



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

October 3, 2023

Justin Drew
VP, Ambulatory and Clinical Services
Middlesex Health
28 Crescent Street
Middletown, CT 06457

SUBJECT: MIDDLESEX HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637142

Dear Justin Drew:

This is in reference to your application dated September 11, 2023, requesting to renew NRC License No. 06-00649-03. In order to continue our review, we need the following additional information:

The following items are referring to sections in NUREG 1556 Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses, Volume 9, Rev. 3. <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>

1. Section 8.9.5 Other Equipment and Facilities provides licensees with additional information that should be provided relative to the safe use of PET radionuclides and remote after loader facilities.
 - a. Please describe the additional safety measures and equipment that will be utilized to reduce workers exposure to PET radionuclides.
 - b. For your HDR treatment room, please describe and indicate its location within the treatment room:
 - i. Warning systems and restricted area controls (e.g., locks, signs, warning lights & alarms, interlock systems);
 - ii. Area radiation monitoring equipment;
 - iii. Viewing and intercom systems; and
 - iv. Emergency response equipment.
2. Please confirm that you do not possess sealed sources that are not addressed by 10 CFR 35.65, other than your HDR source.
3. Under the submitted High Dose Rate Quality Management Program, Section 2.7 Maintenance Procedures, it indicates that Nucletron is contracted to perform maintenance activities. It does not indicate that you will NOT perform any of these functions. Please confirm that you do NOT perform source installations or maintenance on the HDR unit.
4. The PET radiation survey was conducted on June 21, 2016, and the HDR survey was conducted on February 1, 2017. Please confirm that the workload and occupancy factors used are consistent with current operations and studies.
5. Please confirm that you do not possess a Sr-82/Rb-82 generator.

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. Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be sent by regular mail.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. 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," 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 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 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) 337-5076 or via electronic mail at Robin.Elliott@nrc.gov. Additionally, please note that we have combined your amendment request dated August 2, 2023, to remove the authorization for 10 CFR 35.400 uses with your renewal application; accordingly that change will be reflected on your renewed license.

Thank you for your cooperation.

Sincerely,

Robin L. Elliott, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-00649-03
Docket No. 030-01242
Mail Control No. 637142

cc: Jason Marsden
Radiation Safety Officer

MIDDLESEX HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637142 DATED OCTOBER 3, 2023

DOCUMENT NAME: G:\WBL Documents\WBL License RA\L06-00649-03.637142.docx

SUNSI Review Complete: RElliott

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NAME	RElliott (RLE)						
DATE	10/3/2023						

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