



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

February 21, 2023

Brandon Hatcher, PhD, RBP, CBSP
Director, Office of Laboratory Safety, OLSS
U.S. Department of Health & Human Services
Centers for Disease Control & Prevention
MS H21-2
1600 Clifton Road N.E.
Atlanta, GA 30333

SUBJECT: U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, CENTERS FOR DISEASE CONTROL & PREVENTION, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 633497

Dear Dr. Hatcher:

This is in reference to your application dated October 11, 2022, requesting to renew NRC License No. 10-06772-02. In order to continue our review, we need the following additional information:

1. Confirm if you wish to authorize on your broad scope License No. 10-06772-01, the irradiators currently authorized under your specific License No. 10-06772-02. Please see the separate letters requesting additional information for the financial assurance required for the licenses, and for the renewal of the broad scope license. If you wish to make this change, you will need to 1) request to authorize the irradiators under License No. 10-06772-01; 2) request to terminate License No. 10-06772-01; 3) revise the Certification of Financial Assurance currently provided for License No. 10-06772-01 to list the irradiators; and 4) submit a revised Statement of Intent to provide the financial assurance for the irradiators under License No. 10-06772-01.
2. In accordance with Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," of NUREG-1556, Volume 5, Revision 1 "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Self-shielded Irradiator Licenses" (NUREG-1556, Vol. 5, Rev. 1), state 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 NRC Regional Office."
3. Section 8 "Training for Individuals Working in or Frequenting Restricted Areas" does not address the requirements of NUREG-1556, Vol. 5, Rev. 1, Section 8.7.2 "Authorized Users." This section address training for persons who will use, or supervise the use of the irradiators, and has received the training described in Appendix F "Model Self-Shielded Irradiator Training Program." Appendix F contains topics not addressed in your

Section 8, such as security requirements, regulations and reporting requirements. In accordance with NUREG-1556, Vol. 5, Rev. 1, Section 8.7.2, confirm that, before using licensed materials, authorized users will receive training described in Appendix F.

4. In addition to the information provided in Section 9.C "Irradiator Wipe Tests and Maintenance," in accordance with NUREG-1556, Vol. 5, Section 8.10.8 "Maintenance,"
 - a. Confirm that you will conduct electrical and mechanical safety interlock checks of each irradiator at least quarterly, in accordance with the irradiator's user's manual.
 - b. Confirm that you will maintain documentation of the use of all non-original equipment manufacturer (OEM) replacement parts and components. If OEM replacement parts cannot be used for the shielding of any sealed sources, the driving unit of any sources, safety interlocks, or other electrical or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or any sources, we will obtain and document NRC approval before beginning the nonroutine maintenance activity. In addition, if a service provider plans to remove any aspect of the Global Threat Reduction Initiative irradiator-hardening hardware, we will discuss this matter with the NRC before allowing this service to be initiated.
5. Section 10.C "Material Receipt and Accountability" does not include discussion of the National Source Tracking System (NSTS). In accordance with NUREG-1556, Vol. 5, Rev. 1, Section 8.10.3.2 "National Source Tracking System," confirm that you will comply with the NSTS reporting requirement described in 10 CFR 20.2207.
6. Section 10.D "Occupational Dose" of your application states that all personnel using irradiators will wear dosimetry. Confirm that personnel dosimeters that require processing are supplied and evaluated by a NVLAP-approved processor. Please note that bioassay procedures included in the renewal application for the irradiator License No. 10-06772-02 are not applicable to use of the irradiators, but this bioassay information was not included in the application for the broad scope license.

We will continue our review upon receipt of this information. You may respond by providing a pdf copy of a signed response letter attached to an email to Elizabeth.Ullrich@nrc.gov . Alternately, you may send a hard copy response by regular mail to my attention at:

Mail Control No. 633497
USNRC, Region I
Division of Radiological Safety and Security
475 Allendale Road – Suite 102
King of Prussia, PA 19406

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 "Agency Rules of Practice and Procedure," 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 from 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 or by electronic mail to Elizabeth.Ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

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

License No. 10-06772-02
Docket No. 030-13108
Mail Control No. 633497

cc: E. Jones, Radiation Safety Officer

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, CENTERS FOR DISEASE CONTROL & PREVENTION, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 633497 DATED FEBRUARY 21, 2023

DOCUMENT NAME: [\\nrc.gov\nrc\R1\Office\DNMS\WBL Documents\WBL License RAIL10-06772-02.633497.docx

SUNSI Review Complete: Betsy Ullrich

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DRSS	N	RI:DRSS	N	RI:DRSS	N		
NAME	MWutklowksi		JvonEhr		EUllrich			
DATE					2/21/23 exu			

OFFICIAL RECORD COPY