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

July 21, 2021

Nasser Razmianfar, Director
and Radiation Safety Officer
West Virginia University
64 Medical Center Drive
P. O. Box 9006
Morgantown, WV 26506-9006

SUBJECT: WEST VIRGINIA UNIVERSITY, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 624989

Dear Mr. Razmianfar:

This is in reference to your application dated March 8, 2021, requesting to renew NRC License No. 47-23035-01. In order to continue our review, we need the following additional information:

1. Item 3 of your application, "Address Where Licensed Material Will be Used or Possessed," lists only the West Virginia University Morgantown Campus as a location of use. Amendment 27 of your license lists the following locations of use: WVU Downtown Campus, WVU Evansdale Campus, WVU Health Sciences Campus, and WVU Farm.

    a. Please confirm if licensed activities are being conducted at the locations of use listed in Amendment 27 of your license. Also, provide a more complete description of each location of use including the address, city and state or a more descriptive address.

    b. If the locations of use are to be released for unrestricted use, documentation must be provided showing that the locations of use meet the release criteria established by the Commission. This action should be submitted as an amendment separate from this renewal action.

    c. If you are adding locations of use, then provide a complete description of each location of use including the address, city, state or a more descriptive location.

2. Item 5, "Radioactive Material" of your application requests an increase in your possession limit for Subitem 6.A. of your license from 1,000 millicuries total to 500 millicuries per radionuclide and 4,000 millicuries total.

    a. Please confirm and provide the reason for the requested increase.

    b. The following isotopes, which were not requested in your application, will be delisted from the license and will come under the authorization of Subitem 6.A.:

        i. 500 millicuries of Phosphorus-32,
        ii. 300 millicuries of Phosphorus-33,

iii. 500 millicuries of Sulfur-35,
iv. 300 millicuries of Chromium-51,
v. 10 millicuries of Rubidium-86,
vi. 100 millicuries of Technetium-99m,
vii. 50 millicuries of Tin-125,
viii. 500 millicuries of Iodine-125,
ix. 100 millicuries of Iodine-131, and
x. 60 millicuries of Tellurium-129.

c. Please confirm that you will administratively restrict possession of quantities of licensed material so that you would not require consideration of the need for an emergency plan for responding to a release. For combinations of licensed materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each licensed material authorized to the quantity listed for that material in 10 CFR 30.72 Schedule C exceeds one.

3. Item 7, “Executive Management,” Section 8.7.1 of NUREG-1556, Volume 11, Revision 1 requires a description of administrative controls and provisions relating to organization, management, and management review necessary to ensure safe operations. It does not appear this information was included in your renewal application. Please describe the controls and provisions related to organization, management, and management review used to ensure safe operations.

4. Item 7, “radiation Safety Committee,” Section 8.7.2 of NUREG-1556, Volume 11, Revision 1 requests a description of the duties and responsibilities of the Radiation Safety Committee (RSC). It does not appear that the information was included in your renewal application.

a. If you do not want authorization to have flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license. Please describe the duties and responsibilities of the RSC.

b. If you want authorization for the above flexibility, then you will need to provide the following:

i. A description of the duties and responsibilities of the RSC including the following:

1. Review and approval of the permitted program and procedural changes prior to implementation,

2. Implementation of program and procedural changes,

3. Audit of licensed operations to determine compliance, and

4. The appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

ii. A description of 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.)

5. Item 8, "Training for Individuals Working in or Frequenting Restricted Areas," Section 8.8 of NUREG-1556, Volume 11, Revision 1 requests a description of the process that will be used to revise and implement the submitted training programs by the RSC. It does not appear that this information was submitted with your license renewal application. Please describe the process that will be used to revise and implement the submitted training programs by the RSC.

6. Item 8, "Training for Individuals Working in or Frequenting Restricted Areas," Section 8.8g of NUREG-1556, Volume 11, Revision 1 requests a description of the minimum required training and experience that a person must have before being an Authorized User or Principal Investigator. It does not appear that this information was included in your renewal application. Please describe the minimum required training and experience that a person must have before being an Authorized User or Principal Investigator.

7. Item 8, "Training for Individuals Working in or Frequenting Restricted Areas" states that you will implement the model training program described in Appendix F of NUREG-1556, Volume 7. Please confirm that you are implementing the model training program from Appendix F of NUREG-1556, Volume 7, Revision 1.

8. Item 9, "Facilities and Equipment," Section 8.9 of NUREG-1556, Volume 11, Revision 1 requests a description of the criteria the RSC and/or the Radiation Safety Officer (RSO) will use to review and approve facilities and equipment. It does not appear that this information was included in your renewal application. Describe the criteria the RSC and/or the RSO will use to review and approve facilities and equipment.

9. Item 10, "Audit Program," Section 8.10.2 of NUREG-1556, Volume 11, Revision 1 states that no submittal of the audit program is required. However, it is requested that the applicant describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised as well as the RSC's involvement in this oversight mechanism. Also, it is requested that the applicant describe the audit mechanism implemented by the RSO and/or RSC to determine user compliance with NRC regulations, the NRC license, and good health practices. It does not appear that this information was included in your renewal application. Please describe the mechanisms executive management uses to ensure adequate oversight of the program. Specifically, describe the RSC's involvement in these oversight mechanisms and the audit mechanism implemented by the RSO and/or RSC to determine user compliance with NRC regulations, the NRC license, and good health practices.

In addition, please state whether you request the flexibility to revise the audit mechanism implemented by the RSO without amendment to the license. If you wish to request the flexibility, describe the process they will use to revise and implement the audit program.

10. Item 10, “Radiation Monitoring Instruments,” Section 8.10.12 of NUREG-1556, Volume 11, Revision 1 requests a description of how the RSC and/or the RSO will ensure that instruments are properly calibrated at the prescribed frequencies. It does not appear this information was included in your renewal application. Please describe how the RSC and/or RSO will ensure that instruments are properly calibrated at the prescribed frequencies.

    In addition, please state whether you request the flexibility to revise instrument specifications and procedure for calibration of instruments without amendment of the license. If you wish to request the flexibility, describe the process that will be used to revise and implement the submitted procedures.

11. Item 10, “Radiation Monitoring Instruments,” Section 8.10.12 of NUREG-1556, Volume 11, Revision 1 requests that you state the frequency at which instruments will be calibrated. It does not appear that this information was included in your renewal application. Please state the frequency at which instruments will be calibrated.

12. Please confirm the following statement from Item 10, “Material Receipt and Accountability,” Section 8.10.3 of NUREG-1556, Volume 11, Revision 1: “We will develop, implement, and maintain procedures for ensuring accountability of licensed material at all times.”

13. Item 10, “Material Receipt and Accountability,” Section 8.10.3 of NUREG-1556, Volume 11, Revision 1 requests a description of the administrative controls and provisions related to materials control, accounting, and security. It does not appear that this information was include in your renewal application. Please describe the administrative controls and provisions related to materials control, accountability, and security.

14. Please revise your statement to reflect the correct Appendix of Item 10, “Surveys,”: “We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and the contamination levels published in Appendix L of NUREG-1445, Volume 11, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.””

15. Please confirm the following: “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 Regional Office.”

16. Upon completion of the renewal of your license, certain issues regarding your financial assurance submittal will need to be addressed which may change based on your

responses to this Request for Additional Information. Please note the following:

a. The Certification of Financial Assurance enclosed with the license renewal application does not list all of the isotopes that are listed as "any" form with a half-life of greater than 120 days. If there are no changes in your requested licensed material, Germanium-68 at 10 millicuries would need to be added to the Certification of Financial Assurance.

b. The Statement of Intent enclosed with the license renewal application lists only the facilities at 64 Medical Center Drive, Morgantown, WV. The license renewal application indicates that the location of use is the West Virginia University Morgantown Campus. Amendment 27 of your license indicates the locations of use are WVU Evansdale Campus, WVU Downtown Campus, WVU Health Sciences Campus, and the WVU Farm. Once the discrepancy is resolved, it will be determined if the Statement of Intent needs to be revised.

c. The increase in the possession limit of Sodium-22 and the addition of Iron-55 and Germanium-68 in "any" form to your license will require the submission of a Decommissioning Funding Plan (DFP) if not addressed during the license renewal process. A DFP is required when the possession limit of the requested licensed material is greater than 10^5 times the value of Appendix B of 10 CFR Part 30. In the case of multiple isotopes being requested, the sum of the fractions as outlined in the notes to Appendix B of Part 30 which is called "The Unity Rule" is used. You may choose on the following options:

    i. Decrease your possession limits so that the "Unity Rule" value of the licensed material authorized is less than 1.

    ii. Determine if any of the requested items need not be in "any" form and can be possessed as sealed sources (Provide Manufacturer name, model number of sealed sources to be possessed).

    iii. Make no changes to the requested authorizations and provide a DFP.

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) 337-5075 or via electronic mail at Steven.Courtemanche@nrc.gov.

Thank you for your cooperation.

Sincerely,

Steven R. Courtemanche

Digitally signed by Steven R. Courtemanche
Date: 2021.07.21 15:59:54 -04'00'

Steven Courtemanche, Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 47-23035-01
Docket No. 03020199
Mail Control No. 624989

WEST VIRGINIA UNIVERSITY, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 624989 DATED JULY 21, 2021

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