



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

December 10, 2024

Brian L. Baker, Center Director  
US Department of Health and Human Services  
Food and Drug Administration  
109 Holton Street  
Winchester Engineering and Analytical Center  
Winchester, Massachusetts, 01890-1197

SUBJECT: US DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG  
ADMINISTRATION, LICENSE AMENDMENT, MAIL CONTROL NO. 643146

Dear Brian L. Baker:

This refers to your license amendment application dated September 9, 2024. Please find enclosed Amendment No. 49, authorizing a new organizational structure.

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 610-310-7799 or via electronic mail at [Randolph.Ragland@nrc.gov](mailto:Randolph.Ragland@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](http://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,

Randolph C. Ragland, Jr., Senior Health  
Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Radiological Safety and Security  
Region I

Docket No. 03004675  
License No. 20-08361-01  
Mail Control No. 643146

Enclosure:  
Amendment No. 49

cc: Elon Malkin, PhD, Radiation Safety  
Officer

SUBJECT: US DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG  
ADMINISTRATION, LICENSE AMENDMENT, MAIL CONTROL NO. 643146,  
DATED DECEMBER 10, 2024

SUNSI Review Complete: RRagland

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

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NAME	RRagland rcr1			
DATE	12/10/2024			

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