



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

October 29, 2019

Evan T. Western, CHP, Manager,
Health Physics
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: CARDINAL HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL
CONTROL NO.614053

Dear Mr. Western:

This is in reference to your letters dated July 2 and September 17, 2019, requesting to amend NRC License No. 34-32780-02. In order to continue our review, we need the following additional information:

1. The letter dated July 2 states that the second cyclotron is a General Electric PETtrace 880 machine, and that this model is the same as the existing cyclotron at this location. However, the diagram shows an outline of the second cyclotron, but no comparable outline of a cyclotron is shown in Vault 1; and the construction of Vault 2 is different than Vault 1. The letter further describes the second cyclotron as "in a self-shielding apparatus". Please provide additional information about the similarities and differences in the two cyclotrons, their shielding, their vaults, and their safety systems.
2. Site Description
 - a. Item 9 of Attachment B to the letter dated July 2 states that there are separate HVAC zones for the unrestricted areas and the restricted areas. However, the new cyclotron will be located in an area that is currently unrestricted. Confirm if the HVAC zones will be re-configured for the change of this area from 'unrestricted' to 'restricted'. See also Item 2.f. below.
 - b. Item 9 of Attachment B of the letter dated July 2 describes the release point for the fume hood stack. See also Item 2.f. below.
 - i. Specify the location of this fume hood and describe its use, and if the same fume hood will be used for the second cyclotron facility or if another fume hood will be installed.
 - ii. It appears from the diagrams submitted that there are multiple fume hoods, and from the Decommissioning Funding Plan (DFP) that there are also Hot Cells. It is not clear if these are separate ventilation systems with separate release points from that of the "fume hood stack" described in Attachment B.

- iii. Describe the ventilation release points for the current cyclotron, and for the second proposed cyclotron.
- c. Item 9 of Attachment B of the letter dated July 2 describes the facilities in the Restricted Area.
 - i. Control Room 1 and Control Room 2 are shown on the diagram of the proposed facility. Based on the diagram, it appears that Control Room 1 is the current control room for the existing cyclotron, and Control Room 2 will be for the proposed cyclotron. If this is correct, no further information is necessary.
 - ii. Only one Mechanical Room is shown on the diagram of the proposed facility. Confirm if a single Mechanical Room will be used for both cyclotrons.
 - iii. The "Cyclotron Control Area" does not appear on either the existing facility diagram, or the proposed facility diagram. Explain if this area is different than Control Room 1 and Control Room 2, and if so, where it is located. Also, explain if one cyclotron control area will be used for both cyclotrons, or if each will have their own cyclotron control area.
 - iv. The descriptions refer to a quality control area and DOT area, but neither of these areas are shown on the diagrams. Explain where these areas are located, and if these facilities will be shared by both cyclotrons.
 - v. The Synthesis Area (Production Room) appears from its description to be shared by both cyclotrons. Given the high doses to staff from the current volume of radioactive materials used in that area for production from a single cyclotron, explain if additional hot cells, synthesis units and mini-cells will be added to this room and/or other areas of the facility.
 - vi. Areas shown as "PET Lab" on the existing diagram, and the "Hot Lab" on the proposed diagram, are not described. Please describe these areas and explain their location(s) on the diagrams.
 - vii. The diagram of the proposed facility shows 3-5 doors, other than the access door to the Quarantine Area, that appear to be accessible from the Unrestricted Areas. Explain how these access points will be secured or monitored so that the Restricted Area is maintained.
- d. Item 9 of Attachment B of the July 2 letter states that a storage pit is located in the maze of Vault 1, that is used for decay-in-storage of activated targets and cyclotron components. Confirm if there is sufficient room in this storage pit for targets and components from the second cyclotron or describe alternate waste storage locations and methods for the items from the second cyclotron.
- e. Item 9 of Attachment B of the letter dated July 2 states that radioactive waste is

stored in the "control rooms", the mechanical room, and the cyclotron vault. Please describe the types of wastes that will be stored in these areas and estimate the expected volume given production from two cyclotrons; how waste will be shielded, secured, and contained, especially if it is likely to become airborne; the proximity of waste to workers in the area and how you will maintain their doses ALARA; and how you will ensure that waste storage in these areas will not interfere with necessary work in these areas.

- f. In accordance with NUREG-1556, Volume 21 "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material using an Accelerator" (NUREG-1556, Vol. 21), Section 8.9, "Facilities and Equipment," please provide for the second cyclotron, as well as for the first cyclotron facilities if changes will be made to the existing facilities for the first cyclotron:
 - i. A description and diagrams that show the locations of delivery lines, shielded areas and equipment (hot cells, waste storage, etc.), and the proximity of radiation sources to unrestricted areas and other items related to radiation safety.
 - ii. A diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, fume hoods, etc. Pertinent airflow rates, differential pressures, filtration equipment and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne.
 - iii. Verification that the ventilations systems, with the second additional cyclotron, will ensure that effluents are ALARA, are within the limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).
3. The information for proposed authorized users submitted with the July 2 letter did not include any information about their educational background. As discussed in NUREG-1556, Vol. 21, Section 8.7.2, "Individuals Authorized to Handle Licensed Material," authorized individuals should have (1) a college degree at the Bachelor level or equivalent training and experience in physical, chemical or biological sciences or engineering, and (2) training and experience commensurate with the proposed activities. Please provide information for the proposed authorized users/cyclotron operators related to their college (or equivalent) education.
4. The information submitted with the September 17 letter for the proposed Radiation Safety Officer (RSO) did not include any information about his educational background, or his training related to the job of RSO. As discussed in NUREG-1556, Vol. 21, Section 8.7.1, "Radiation Safety Officer," it is expected that the proposed RSO will have (1) at a minimum, a college degree at the Bachelor level or equivalent training and experience in physical, chemical or biological sciences or engineering, and (2) training and experience commensurate with the proposed activities. Training should include NRC regulations, requirements and standards; a formal course designed for RSOs that is presented by an academic institution, commercial radiation safety consulting company

or a professional organization of radiation protection experts. The individual should also have experience performing the duties of an RSO, which are different than the duties of an authorized user, such as conducting evaluations, surveys and measurements; training individuals; decontamination; investigating incidents and events and determining appropriate corrective actions; and interacting with the NRC and other regulatory agencies. Please provide the following information for the proposed RSO:

- a. His educational background information; a description of formal training for the job of RSO (include topics covered and the duration of training); and his experience in performing the activities of an RSO (this should include a description of the RSO activities performed, the length of time for each, and the location(s) where the experience was gained)
 - b. Contact information (telephone, email and mailing address) for the proposed RSO where the individual can be reached as RSO for this license.
5. Decommissioning Funding Plan (DFP) submitted with the letter dated September 17:
- a. The description of the typical waste products does not describe wastes that will be stored in the cyclotron vault(s), control rooms, or mechanical room. Please note that the DFP should include the expected amount of waste that could be present if the facility were to shut down, and not assume that all waste is offsite. During the recent inspection, it was noted that large quantities of waste were stored in the maze of Vault 1.
 - b. The letter stated that the August 2018 DFP assumed the presence of shielding tanks and water which, in fact, were not in place. These items were removed from the "Cyclotron Vault 1" list of equipment that may contain activated materials, but there does not seem to be any changes to reflect a lesser amount of shielding (additional equipment or change in the volume of estimated contaminated components). Please confirm if additional activated materials should be accounted for, due to the lack of the shielding tanks. If so, please revise the table and cost estimate.
 - c. The listing of component number and dimensions of components such as floors, walls and ceiling are exactly the same for Vault 2 as for Vault 1, except that shielding tanks and water are now listed for Vault 2, and there is no waste storage pit in Vault 2. Confirm that the identical number and dimensions of components are correct, considering the difference in the shielding designs and the configurations of the vault rooms.
 - d. Explain why there is no listing of maintenance or equipment decon areas on your list of components. Typically, there is an area for target cleaning and maintenance, or work with other such activated components. If such an area should be considered when decommissioning, please revise the cost estimate to include that area.

- e. Explain why the amount of time to restore contaminated floors remained the same as on the 2019 cost estimate, considering that the amount of floor volume listed in total for two vaults in the September 2019 cost estimate is double the floor volume as was considered in 2018.
- f. Explain why the 2019 cost estimate does not include clerical costs for site stabilization, as it did in 2018.

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

Betsy Ullrich
Mail Control No. 614053
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

Or

R1DNMSMail.Resource@nrc.gov
Reference – Betsy Ullrich
Mail Control No. 614053

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.

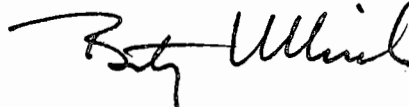
An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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If you have any questions regarding this request for additional information, please contact me at (610) 337-5040 or by electronic mail to Elizabeth.Ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read "Betsy Ullrich". The signature is fluid and cursive, with the first name "Betsy" and last name "Ullrich" clearly distinguishable.

Betsy Ullrich, CHP, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

License No. 34-32780-02
Docket No. 030-38331
Mail Control No. 614053

cc: Arshad Mehmood, Site Supervisor

E. Western

CARDINAL HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL
NO.614053 DATED OCTOBER 29, 2019

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SUNSI Review Complete: Betsy Ullrich

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