

## Lawyer, Dennis

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**From:** Lawyer, Dennis  
**Sent:** Wednesday, February 24, 2016 12:19 PM  
**To:** 'michael.noska@fda.hhs.gov'  
**Cc:** Cassata, James  
**Subject:** Request for Additional Info Regarding License Renewal; Lic 19-07538-05; Doc 03031689; Control 588936

License No.: 19-07538-05

Docket No: 03031689

Control No: 588936

Licensee Name: Department of Health and Human Services

RSO: CAPT Michael A. Noska; Office 301-796-8313; business Cell 301-526-7956

CAPT Noska,

Thank you for your reply, dated February 2, 2016, to the first request for additional information. NRC Staff have reviewed your responses and further reviewed your application. Please address the following additional items:

1. Concerning the mailing address listed in Item 2 of the NRC Form 313 dated September 16, 2015, you did not include "White Oak Campus". Since this was included in the past, please either confirm that you desire to have it left out of your mailing address, or alternatively, added.
2. Concerning your statement in your application dated September 16, 2015, under the section labelled "A2. Radiation Safety Committee Charter", subsection "Administrative Changes", please affirm that changes in the Charter that involve commitments made in license and application will require a license amendment prior to the implementation of changes, except those areas where you have been granted the flexibility to make changes to your policies and procedures (such as training, instrumentation, monitoring, procedures for safe handling and emergency response, significant changes to facilities or procedures which involve a potential increase in risk to workers or the general public, changes to the layout of posted areas and the designation of new areas for radioactive material use on the Campus) as long the commitments made in the licensee application and the requirements of Section 8.7.2 of NUREG-1556 Vol 11, 1999, are followed.
3. The last paragraph of Section 7.3 of your application dated September 16, 2015, (which states, "within 30 days of naming a new RSO, we will submit the new RSO's name to the NRC to include in our license") needs clarification. The designation of the RSO is a license condition. Changes to the RSO listed on the license require amendment of the license. The licensee should submit an application for amendment and received a signed copy of the amended license prior to the new RSO taking charge. Please revise statement as necessary.
4. Concerning Section 7.10 of your application dated September 16, 2015, please include a statement after each reference to Regulatory Guide 8.23, that for decommissioning and release of facilities and sites for unrestricted use that NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIIM)", should be followed to meet criteria set forth in 10 CFR 20.1402 .
5. Concerning Section 11.3 of your application dated September 16, 2015, please confirm or state otherwise that the sink drain goes into a public sewer.

6. Please provide the names of the device manufacturers and model numbers that are currently in your possession for any devices using the sources listed on rows F and G of Table 5.1 in your reply dated February 2, 2016.

Note, approval of your financial assurance "Statement of Intent" letter is being reviewed as a separate license action from your application for license renewal. I will be contacting you under separate correspondence concerning that licensing action.

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. 588936. If you have technical questions regarding this letter, please call James Cassata at (610) 337-5303.

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 **10** calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

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.

Thank you for your prompt attention and cooperation.

Dennis Lawyer  
U.S. NRC Region 1  
Health Physicist  
610-337-5366

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

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