

From: [Frank Tran](mailto:Frank.Tran@nrc.gov)
To: llunampcphysics.com
Cc: megan.miller1@mclaren.org
Subject: Request additional information for NRC Materials License No. 21-04081-03
Date: Friday, April 26, 2024 12:58:00 PM

Dear Laura Luna,

This refers to the license renewal application dated March 21, 2024, for NRC License No. 21-04081-03 for McLaren Oakland. We reviewed the application in accordance with the licensing guidance in NUREG-1556, Volume 9, Rev. 3 and Volume 20, Rev. 1. Based on the NRC policy, a materials license will be renewed in its entirety. Accordingly, we will need the following.

1. The licensee requests to possess and use Y-90 microsphere as permitted by 10 CFR 35.1000; however, we could not locate the information as discussed in the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance dated April 20, 2021 (Revision 10.2). Please provide additional information, as needed, per that guidance. A pdf copy of the guidance can be downloaded from the NRC's website at: <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>.
2. For unsealed and/or sealed licensed materials as permitted by 10 CFR 35.300, 35.400, and 35.1000, please confirm if they will be used for inpatients or outpatients. If they will be used for inpatients, provide the radiation shielding calculations including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used and the description of surrounding areas (indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003) with the occupancy factors.
3. The licensee requests to possess and use licensed materials for manual brachytherapy (as permitted by 10 CFR 35.400). Based on the licensing guidance, provide a description of the emergency response equipment related to the use, as applicable.

To continue the review of the application, we request that you submit your response under a dated and signed cover letter by May 24, 2024. In the cover letter, please reference the license number and Mail Control No. 640164. 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,

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Fax: 630-515-1078
Email: Frank.Tran@nrc.gov



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>
NUREG-1757 Series: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/index.html>
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