

From: [Frank Tran](#)
To: [Jim Botti](#)
Subject: Request additional information NRC Materials License No. 21-08966-01 for McLaren Central Michigan
Date: Wednesday, July 10, 2024 9:58:00 AM

Dear Mr. Botti,

This refers to the license renewal application for McLaren Central Michigan (the licensee), NRC Materials License No. 21-08966-01. Based on the licensing guidance in NUREG-1556, Volume 20, Revision 1, the NRC will renew a materials license in its entirety. We will need all information as required in NRC Form 313, "Application for Materials License"; 10 CFR 30.32, "Application for specific licenses"; and the applicable licensing guidance. Based on the proposed licensed materials and use in your application, we reviewed your application in accordance with the licensing guidance in NUREG-1556, Volume 9, Revision 3. An electronic copy of the guidance can be downloaded directly from the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html>. Based on the review, we will need the following.

1. For 10 CFR 35.200 material for imaging and localization studies, please indicate if Positron Emission Tomography (PET) will be used or not. If PET isotopes will be used, provide a facility diagram indicating the room(s) where PET isotopes will be used and radiation shielding evaluations (include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations; a description of surrounding areas and above and below the rooms, including the occupancy factors, and indicate whether the areas are restricted or unrestricted; and a description of any portable shields used (including the dimensions of any portable shield, if one is used; source storage safe); and describe the additional equipment for these uses (syringe radiation shielding, tong, etc.), as applicable. The calculations should include the workload assumptions used.
2. The facility diagram showed one hot lab and imaging room; however, the description described two hot labs (one with a dimension of 12' x 12' and one with a dimension of 4' x 6') and two imaging rooms (one with a dimension of 16' x 23' and one with a dimension of 14' x 10'). In addition, it stated that the facility is a single-story building but it also stated that above and below the imaging suite is medical office space. Please provide the explanation for the discrepancies above.
3. The regulations cited in Section 10.14, "Safe Use of Unsealed Licensed Material" are incorrect (10 CFR 20.1501 and 10 CFR 35.70). It should cite the requirements in 10 CFR 20.1101 and 20.1201. 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."
4. Based on the information provided, the proposed Radiation Safety Officer (RSO) is an outside consultant or contractor. Based on the licensing guidance, please identify an in-house representative who will serve as the point of contact during the RSO's

absence and provide the contact information (work phone and/or email).

To continue the review of your application, we request that you submit your response under a dated and signed cover letter by August 8, 2024. In the cover letter, please reference the license number and Mail Control No. 641395. 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 Title 10 of the *Code of Federal Regulations* (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

Senior Health Physicist/License Reviewer

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References:

NRC Regulations: <https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html>

NUREG-1556 Series: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html>

NRC Forms: <https://www.nrc.gov/reading-rm/doc-collections/forms/index.html>

NRC License Fees: <https://www.nrc.gov/about-nrc/regulatory/licensing/fees.html>