From: Frank Tran
To: jmcever1@emich.edu
Subject: Request additional information for NRC Materials License No. 21-06885-01
Date: Monday, October 3, 2022 11:00:00 AM

Dear Mr. McEvers:

This refers to the license renewal application for Eastern Michigan University, NRC Materials License No. 21-06885-01. We reviewed the application in accordance with the NRC regulations and licensing guidance; specifically, NUREG-1556, Volume 7, Revision 1; Volume 11, Revision 1; and Volume 20, Revision 1. Based on the review, we will need the following information.

1. Your current license is authorized for research and development as specified in 10 CFR 30.4, including using licensed material in/on animals. If you are no longer conducting licensed activities involving animals, please state. If animals will be used, please state and provide information as discussed in Appendix D, “Guidance for Laboratory Animal and Veterinary Medicine Uses”, to NUREG-1556, Vol. 7, Rev. 1. Alternatively, you can commit to develop, implement, and maintain a radiation safety program for the use of licensed material in animals according to Appendix D, “Guidance for Laboratory Animal and Veterinary Medicine Uses”, to NUREG-1556, Vol. 7, Rev. 1.

2. Based on section 8.7.1, “Executive management”, in NUREG-1556, Vol. 11, Rev. 1, provide an organizational chart that describes the management structure, reporting paths, and the flow of authority between executive management and the Radiation Safety Officer (RSO).

3. Provide a copy of the delegation of authority for RSO. For your reference, an example of the memo is in Appendix D of NUREG-1556, Vol. 11, Rev. 1.

4. Submit the criteria used by the RSO to approve new users and uses of byproduct material. Alternatively, you can commit that authorized users (AU) will have at least a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and complete a minimum 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used; the amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated (see section 8.7.2, “Authorized User”, in NUREG-1556, Vol. 7, Rev. 1). State that the licensee will document and maintain records of individuals designated as users for at least 3 years after the individual's last use of licensed material.

5. Submit the criteria which the RSO will use to evaluate the radiation safety aspects of proposed uses from users, prior to approval (e.g., type and quantities of licensed

material use, radiation risks from the use of license material, PPE, facility and equipment, ventilation and effluent releases, radiation monitoring, radioactive waste). For your references, Appendixes E, H, K, and L of NUREG-1556, Vol. 11, Rev. 1 provide more details about the radiation safety aspects in those areas.

6. Describe the training in radiation safety which the licensee will provide to individuals who may working in or frequenting the restricted areas (e.g., ancillary staff, students), if applicable. Provide the method of training (e.g., classroom, virtual, or online) and describe the method for assessing the success of the training (e.g., test with an 80% passing grade).

7. Describe the qualification of individuals who will provide the radiation safety training to others (note: the person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or AU on the license and is familiar with the licensee's program).

8. Section 8.10.1, "Audit and Review of Program", did not specify that an audit or review of the radiation safety program will be conducted. Please confirm that the licensee will conduct periodic assessment of the radiation safety program and will take corrective actions, as necessary, to comply with the NRC license and regulations, including but not limited to 10 CFR 20.1101(b). Provide the frequency the audit will be conducted.

9. Section IV.A.8 of the procedure "Radioactive Waste Held for Decay in Storage Guideline" described the items that will be in the record; however, it did not list all needed items as discussed in the licensing guidance. Please confirm that the licensee will also list in the record the name of radionuclides and the date on which the byproduct material was placed in storage.

10. Section 8.11, "Waste Management", refers to procedures EMU DPS-EHS-P030 and EMU-EHS-P032. Those procedures discussed the methods for disposing radioactive wastes by decay-in-storage and for storing and sending to Environmental Health and Safety. Describe how radioactive wastes which are not permitted to dispose by decay-in-storage will be handled (e.g., transfer to other authorized licenses).

11. If the licensee will review and add new areas for use with licensed material without submitting a license amendment request, please provide information in section 8.9, 'Item 9: Facilities and Equipment", in NUREG-1566, Vol. 11, Rev. 1. If the licensee will not add an area of use prior to the NRC approval, please state.

12. If there will be air effluent release from the laboratories, describe the engineering control and administrative control to maintain ALARA and provide the air effluent release assessment. If there will be no air effluent release from the laboratory because no gaseous or particulate radioactive material will be released, please state.

To continue the review of your application, we request that you submit your response under

a dated and signed cover letter by October 31, 2022. In the cover letter, please reference Mail Control No. 631504. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Best regards,

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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

References:

NRC Regulations: https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html
NUREG-1556 Series: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html
NUREG-1757: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/index.html