.

4. The following items refer to NUREG-1556, Vol. 21, Section 8.9, “Facilities and Equipment,” and your application, Item 9 “Facilities and Equipment,” of your application: Subitems 3-7. Please note that, if you re-submit the information describing the facility in the letters dated November 19, 2019, and February 3, 2020, (both current commitments of your license) with any updated information and addressing the information below, that is also acceptable.

a. Your application references a floor plan and facility layout as Figure 5. The provided diagram is listed as Figure 4. Please confirm if the reference intended to reference Figure 4. If additional figures were intended to be submitted, please provide them.

b. Your application refers to this layout as the “proposed updated” floor plan: if the layout provided in Figure 4 is not the present layout of the facility, provide the current facility diagram. If the provided layout is proposed for the future, please provide the intended renovation timeline.

c. Your application does not state if vault 1 still contains a cyclotron, and the application does not always refer to multiple cyclotrons. Please confirm if a cyclotron is still located, and if it is used, in vault 1. The application further specified that a self-shielded cyclotron is in vault 2. Please describe the type of cyclotron, if any, in vault 1.

d. Item 9 of your application states that the maze to vault 1 contains a storage pit used for decay-in-storage of activated targets or cyclotron components. Item 11 “Waste Management” under “Long Lived Wastes” states that consumable [cyclotron] parts will be isolated inside the cyclotron vault but does not specify which vault. Please provide additional information concerning these practices, including where within the vault(s) such wastes will be segregated; if or how these wastes will be shielded; and how these wastes will be stored so that they do not interfere with the safe operation of the cyclotron or safe access to the cyclotron. Please note that such details may have been present in the provided diagram but were lost in the reduced resolution of the image.

e. The facility diagram does not appear to show the following areas:

   i. Delivery lines from the cyclotron to the hot cells, unless the green lines on the diagram are intended to show the location of the delivery lines. If not, identify the purpose of the green lines shown in Figure 4. Also provide additional information concerning the shielding for the pneumatic transfer line and estimated dose rates.
   ii. Other shielded areas such as hot cells, production units (chemistry, syntheses etc.), waste storage areas, and target re-build work areas.

f. Provide additional information concerning the facility's ceiling above the cyclotron vaults. This information should include estimated or measured radiation levels, any applicable shielding, and whether the roof is a restricted or unrestricted area.

g. Provide a diagram showing the emissions/effluent pathway from the origination points (e.g. the vent hoods) to the facility stack/exit point, and include descriptions, as applicable, of minimum volume flow rates or linear velocities, minimum negative pressure(s), filtration equipment, and effluent monitoring points. The diagram should identify the two zones that are mentioned in your Item 9.6.I "Air Handling Systems." We also note that the description of the ventilation system provided on page 20 is somewhat different than that on page 29 of the application, specifically the described minimum distance above the roof for the fume hood stack. Please clarify whether the hood stack is 5 feet or 6 feet (or a difference distance) from the roof-line.

5. Section 8.10.2, "Radiation Monitoring Instrument," of NUREG-1556, Vol. 21, requests that you both describe the instrumentation that will be used and include the calibration procedures that will be implemented unless an authorized calibration services vendor is used. Some of the required information was provided in Item 7.9, "Equipment" of your application. For each of the following, specify if the manufacturer or licensed commercial calibration vendor will perform the calibration; or if you will perform the calibration, provide the calibration procedures.

   a. Electronic personal dosimeters;
   b. Multichannel analyzer with NaI detector;
   c. Area monitor(s) for real-time exposure rate measurements;
   d. Pocket dosimeters;
   e. Real-time effluent monitors;
   f. Rotometers or other air flow rate or volume measurement instrumentation providing information critical to effluent dose calculations;

6. In accordance with NUREG-1556, Vol. 21, Section 8.10.3, "Material Security and Accountability," confirm that you have procedures for the transfer of licensed materials that include verification of the recipient's license in accordance with 10 CFR 30.41 and maintaining required transfer records in accordance with 10 CFR 30.51(a). Item 10, subitem 11, "Distribution Procedures" of your application does not include this information.

7. NUREG-1556, Section 8.10.4, “Occupational Dose” covers the area of your application that is in Item 10, Subitem 2 “Personnel Monitoring Program." Your application states that finger extremity monitors will be provided to personnel who elute, prepare, assay or dispense millicurie quantities of radioactive material. Confirm that extremity monitors will be provided to anyone who is likely to exceed 10% of the NRC extremity dose limits, such as persons handling millicurie and curie quantities of licensed materials during manufacturing and production activities, such as synthesis and quality control, target re-build or repair activities, waste handling, calibration of effluent monitors, etcetera.

8. The following items refer to NUREG-1556, Vol. 21, Section 8.10.6, “Safe Operating and Emergency Procedures.”

    a. Package receipt procedures are provided in your application, Item 10 “Radiation Safety Program” Subitem 4 “Procedures for Receiving Shipments Containing Radioactive Material:” your procedures place obligations on actions for the common carrier in the event of a wet or damaged package. Please note that the NRC does not regulate common carriers and cannot place the burden of action on these entities. No response to this item is required.

    b. Package opening procedures are provided in your application, Item 10 “Radiation Safety Program” Subitem 5 “Procedures for Safely Opening Packages Containing Radioactive Material.” Although Section 2 states that the MRSO should be contacted and precautions to minimize contamination should be used if certain problems are identified, Section 3 of your procedure does not address the actions which licensee personnel are to take to mitigate and communicate problems identified in steps 5.3.2, and 5.3.4 through 5.3.7. Confirm that you will revise your procedure to include appropriate actions.

    c. Confirm that you will revise Item 10 “Radiation Safety Program,” Subitem 7 “Emergency Procedures:” to address the following:

        i. Your Emergency Procedures referenced above in your application under Item 10 “Radiation Safety Program,” Subitem 7 “Emergency Procedures,” did not discuss any other potential emergencies outside of spills. Additional anticipated emergencies should be explicitly covered such as those involving events such as target material becoming stuck in the transfer lines; failures in the cyclotron or ventilation system that may require radiologically-safety-significant responses; disconnected lines in synthesis or chemistry units, etcetera, during production; target failures and emergencies during target repair or replacement activities; or other such incidents or events that would occur during production of PET radionuclides.
        ii. Actions that should be taken with the spill or other event following the securing of the room (7.2.4); and
        iii. Assessment of exposure [whole body, extremity or internal, as appropriate] to affected staff involved in the event and its mitigation.

9. In your application, Item 10 “Radiation Safety Program,” Subitem 9 “Customer Procedures for Return of Limited Quantity Shipments of Radioactive Materials to Cardinal Health Facilities,” the Memo states that packages may be returned if the amount of radioactive in the package does not exceed 1.6 millicuries. Wee note that the U.S. Department of Transportation’s requirements for limited quantity package activity are radionuclide-specific activity limits (e.g. 10^{-4} the A_2 value for liquids). Provide the basis for your use of 1.6 millicuries without identifying the radionuclide to be returned.

10. NUREG-1556, Vol. 21, Section 8.10.7, “Surveys and Leak Tests” and Appendix J discuss survey requirements and guidance. In your application, Item 10, Subitem 10, “Area Survey Procedures” refers to compliance with the radiation survey procedures of Appendix R of NUREG-1556, Volume 13, which is the guidance for radiopharmacy licenses, and has been superseded by Appendix N in Volume 13, Revision 2. However, it would be best if you referred to guidance in NUREG-1556, Vol. 21 for procedures related to the cyclotron. Confirm that you will survey your facility and maintain contamination levels in accordance with the radiation survey frequencies and contamination levels published in Appendix J of NUREG-1556, Vol. 21. In addition, please note that Step 5 of your Area Survey Procedures does not identify the serial number of the instrument used, to ensure that a calibrated instrument was used.

11. Your application provides Item 10, subitem 12, “Procedures for Packaging and Transporting Radioactive Materials”. However, in Item 10, Subitem 11, “Distribution Procedures”, it states that transportation will be under the nuclear pharmacy license, and that the cyclotron facility will not transport radioactive material. Please confirm whether or not material will be transported under the cyclotron license and confirm that you will revise your Radiation Safety Program to correct the contradictory commitments.

12. Your application provides Item 10, Subitem 13, “Container Labels,” and Subitem 14, “Product Shielding.” Confirm if these sections are intended to be commitments as part of the cyclotron license, or if these sections are only for the nuclear pharmacy license.

13. Item 10, Subitem 8, “Procedures for Returning Radioactive Waste from customers” of your application refers to receiving returned sealed sources from customers, and Item 10, Subitem 11, “Distribution Procedures” refers transfer of sealed sources to other licensees. Confirm that you will revise these sections to delete references to transfer or receipt of returned sealed sources from customers, because these activities are not authorized under this cyclotron license.

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

Betsy Ullrich
Mail Control No. 627167
USNRC, Region I
Division of Radiological Safety and Security
2100 Renaissance Boulevard
King of Prussia, PA 19406

Or you may email a signed pdf copy of your response directly to Elizabeth.Ullrich@nrc.gov

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: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/mat-toolkits.html. This site also provides the link to the toolbox for updated 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 NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all 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 Mr. Jason vonEhr at (610) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Elizabeth Ullrich

Digitally signed by Elizabeth Ullrich
Date: 2021.10.21 08:09:39 -04'00'

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 34-32780-02
Docket No. 030-38331
Mail Control No. 627167

CARDINAL HEALTH 414, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 627167 DATED OCTOBER 21, 2021

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