

Cardinal Health  
Nuclear Pharmacy Services  
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Dublin, OH 43017  
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Br. 2

July 23, 2010

Licensing Assistance Team  
Division of Nuclear Materials Safety  
U.S. NRC Region I  
475 Allentown Road  
King of Prussia, PA 19406-1415

34-32780-02

L 32780  
03038331  
03210

Re: Application for Radioactive Materials License, Cardinal Health PET Manufacturing Services, East Hartford, CT.

ATTN Licensing:

Cardinal Health Nuclear Pharmacy Services and Manufacturing Services (hereafter Cardinal Health) submits the enclosed application for a Positron Emission Tomography (PET) radiopharmaceutical production Cyclotron Production license, Tax Identification Number [REDACTED]. The cyclotron production facility is located adjacent to the Cardinal Health nuclear pharmacy located at the same address listed on the Cardinal Health U.S. Nuclear Regulatory Commission (NRC) radioactive material license 34-29200-01MD, as follows: 131 East Hartford Street, East Hartford, CT 06108.

The PET cyclotron facility is registered in Connecticut, registration number 01567. The applicable regulatory guidance in NUREG 1556, Volume 21, Cardinal Health is used to provide a description of the activities to be licensed for production of radioactive materials using a particle accelerator, also known as a cyclotron. The production and drug manufacturing processes are linked together for synthesis of radioactive drugs according to the U.S. Food and Drug Administration requirements.

Examples of fostering and maintaining a positive Safety Conscious Work Environment (SCWE) will be used in the supporting documents for the application for the use of radioactive material and all related policies and procedures. In order to prevent a detriment to the customers, health care providers, or adverse health effects for patients, Cardinal Health requests the ability to operate without interruption during your review of this application.

Please refer to the attached delegation of authority for the Corporate Radiation Safety Officer (CRSO) to Willie Regits, Ph.D. If you have any questions regarding this request, please contact Dan Hill at 614.757.5074.

Sincerely,

Willie Regits, Ph.D.  
Corporate Radiation Safety Officer  
Director, Health Physics  
Nuclear Pharmacy Services

Encl: Original + 2 copies  
Amendment Fee \$6500  
Delegation of Authority CRSO

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AUG - 2 AM 10: 34

573262  
NUCLEAR MATERIALS-002

/dh

cc: James Matthews, MRSO, Location 5869  
License File 5869 (2)

This is to acknowledge the receipt of your letter/application dated

7/23/10, and to inform you that the initial processing which includes an administrative review has been performed.

New License Application (03038331)  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 573262.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader