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

August 20, 2024

Oliver Mayorga, M.D.
Chief Medical Officer
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320-4769

SUBJECT: LAWRENCE & MEMORIAL HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 640659

Dear Dr. Mayorga:

This is in reference to your application dated May 7, 2024, requesting to renew NRC License No. 06-09261-01. The specific requests and suggested format for responses to these items may be found in NUREG–1556, Vol. 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In order to continue our review, we need the following additional information:

1. Our records indicated a change of your licensee management representative. Please provide contact information, including a phone number and email address for Richard C. Lisitano, President.

2. Section 8.7.1, Item 7, *Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSOs)* – Please confirm the following:

    a. You have listed the Radiation Safety Officer as Adel Mustafa on your license. Please confirm if Mr. Mustafa is a full-time employee of Lawrence & Memorial as delegated by licensee management.

    b. No response required: The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix I of NUREG-1556, Vol. 9, Rev. 3 also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO. Although, it is not required to be submitted to the Nuclear Regulatory Commission, please be sure to have a Delegation of Authority in your records for the RSO as designated by the licensee representative.

3. Section 8.7.2, Item 7, *Authorized Users (AUs)* – Please provide the following:

    a. Your application lists ten physicians who have 35.200 authorization, without 35.100 authorization as shown. Please indicate if you wish to have them expanded to 35.100. This is not a requirement, but rather acknowledging that 35.200 qualified AUs are automatically considered qualified for 35.100. You may also elect to leave them as-is.

    b. In Item 7.2 of your application, you indicated that you would like to add three new AUs. Your application also indicated that information for the new AUs is provided in attachments 7A and 7B. We received and reviewed your request to add Dr. Ting Chen as an Authorized User on your license, but we did not receive Attachment 7B, as stated, to add Dr. David Zucker to your license or a third AU. Please resubmit the required documentation for any other AUs you would like to add to your license as part of this renewal.

    c. You requested to add Ting Chen, M.D. as an AU for 35.300: Unsealed Byproduct Material–Written Directive Required. For an individual qualifying as an AU by board certification, the board certificate must be issued by a specialty board whose certification process has been recognized by 10 CFR Part 35, Subpart E, as applicable for the use requested. The American Board of Radiology (ABR) board certificate in the area of Interventional Radiology/Diagnostic Radiology that was provided for Dr. Ting Chen is not accepted by the NRC for all of the requested uses under 10 CFR 35.390: Training for Use of Unsealed Byproduct Material for which a Written Directive is Required. More information regarding NRC specialty board certificate recognition can be found on the NRC public website at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html#35290. When an original board certificate is not accepted by the NRC, the "Training and Experience for Proposed Authorized User" pathway on NRC Form 313A (AUT) must be followed. You will not be required to resubmit Form 313A (AUT) with the selection of the third pathway as you have selected both pathways on your form already. In order to add Dr. Ting Chen as an Authorized User on your license for the uses requested, we will not be following the Board Certification pathway but will rather review and accept them under the training and experience pathway upon clarification of the following item:

        i. On NRC Form 313A (AUT), Table 3.a. Training and Experience for Proposed Authorized User, you provided classroom and laboratory training for Dr. Ting Chen including the description, location, hours and dates of training. It appears that 80 hours in five categories equals a total of 400 hours of training, but you have indicated 700 hours of training in those areas. Please confirm how many hours of classroom and laboratory training Dr. Ting Chen completed, in each category and in total. Please note that the requirement for Section 3.a. Classroom and Laboratory Training is 200 hours but 700 total hours including training covered under Section 3.b. Supervised Work Experience.

        ii. Part II – Preceptor Attestation:
            1. Please confirm that Dr. Ting Chen's residency program at the University of Minnesota included 80 hours of classroom and laboratory training, applicable to parenteral administrations listed

in § 35.390(b)(1)(ii)(G)(3).

2. The University of Minnesota has two fellowship programs run by Zuzan Cayci, M.D. – a Nuclear Radiology fellowship and Diagnostic Radiology fellowship. Please indicate which of the two programs Dr. Ting Chen completed.

4. Section 8.8, Item 8, *Training for Individuals Working in or Frequenting Restricted Areas* – Please provide the following full statement:

   "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v)initial training, and (vi) annual refresher training."

5. Section 8.9, Item 9, *Facilities and Equipment* – Please provide the following information:
   a. Please note: Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390."

   b. For the existing/planned Nuclear Medicine Areas at 365 Montauk and existing PET area at 196 Parkway, please submit detailed diagrams of the hot lab, specifically including areas of byproduct preparation, use and storage (i.e. l-block, syringe shields, remote handling devices, equipment used and radioactive waste storage).

   c. You have provided us with specific department room numbers, floor numbers and principal uses of each room for existing and future departments. Please also provide a suite number for each department, if applicable, so that we may differentiate the locations on your license specific to each area. If suite numbers are not applicable, please indicate if you would like us to differentiate the existing and planned areas using floor numbers. Please note, upon approval, both existing and planned areas will appear on your license. Prior to release of the existing Nuclear Medicine Area, you will need to submit an amendment request to decommission and remove the existing Nuclear Medicine Area from your license.

   d. You provided shielding calculations done by Gerald J. Randall in report dated April 25, 2011, for the PET/CT facility at 196 Parkway. Please confirm if there have been any changes in shielding evaluations or workload assumptions since the report. If so, please submit new shielding evaluations and workload assumptions. If no changes, please confirm that the shielding was installed as recommended on the shielding evaluation.

6. Section 8.9.3, Item 9, *Dose Calibrator and Other Dosage Measuring Equipment* – If you are using any alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify any specialized measurement equipment being used and the nationally recognized standard used to calibrate the instruments or provide a copy of the manufacturer's instructions to calibrate the instruments. Alternatively, please confirm if you are not using any alpha emitters where gamma or beta emissions are not

measurable in a traditional dose calibrator.

7. Section 8.9.5, Item 9, *Other Equipment and Facilities* – For the MEDRAD Intego PET Infusion System at 196 Parkway, please confirm following statements:

    a. Please confirm that you will not remove Fluorine-18 (F-18) at any point from the Intego vial shield with the exception of removing decayed vials from the vial shield for quarterly linearity.

    b. Please confirm you will follow all manufacturer instructions for safe operation of the Intego System.

    c. Please provide what quality assurance testing will be performed on the unit and indicate the frequency of the testing.

    d. Please confirm how patient doses will be measured in the case of system failure.

8. Section 8.10.2, Item 10, *Occupational Dose* – Please confirm that you would like to "reserve the right to upgrade your dosimetry processor", as necessary, as long as they are accredited by a National Voluntary Laboratory Accreditation Program (NVLAP) processor.

We will continue our review upon receipt of this information. Please reply to my attention at *hiba.ahmed@nrc.gov* referencing *Mail Control No.* 640659

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 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 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 me at 610-337-5283 or via electronic mail at hiba.ahmed@nrc.gov.

Thank you for your cooperation.

Sincerely,

Hiba Ahmed

Digitally signed by Hiba Ahmed
Date: 2024.08.20 17:14:35 -04'00'

Hiba Ahmed, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-09261-01
Docket No. 030-01275
Mail Control No. 640659

cc: Adel Mustafa, Ph. D., Radiation Safety Officer

LAWRENCE & MEMORIAL HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 640659 DATED AUGUST 20, 2024

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