

**From:** [Lawyer, Dennis](#)  
**To:** [Lawyer, Dennis](#)  
**Subject:** FW: RE: US Department of Health and Human Services, Request for Additional Information Concerning Application for a License Amendment, Control 610307  
**Date:** Tuesday, January 15, 2019 5:31:19 AM

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**From:** Malkin, Elon [<mailto:Elon.Malkin@fda.hhs.gov>]  
**Sent:** Wednesday, December 12, 2018 9:18 AM  
**To:** Lawyer, Dennis <[Dennis.Lawyer@nrc.gov](mailto:Dennis.Lawyer@nrc.gov)>  
**Subject:** [External\_Sender] RE: US Department of Health and Human Services, Request for Additional Information Concerning Application for a License Amendment, Control 610307

Hi Dennis,

We are working on getting the statement of intent. But I suspect we wont make the 30 day deadline for response with the SOI included.

I noticed another error on our license:

On our renewal, we requested "4 millicuries per radionuclide and 20 total" for any radionuclide of Plutonium to make sure that we continue to cover Pu-238, Pu-239, Pu-240, Pu-241, and Pu-242.

Item W. only lists Pu-238 and Pu-239. Im pretty item C doesn't cover Pu since it specially states byproduct material.

We also addressed Plutonium on one of our RAI response letters, dated 9/8/2016; "requesting that 4 millicuries per radionuclide and 20 total would cover our inventory and uses"

If it makes life easier, we can reduce the limits from "4 millicuries per radionuclide and 20 total" to "1 millicuries per radionuclide and 5 total"- we just need to make sure we covered for all the isotopes of Plutonium.

Please let me know what additional actions I need to take regarding item W.

Take care

Elon

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**From:** Lawyer, Dennis <[Dennis.Lawyer@nrc.gov](mailto:Dennis.Lawyer@nrc.gov)>  
**Sent:** Thursday, November 15, 2018 10:06 AM  
**To:** Malkin, Elon <[Elon.Malkin@fda.hhs.gov](mailto:Elon.Malkin@fda.hhs.gov)>  
**Subject:** US Department of Health and Human Services, Request for Additional Information Concerning Application for a License Amendment, Control 610307

Dear Dr. Malkin,

This is in reference to your letter dated October 22, 2018, requesting for amendment to Nuclear Regulatory Commission License No. 20-08361-01, Docket No. 03004675. In order to continue our review, we need the following additional information:

1. You have requested to add a location of use to your license. In your application dated May 17, 2016, you stated, "We will use the method of classifying laboratories based on type, toxicity and quantity of byproduct material described in Appendix K of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope." Please state the classification of this laboratory. Also as stated in Section 8.9 of NUREG-1556, Volume 11, Rev 1, "For facilities and equipment used in special applications, such as those described above, the application will include their locations (i.e., buildings and room numbers) and special considerations that the RSC or RSO (or both) will use in authorizing byproduct material use." If this is a special application, then please state the special application and provide the additional information.
2. Your license requires financial assurance. The location you wish to add will be using unsealed radioactive materials and thus requires financial assurance. Please provide an updated Statement of Intent which includes this new location as well as the location in Jamaica, New York. Please confirm that you will include these locations in your next Decommissioning Funding Plan which is due May 9, 2020. Please review if these additional areas might cause a significant cost such that you should recalculate the decommissioning costs.

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office (Address below) and refer to Mail Control No. 610307. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Your reply must be an originally signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application OR amendment request.

Please respond by e-mail to acknowledge that you have received the e-mail request for additional information.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-2713.

Dennis Lawyer  
U.S. NRC Region 1  
Health Physicist

610-337-5366