



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

OCT 07 2019

Bradley A. Ambs, R.Ph.
Radiation Safety Officer
Medi-Physics, Inc. dba GE Healthcare
12300 Hubbard Rd.
Livonia, MI 48150

Dear Mr. Ambs:

We have reviewed your July 5, 2019 request to add a germanium-68/gallium-68 generator authorization to your NRC Radioactive Materials License, NRC License No. 21-24828-01MD. That letter omitted some information needed by our office prior to authorizing the use of germanium-68/gallium-68 generators, including no legally binding generator return agreement with a manufacturer or distributor of Galliapharm™ generators. In addition, no Decommissioning Financial Assurance – as required under Title 10 of the *Code of Federal Regulations* Section 30.35 – has been submitted to our office, in support of this request.

We have attempted to contact you via phone and email starting on September 23, 2019, with no response. Because we were unable to reach you, we spoke with an Authorized Nuclear Pharmacist (ANP) at your facility on September 27, 2019. As discussed with Ms. Twehues, additional information is needed from your company in order to complete our review of the application. To date, we have received no additional information in accordance with our request.

In accordance with our conversation with Ms. Twehues, we have voided your request to add an authorization for the possession and use of germanium-68/gallium-68 generators, under the license. This action is without prejudice to resubmission. However, in resubmitting your request, please be reminded that 10 CFR 30.9 and 30.10 require that information provided to the Commission by a licensee to be complete and accurate in all material aspects. Deliberate submittal of incomplete or inaccurate information that is material to the Commission could subject the licensee to enforcement action.

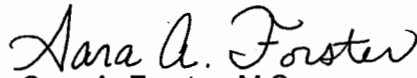
If you have any questions in responding to this request, please call me at the Region III office at (630) 829-9892 so that our office may provide appropriate corrections and answers.

B. Ambs

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

Sincerely,

A handwritten signature in cursive script that reads "Sara A. Forster".

Sara A. Forster, M.S.

Health Physicist

Materials Licensing Branch

License No. 21-24828-01MD
Docket No. 030-29642