UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

September 10, 2021

Donald Conner, Jr. BS, MA
Unviersity RSO, LSO, Off-Site Safety Coordinator
Virginia Tech University
Environmental Health and Safety
575 Beamer Way
Blacksburg, VA 24061

SUBJECT: VIRGINIA TECH UNIVERSITY, ENVIRONMENTAL HEALTH AND SAFETY, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 628219

Dear Mr. Conner:

This is in reference to your application dated August 12, 2021, requesting for a new NRC License of broad scope. Please note the NRC does not usually issue a license of broad scope to a new applicant. However, given that you are authorized by a license of broad scope in the Commonwealth of Virginia, we are proceeding with the review as a broad scope license applicant. Some of the items referenced below refer to NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses of Broad Scope", February 2017 (NUREG-1556, Vol. 11, Rev.1) which can be found online at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/index.html. In order to continue our review, we need the following additional information:

1. When submitting your response, and any future license amendments, please have the document signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein.

2. Item 2 of your NRC Form 313 provided the name of the applicant as "Virginia Tech University, Environmental Health and Safety." Please clarify the legal name of the applicant. A radioactive materials license 121-225-1, issued by the Commonwealth of Virginia, lists the name of the licensee as "Virginia Polytechnic Institute & State University." In addition, if license 121-225-1 is not your corresponding Commonwealth of Virginia license, please provide a copy of your Agreement State license.

3. Item 3 of your application states that the location of use will be at the Children's National Hospital, Innovation Campus, Virginia Tech – Level 6, 7144 13th Place NW, Washington DC.

    a. Please confirm the correct name of the location where you will be working with materials. Based on an internet search, It appears that the correct name may be "Children's National Research & Innovation Campus."

b. The Children's National Hospital possesses a medical license of broad scope from the NRC. Confirm if activities under their NRC license, or any other licensed entity performing activities with NRC-regulated material, also occur at the Innovation Campus. If so, describe how you will maintain separate facilities and control of licensed materials received, transferred, and disposed of, separately from any other licensed entity at the Innovation Campus.

4. Item 5.A of the application referenced the definition for research and development from 12VAC5-481-10. Please note that research and development authorized under an NRC license will fall under the definition in 10 CFR 30.4. No response is necessary to this item.

5. Item 5.B of the application requested any radionuclide with atomic numbers 1 through 83, as sealed sources or foils, 250 millicuries per source and 4 curies total.

   a. This quantity and form of licensed materials is encompassed by the requested form "any" in Item 5.A. Explain why a separate line item for sealed sources is required, when the quantities per source do not exceed those in "any" form. In addition, explain why 4 curies of such sealed sources would be required for the research you expect to perform under the requested license. Alternately, you may amend your request for sealed sources.

   b. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.5.1, "Unsealed or Sealed Byproduct Material," provide the manufacturer's name and model number for each requested sealed source and device so that the NRC can verify that they have been evaluated in a SSD registration certificate or specifically approved on a license. For sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must have adequate training and experience and facilities and equipment to handle comparable quantities of material in any form under 10 CFR 30.33(a)(2) and (3) and must provide information about the unregistered sealed sources and devices in accordance with 10 CFR 30.32(g)(4)

6. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," provide:

   a. the statement for maintaining records important to decommissioning; and

   b. the required financial assurance for the materials for which you requested authorization. Please note that there are a variety of ways to adjust your requested authorized materials that will affect the amount of financial assurance required, or eliminate the need for financial assurance.

7. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.7.1, "Executive Management," provide an organization chart that describes the management structure, reporting paths, and the flow of authority between executive management, the RSC, and the RSO. Although your description of the RSC references an organization chart contained in Appendix 1 of your Radioactive Material Safety Program, this Appendix was not part of your license application.

8. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.7.2 “Radiation Safety Committee,” please provide additional information:

    a. Criteria for selecting members of the RSC, including what members and the number of members which constitute a quorum;

    b. criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses; and

    c. confirm if you are requesting the authorization for flexibility to make certain program changes and revise select procedures previously approved by the NRC without a license amendment. If so, additional information should be provided concerning a description of:

        i. Review and approval of permitted program and procedural changes prior to implementation;
        ii. Implementation of program and procedural changes;
        iii. Audit of licensed operations to determine compliance;
        iv. Appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence; and
        v. The process for procedure and program review and approval, including documentation of the specific change (At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.).

9. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.7.3, “Radiation Safety Office,” submit a statement delineating the RSO’s duties and responsibilities, and a radiation safety officer delegation of authority memorandum signed by the licensee’s executive management.

10. Item 8 of your license application “Training for Individuals Working In or Frequenting Restricted Areas” briefly described your training program only for all individuals working with radioisotopes in laboratories. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 8.8,

    a. describe the training for other groups of workers who may work in the vicinity of licensed materials, such as other laboratory workers; ancillary workers such as maintenance and housekeeping staff; and radiation safety staff members.

    b. describe the method of training and the frequency of training and/or refresher training for each group of workers. This training program may be required at any regular periodicity (e.g. annually), or if individuals who are absent from applicable laboratories after a period of time would be required to re-take this training prior to working with these laboratories again.

    c. Confirm if you are requesting the authorization for flexibility to make changes to this training program without a license amendment. If so, please describe the process that will be used to revise and implement the submitted training programs.

11. Item No. 9 of your license application “Facilities and Equipment” describes the address for your proposed location(s) of use and includes a commitment regarding security.

    a. Provide additional information delineating your space in the Innovation Center, such as the floors(s) on which you will be located (Level 6 may or may not be the 6th floor); the approximate size (number of laboratories etc) that you will have and the number of expected labs in which licensed materials will be used; the location of receipt, storage and/or disposal facilities for material if it is other than within your Level 6 space; and any other pertinent description of the potential locations where licensed materials may be approved for use under this license.

    b. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 9, “Facilities and Equipment, “ describe the criteria the RSC will use to review and approve facilities and equipment (e.g. research laboratories, waste storage facilities, survey and counting equipment, etc.). The description must include the method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. A description or sample diagrams should be provided for facilities where radioactive materials may become airborne, with a description of the ventilations system(s).

    c. In accordance with NUREG-1556, Vol. 11, Rev. 1, Section 9, “Facilities and Equipment, “ describe facilities used in special applications, such as synthesis of labelled compounds, areas where licensed materials may become airborne, hot cells, waste treatment, or animal research and housing. Item 5 of your application requested authorization for research and development, including animal studies. In accordance with NUREG-1556, Volume 11, Revision 1, Section 8.9, please provide additional information include specific locations and a description of the animal handling and housing facilities sufficient to address the applicable sections of NUREG-1556, Volume 7, Revision 1, Section 8.9 “Facilities and Equipment” and “Contamination Control” in Volume 7’s Appendix D “Guidance for Laboratory Animal and Veterinary Medicine Uses.” A link to that document is: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html .

12. The application contained a portion of your “Radioactive Material Safety Program” but was not sufficient to meet the requirements of our guidance for broad scope license. Rather than submit the document in full, please review NUREG-1556, Vol. 11, Rev. 1, Section 8.10 “Radiation Safety Program,” and provide the information requested in the “Response from Applicant” in each sub-section. You may also use Appendix B “Suggested Format For Providing Information Requested in Items 5 through 11 of U.S. Nuclear Regulatory Commission Form 313.” Responsive information may be contained in your Radioactive Material Safety Program, of which only the first pages were included in your application. You may choose to submit the responsive portions of this document. If you choose to provide the document in its entirety, note that the entire document will be listed as a commitment of the license and any revision of the document will require amendment of the license. If the entire document is provided, clearly label or otherwise call out the responsive sections to each pertinent request.

13. In accordance with Section 8.11, “Waste Management,” provide the procedures for waste collection, storage, and the disposal by any of the authorized methods described in that section.

We will continue our review upon receipt of this information. Please reply to my attention at:

Betsy Ullrich
Mail Control No. 628219
USNRC, Region I
Division of Radiological Safety and Security
2100 Renaissance Boulevard
King of Prussia, PA 19406

Alternately, you may attach a pdf copy of a signed response to my attention at Elizabeth.Ullrich@nrc.gov. Please reference Mail Control No. 628219.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/mat-toolkits.html. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5040 or via electronic mail at Elizabeth.Ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

Elizabeth Ullrich

Digitally signed by Elizabeth Ullrich
Date: 2021.09.10 10:44:51 -04'00'

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 45-35651-01
Docket No. 030-39283
Mail Control No. 628219

VIRGINIA TECH UNIVERSITY, ENVIRONMENTAL HEALTH AND SAFETY, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 628219 DATED SEPTEMBER 10, 2021

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DATE	09/10/2021 (JEV)				9/10/21 exu			

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