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

11/23/2022

Rachna Khanna, Administrator
Eastern CT Cardiology Associates, LLC
43 West Middle Turnpike
Manchester, CT 06040

SUBJECT: EASTERN CT CARDIOLOGY ASSOCIATES, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 633355

Dear Ms. Khanna:

This is in reference to your application dated October 11, 2022, requesting to renew NRC License No. 06-30417-01. In order to continue our review, we need the following additional information:

1. For Item 2, Name and Mailing Address of Applicant, an update will be made to the name on your license. On your previous license, the facility name was written as “Eastern CT Cardiology Asociates, LLC,” whereas the facility name on your current renewal application, and on the facility letterhead, is “Eastern CT Cardiology Associates, LLC.” For consistency, the name and mailing address on your renewal license will be updated to “Eastern CT Cardiology Associates, LLC.” No action is required on your part to implement this update.

2. In regard to Item 7, Individuals Responsible for Radiation Safety Program and Their Training and Experience, it appears that the current RSO, Peter Mas, is an outside contractor/consultant. If so, please address the following:

    a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

    b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related requirements.

    c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO, as described in the regulations. State the consultant-RSO’s minimum amount of onsite time (hours per week or days per quarter, as appropriate).

    d. Identify an in-house representative who will serve as the point of contact during the RSO’s absence. This person may be allowed to assist the consultant-RSO in his/her duties. Any such duties should be clearly defined.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the consultant RSO to arrive at the facility, in the event of an emergency that requires his presence.

f. Please assure that a delegation of authority for Mr. Mas is executed: e.g. signed by management and Mr. Mas accepting the responsibility. This can be submitted or, if not, will be examined during inspection.

3. Regarding Item 7, please clarify the requested material and use for each of the authorized users. On your current license, both Parveen Khanna, M.D. and Thomas Knox, M.D. are authorized for both 10 CFR 35.100 and 35.200 use. Please confirm that each authorized user is requesting authorization for both 10 CFR 35.100 and 10 CFR 35.200 uses.

4. In regard to Item 8, Training for Individuals Working in or Frequenting Restricted Areas, please confirm that you "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. For Item 9, Facilities and Equipment, please provide the following:

   a. Label all room numbers, if they exist (e.g., imaging room, hot lab).

   b. Specify which doors are access controlled (i.e., locked) and indicate who has access.

   c. For the Manchester facility, please indicate where byproduct material (e.g., sealed sources, waste for decay-in-storage) is stored.

6. Please confirm that "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations." Additionally, provide a description of the dose calibrator in use at the Manchester location.

7. Regarding Section 8.10.2 of your application, Occupational Dose, you commit that you "will perform and document a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20.1502(a)." Please confirm if you meant to reference the occupational dose limits in 10 CFR 20.1201 rather than 20.1502(a) as these doses are already reduced to 10% of the occupational limit. Additionally, your statements only commit to evaluating the deep dose equivalent for declared pregnant women, whereas 10 CFR 20.1502 also requires that declared pregnant women who are likely to receive an occupational intake in excess of 0.1 rem committed effective dose equivalent are monitored. Please either clarify your submittal to be consistent with the requirements expressed in Section 8.10.2 Occupational Dose of NUREG-1556 Vol.9 Rev. 3, or provide one of the following statements:

a. "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502. **OR**

b. We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"

8. Please confirm that Safe Use of Unsealed Licensed Material procedures described in Section 8.10.14 of your renewal application will be written.

9. Regarding Item 13, Certifying Officer, there is no date of signature on your application. Please confirm that the date the application was prepared is the same as the date on the cover letter. For future licensing actions, please ensure that the application is signed and dated by the certifying officer to confirm their acknowledgement of the current request.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days. When submitting your response, please have Dr. Khanna sign the letter transmitting the information. You may respond to my attention in writing by submitting a letter scanned and attached to an email at **Valerie.Gray@nrc.gov**.

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 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 **1-610-337-5193** or via electronic mail at **Valerie.Gray@nrc.gov**.

Thank you for your cooperation.

Sincerely,

Valerie A. Stowell

Digitally signed by Valerie A. Stowell
Date: 2022.11.23 11:33:53 -05'00'

Valerie Stowell, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 06-30417-01
Docket No. 030-34595
Mail Control No. 633355

cc: Peter J. Mas, RSO
Robin Elliott, Senior Health Physicist

EASTERN CT CARDIOLOGY ASSOCIATES, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 633355 DATED 11/23/2022

DOCUMENT NAME:G:\WBL Documents\WBL License RAI\L06-30417-01.633355.docx
SUNSI Review Complete: V. Stowell
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