

**From:** [Forster, Sara](#)  
**To:** [mark.sitek@bamfhealth.com](mailto:mark.sitek@bamfhealth.com)  
**Subject:** Additional Information to BAMF Health Amendment Request, NRC License No. 21-35632-03MD, CN 631433  
**Date:** Friday, July 15, 2022 9:43:00 AM

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Good morning, Mr. Sitek:

Our office has reviewed the licensee representative's – Matthew DeLong's – May 31, 2022 letter requesting to add an authorization for lutetium-177 for the referenced license. While the letter indicated a requested authorized use for the added radionuclide that was consistent with other radiopharmacy uses listed on the license, the request suggested a possibility that the licensee will use lutetium-177 will to "radiolabel and prepare investigational new drugs." However, the request also indicated that a co-located nuclear medicine clinic, NRC License No. 21-35632-01, is authorized to receive, store, and handle multi-curie amounts of lutetium-177.

To complete our review, could you please confirm that the use of lutetium-177 under the NRC License No. 21-35632-03MD will be limited to preparation and distribution? Please confirm that lutetium-177 use, under the license, will not include radiolabeling using lutetium-177. If radiolabeling is to be authorized under the license, additional details regarding the procedures, facilities and equipment to be used for that purpose will be needed.

you could provide the information within the next 14 days (on or before July 29, 2022), it is appreciated. You may submit your information electronically as a signed and dated letter attached in pdf format, to an email message.

If you have any questions regarding this request, please do not hesitate to call or email me.

Sincerely,

**Sara A. Forster, Health Physicist Licensing Reviewer**

U.S. Nuclear Regulatory Commission - Region III

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