



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

June 14, 2022

Brian Baker, Director
Department of Health and Human Services
US Food & Drug Administration
Public Health Service
Winchester Engineering and Analytical Center
109 Holton Street,
Winchester, MA 01890

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, US FOOD & DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, WINCHESTER ENGINEERING AND ANALYTICAL CENTER, LICENSE AMENDMENT, MAIL CONTROL NO. 631359

Dear Mr. Baker:

This refers to your license amendment request dated April 28, 2022. Please find enclosed Amendment No. 48 authorizing the new facility.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at 240-704-4585 or by electronic mail to Elizabeth.Ullrich@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosure 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>.

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

Docket No. 030-04675
License No. 20-08361-01
Mail Control No. 631359

Enclosure:
Amendment No. 48

cc: Elon Malkin, Ph.D., Radiation Safety Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES, US FOOD & DRUG
ADMINISTRATION, PUBLIC HEALTH SERVICE, WINCHESTER ENGINEERING AND
ANALYTICAL CENTER, LICENSE AMENDMENT, MAIL CONTROL NO. 631359 DATED JUNE
14, 2022

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SUNSI Review Complete: Betsy Ullrich

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NAME	Betsy Ullrich						
DATE	6/14/22 exu						

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