

**From:** [Tran, Frank](#)  
**To:** [lxu@endocyte.com](mailto:lxu@endocyte.com)  
**Subject:** Request for additional information regarding the renewal application for NRC License No. 13-32212-01  
**Date:** Friday, February 14, 2020 4:43:00 PM

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Dear Dr. Xu:

We have reviewed the license renewal application for NRC License No. 13-32212-01. We utilized NUREG-1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" in the review of your application. For your references, an electronic copy of NUREG-1556, Volume 7, Revision 1 can be found on the NRC's Web site at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/>. Please note that based on our licensing policy, the nuclear materials license renewal application is independent from all previous submittals. Based on the review, we will need the following.

- 1) Provide a copy of the delegation of authority memorandum for the Radiation Safety Officer (RSO). For your reference, a sample of the memorandum is listed in NUREG-1556, Vol. 7, Rev. 1, Appendix E.
- 2) The application did not provide specific licensed materials and uses for each proposed authorized user. Please provide the specific licensed materials and uses for each user. If there are no changes to their authorization as listed in the previous amendment (No. 18), please state.
- 3) Your application did not address the following licensed material: phosphorus-32, phosphorus-33, sulfur-35, technetium-99, and radium-223. If you have never possessed them, please state. If you possessed them, please confirm that all of them have been properly disposed and you don't currently have any of their residue activities including in decay-in-storage.
- 4) You request to possess and use many radionuclides in any physical and chemical form. Where radioactive materials may become airborne, please provide schematic descriptions of the ventilation systems with pertinent airflow rates, pressures, filtration equipment, and monitoring systems.
- 5) With regarding to the radiation safety refresher training frequency for individuals working in or frequenting restricted areas, NUREG-1556, Vol. 7, Rev. 1, recommends an annual frequency. However, you proposed a radiation safety refresher training every two years. Please provide a justification for choosing the biennial radiation safety refresher training frequency.
- 6) Provide a description of the hands-on training program which will be provided to individuals who will be working with animals that licensed material were administered, including who will provide the instructions. Please see NUREG-1556, Vol. 7, Rev. 1, Appendix D for reference.
- 7) Provide the following statement: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG-1556, Vol.

7, Rev. 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary. Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration."

- 8) Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."
- 9) If you will possess any sealed source containing licensed material (not for use as in a general license device or as exempt quantity source), provide the following statement: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 3 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory." If you will not possess any sealed source under the authorization of this license, please state.
- 10) If the leak test will be required for the sealed sources discussed in Question 8 above, please specify who will perform the leak test and associated information (see NUREG-1556, Vol. 7, Rev. 1, Section 8.10.7, "Surveys and Leak Tests" for reference.)
- 11) Provide a description of how licensed material will be secured at your facility to prevent an unauthorized access and theft.
- 12) Provide the following statement: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG-1556, Vol. 7, Rev. 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

In addition, please address the following:

- a. Item 10.6 (1) stated that the licensee will perform ambient radiation survey to ensure they meet the requirement in 10 CFR 20. It mentioned about a threshold for a dose rate of 32 mR/hr. Please provide a justification for this threshold or a correction if necessary.
- b. Item 10.6 (3) stated that an area with less than 200 microcuries of licensed material was used at one time will be surveyed on a monthly basis. However, NUREG-1556, Vol. 7, Rev. 1, recommends in Appendix M that if a quantity of licensed material equal to or greater than an annual limit for intake (ALI) which has been used at any one time at any particular location, that location should be surveyed daily. For your information, an ALI for I-131 listed in 10 CFR 20 is 50 microcuries. Provide a justification or correction if necessary.
- c. Item 10.6 (4) stated that your criteria for surface contamination for release of facility or equipment is 5000dpm/100cm<sup>2</sup> (average), 15000dpm/100cm<sup>2</sup> (maximum) or 1000dpm/100cm<sup>2</sup> (removable). However, for such as I-125 as authorized in your license NUREG-1556, Vol. 7, Rev. 1, Appendix M, Table M-2 recommends the release criteria as 100dpm/100cm<sup>2</sup> (average), 300dpm/100cm<sup>2</sup> (maximum) or 20dpm/100cm<sup>2</sup> (removable). Provide a

justification or correction if necessary.

- 13) Provide the following statement: "Pursuant to 10 CFR 30.35(g) we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office."

Please provide the response in writing with date and authorized signature by March 13, 2020. To facilitate proper handling of correspondences in our office, please reference Mail Control No. 616030 in your response. For your conveniences, you could fax the response to 630-515-1078. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact me at 630-829-9887 or [frank.tran@nrc.gov](mailto:frank.tran@nrc.gov).

Sincerely,

*Frank Tran*

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