

From: [Tran, Frank](#)
To: ["rayacarlson@att.net"](mailto:rayacarlson@att.net)
Subject: Request additional information for NRC License No. 21-26393-01
Date: Wednesday, April 06, 2022 8:24:00 AM
Attachments: [Sample - Delegation of Authority to RSO.docx](#)

Dear Mr. Carlson:

We have reviewed the license renewal application dated March 3, 2022 for NRC License No. 21-26393-01 for Eastlake Cardiovascular, P.C. We reviewed the application in accordance with the NRC regulations and licensing guidance in NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees" which can be found on the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>. It appears that the application were prepared using outdated NUREG-1556, Volumes 1 and 2. Based on the review, we will need the following information.

1. Confirming if the licensee will use Positron Emission Tomography (PET) isotope at its facility. If yes, please provide information of the areas of use, radiation shielding evaluation and any radiation shielding, if applicable.
2. Provide the dimension and/or scale for the facility diagram and a description of the areas above and below. In addition, please indicate if the door from the Hot Lab to the outside is locked or not. Indicate the location where radioactive waste will be stored.
3. Provide a copy of the delegation of authority for the Radiation Safety Officer (RSO). A sample from NUREG-1556, Vol. 9, Rev. 3 is attached for your reference. Provide contact information for the RSO (business phone, email and/or fax).
4. The State of Michigan could not locate the medical license for Marc Gosselin, M.D.; therefore, we could not confirm if his medical license was valid and active. There may be a typo in his name or his professional title (the suffix). Please provide a copy of his medical license issued by the state licensing authority.
5. Provide the following 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."
6. Provide the following statement: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."
7. Provide one of the followings:
 - a. A statement that: "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.”

- b. A statement that: “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.’”
 - c. A description of an alternative method for demonstrating compliance with the NRC regulation in 10 CFR 20.1502.
8. Provide the following statement: “We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; and records of receipt (either from the licensee’s own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.”
9. Please confirm if the licensee will collect and analyze leak test samples. If yes, please provide information discussed in Section 8.10.11, “Leak Tests”, in NUREG-1556, Vol. 9, Rev. 3. If not, provide the following statement: “Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit. leak test.”
10. Provide the following statement: “We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201.”

To continue the review of the application, we request that the licensee submits the response under a dated and signed cover letter by May 6, 2022. In the cover letter, please reference the license number, docket number and Mail Control No. 630395.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Best regards,

Frank Tran

Health Physicist/License Reviewer

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