

From: [Sara Forster](#)
To: [James Nunn](#)
Subject: Additional Information Request re PharmaLogic Michigan, L.L.C., NRC License No. 21-32190-01MD, CN 635954
Date: Thursday, July 13, 2023 3:38:00 PM

Good afternoon, James:

Our office is in receipt of PharmaLogic Michigan, L.L.C.'s (your) August 1, 2022 application requesting the use of up to 400 millicuries each of germanium-68 and gallium-68. In your request, no request to be authorized to update the program in accordance with updated regulations or revised licensing guidance was included. Further, we have noted your statements that no updates to the program will be needed. Regarding the omission of a request to be able to update the program, please confirm that (1) absent a license amendment, the licensee's radiation protection program, as it relates to Ge-68/Ga-68 generators, will not be updated; or (2) the indicated statements, aligned with those in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.26 and on pages 6-7 of NRC's Ge-68/Ga-68 licensing guidance dated July 2019 will be adhered to. A response to this message is needed to complete the review.

Title 10 CFR Section 35.26 may be found at the NRC's website at:
<https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0026.html>

The guidance regarding Ge-68/Ga-68 generators may be found at the NRC's website at:
<https://www.nrc.gov/docs/ML1910/ML19106A367.pdf>.

Please provide a response via a signed and dated letter within 14 days (on or before July 27, 2023). If you are unable to provide a response before then, please provide a signed and dated letter by that date indicating the date by which you will be able to provide a written response to this request. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me by phone or email.

Sincerely yours,

Sara A. Forster, Health Physicist
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