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

August 26, 2021

Colonel E. Darrin Cox, Commander
Department of the Army
U. S. Army Medical Research Insititute
of Infectious Diseases
1425 Porter Street
Fort Detrick, MD 21702-5011

SUBJECT: DEPARTMENT OF THE ARMY, U. S. ARMY MEDICAL RESEARCH INSITITUTE OF INFECTIOUS DISEASES, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 626862

Dear Colonel Cox:

This is in reference to your letter dated April 26, 2021, requesting to renew NRC License No. 19-11831-03. In order to continue our review, we need the following additional information:

1. Item 5, Radioactive Material: You requested authorization for 10 curies of In-111 in any form and 10 Curies of Zr-89 in any form. In-111 and Zr-89 are not specified in 10 CFR 33.100 Schedule A and are therefore should be limited 0.1 curies in accordance with the 10 CFR Part 33,100 Schedule A line item “Any byproduct material other than alpha emitting byproduct material not listed above.” We further note that the current license lists a large number of sealed sources other than the self-shielded irradiator, which should be under the 10 CFR 33.100 Schedule A, not in addition to that limit. Also, Condition 12 of your license further limits the quantities of a Type B license of broad scope to quantities which allow use of the pre-set amount of financial assurance $1,125,000 for unsealed materials, so that a decommissioning funding plan (DFP) is not required.

   These quantities are listed on your current license as line items, but it does not appear that the reviewers at that time were aware of the limits in 10 CFR 33.100 or the guidance in Section 8.5.1 of NUREG–1556, Vol. 11, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope, Final Report’ (NUREG-1556 Vol. 11, Rev. 1) or its previous revision, which states that Type B broad scope applicants/licensees that require materials not specified in Schedule A should either: (1) develop Type A broad scope programs, or (2) carry these additional materials under a separate specific license of limited scope. In addition, Item E.2) of your Radiation Safety Program requested flexibility which is limited to Type A licenses of broad scope. Please determine which of the following options will best fit your needs and allow us to continue the renewal process:

   a. You may revise your request to limit In-111 and Zr-89 to 0.1 curies each in accordance with the 10 CFR Part 33, Schedule A line item “Any byproduct material other than alpha emitting byproduct material not listed above.” Because both of these radionuclides have half-lives less than 120 days, this would not

affect your financial assurance. Please note that the unity rule applies to the values in 10 CFR 33.100 Schedule A, including the additional materials.

OR

b. You may revise your application to request a Type A license of broad scope.

   i. Such a license requires you to provide the information about the activities of the Radiation Safety Committee as requested in NUREG -1556, Vol. 11, Rev. 1, Section 8.7.2, "Radiation Safety Committee." We understand that you have been operating your licensed program with a Radiation Safety Committee that has been functioning for many years. This option would allow you to have the flexibility requested throughout the application. This option would not affect your annual fee.

   ii. The majority of your authorized materials would change as follows: "Any byproduct material with atomic numbers 1 through 83" in "any" form, and you would need to set a limit per radionuclide and total limit, such as "1 curie per radionuclide and 20 curies total.". In addition, if you commit to limiting quantities to those that allow you to maintain your financial assurance at its current levels of $1,125,000 for unsealed byproduct materials, the current Condition 12 would be replaced with a statement that confirms the commitment. Because the unity rule applies to the quantities for financial assurance, if you opt to become a Type A broad scope license, you should confirm that you will maintain an inventory of material on site that demonstrates you are within the limits for the financial assurance provided.

OR

c. You may apply for a separate specific license of limited scope for those radionuclides that are not listed 10 CFR 33.100 Schedule A, or above the limits of that table. This option requires a new license application fee and would be assessed a separate annual fee in the future. This option could require additional financial assurance, depending on the radionuclides requested, but would not for the In-111 or Zr-89.

Please note that you may identify other options. If so, we would be happy to discuss them with you.

2. Item 5, Radioactive Material: The application requested "Any byproduct material, other than alpha emitting byproduct material, not listed in 10 CFR 33.100, Schedule A with a half-life >120 days". Please note that Condition 12.B. of your current license authorizes you to possess "any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A" for all radionuclides regardless of half-life. We understand that your current Certification of Financial Assurance (CFA) does include the "half-life > 120 days" but this is because financial assurance is applicable only to radionuclides with half-lives greater than 120 days. If you will continue as a Type B license of broad scope, confirm that the limit for "any byproduct material other than alpha.." is acceptable as currently stated in Condition 12 of your license.

3. Item 5, Radioactive Material: The application did not address the sealed sources, although the current license lists a number of radionuclides in the form of sealed sources. Confirm if the current list should continue to be authorized. If other sealed sources are needed, please provide the manufacturer's or distributor's name and model number for each sealed source and device requested; and specify the maximum activity per source.

4. Item 5.2, Financial Assurance and Recordkeeping for Decommissioning: This item states that "If financial assurance is required..." Please note that your license does require financial assurance in the amount of $1,125,000 for the unsealed material, and $113.000 for the self-shielded irradiators and other sealed sources. The current financial assurance instruments for your license are the Certification of Financial Assurance (CFA) dated June 4, 2010, and a Statement of Intent (SI) dated March 18, 2009. No response to this item is required.

5. Item 7.A., Executive Management: In accordance with Section 8.7.1 of NUREG-1556, Vol 11, Rev. 1, please submit an organizational chart that describes the management structure, reporting paths, and the flow of authority between executive management and the RSO.

6. Item 7.B, Radiation Safety Officer: The application discusses the duties and responsibilities of the RSO, corrective actions for spills and/or contaminations, and the documentation of identified violations. However, there is no discussion of analysis of the cause(s) of problems or if corrective and preventative actions will be taken if deficiencies are identified. In accordance with Section 8.7.3 and Appendix D "Model Delegation of Authority for Radiation Safety Officer", confirm that the RSO duties will include initiating, recommending, or providing corrective actions; and verifying implementation of corrective actions if deficiencies are identified.

7. Item 7.B, Radiation Safety Officer: The application states that the licensee will notify the NRC within 30 days of naming a new RSO. Please confirm that, unless there are extenuating circumstances, you will submit the name of a proposed RSO to the NRC for approval, with a request to amend the license, prior to the change in RSO. The amendment request should include a description of the individual's qualifications as described in Section 8.7.3 of NUREG-156, Vol 11, Rev. 1.

8. Item 8, Training: The application states that (8.A.) radioisotope users will receive training described in Appendix G in NUREG-1556, Vol.7, Revision 1 dated January 2014; (8.B.) authorized irradiator users will receive the training described in Appendix F of NUREG -1556, Vol 5, Revision 1 dated June 2018; and (8.C.) occupational workers and ancillary personal will receive training as described in Appendix G in NUREG-1556 Vol 5 Revision 1 and/or Appendix J of NUREG-1556, Vol. 7, Rev. 1, dated February 2018.

    a. The current revision of NUREG-1556, Volume 7, "Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope" is Revision 1, issued February 2018. Please note that Appendix F, "Radiation Safety Training Topics" is not a model training program, only a list of topics that should be considered and adapted according to the various groups of

workers to be trained. For the response in sections 8.A, and 8.C, please refer to the correct Appendix for the topics to be considered, and, in accordance with Section 8.8 of NUREG-1556 Vol. 11, Rev. 1, submit a description of the radiation safety training program developed for each group of workers, including topics covered, qualifications of instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training.

b. The NUREG-1556, Vol. 5, Revision 1, Appendix F, "Model Self-shielded Irradiator Training Program" is acceptable for users of the irradiators. No response to this item is required.

c. Appendix G of NUREG-1556, Vol. 5, Rev. 1 is "Typical Duties and Responsibilities of the Radiation Safety Officer" and Appendix J of NUREG-1556, Vol. 7, Rev. 1 is "Material Receipt and Accountability." Confirm that you will remove references to these appendices, as neither is applicable to training of occupational workers and ancillary personnel working in the vicinity of licensed materials. If training of this group of workers (Medical Maintenance and Warehouse Personnel) is not covered in Items 8.a or 8.b above, submit a description of the radiation safety training program developed for this group of workers, including topics covered, qualifications of instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training.

9. Item 10, Radiation Safety Program: Radiation Monitoring Instruments: Item 10.B. 5.) of the application states that instruments used for surveys of the irradiators will be calibrated every 12 months; Item 10.B.6.) states that stationary laboratory instruments will be calibrated yearly. Please confirm that portable instruments used in areas other than the irradiators, will be calibrated annually or after any repair.

10. In the Radiation Safety Program, Section E.2), flexibility was requested that is limited to Type A licenses of broad scope. If you will continue as a Type B license of broad scope, confirm that you will revise Section E.2 to remove this flexibility all authorized materials.

11. Item 10, Radiation Safety Program, Safe Use of Radionuclides and Emergency Procedures:

    a. In accordance with NUREG-1556, Vol. 5, Rev. 1, for your self-shielded irradiators, please update your commitment to include distribution of the revised procedures. The full statement should be: "Operating, emergency, and security procedures will be developed, implemented, maintained, **and distributed and** will meet the Criteria in the section entitled 'Radiation Safety Program - Operating and Emergency Procedures' in NUREG-1556, Volume 5, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses."

    b. Confirm that you understand that this flexibility applies only to the procedures for self-shielded irradiators, unless you elect to change from a Type B broad license to a Type A broad license.

12. Item 11,Waste Management: The application stated that short-lived waste (physical

half-life of less than or equal to 120 days) will be "decayed in storage" for more than ten half-lives and will be surveyed before disposal...We will adopt the procedures for disposal by decay-in-storage as published in Appendix V of NUREG 1556, Volume 11..."

a. Confirm that you will revise this item to refer to the correct Appendix O.

b. Please note that the procedure in Appendix O, and the conditions does not require that waste be held for 10 half-lives but does require that waste be held until surveys demonstrate that radiation levels cannot be distinguished from background. No response to this item is required unless you wish to retract the commitment to hold such waste for 10 half-lives.

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

Betsy Ullrich, Senior Health Physicist
Mail Control No. 626862
USNRC, Region I
Division of Radiological Safety and Security
2100 Renaissance Boulevard
King of Prussia, PA 19406

You may also send a pdf copy of your signed response letter directly to me by elelctronic mail to Elizabeth.ullrich@nrc.gov.

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 240-704-4575 (cell phone) or by electronic mail to Elizabeth.ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

Elizabeth Ullrich Digitally signed by Elizabeth Ullrich
Date: 2021.08.26 07:16:39 -04'00'

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

License No. 19-11831-03
Docket No. 030-31743
Mail Control No. 626862

cc: Josephine Estaban-Trexler, Radiation Safety Officer

DEPARTMENT OF THE ARMY, U. S. ARMY MEDICAL RESEARCH INSITITUTE OF INFECTIOUS DISEASES, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 626862 DATED AUGUST 26, 2021

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SUNSI Review Complete: Betsy Ullrich

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