



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

May 9, 2017

James Zelinsky, Occupational Safety and Health Manager  
Department of Health & Human Services  
Food and Drug Administration  
Harvey W. Wiley Building, HFS-657  
5001 Campus Drive  
College Park, MD 20740

**SUBJECT:** DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG  
ADMINISTRATION, LICENSE AMENDMENT, MAIL CONTROL NO. 594437

Dear Mr. Zelinski:

This refers to your license amendment request dated March 29, 2017. Please find enclosed Amendment No. 16 authorizing Michael Myers, Ph.D. as an authorized user of radioactive material, deleting other authorized users, and changing your address to 5001 Campus Drive, College Park, MD 20740.

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 610-337-5089 or via electronic mail at [john.miller@nrc.gov](mailto:john.miller@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).

J. Zelinsky

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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 "Rules of Practice," 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,

*/RA/*

John Miller, Health Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Nuclear Materials Safety  
Region I

License No. 19-30771-01  
Docket No. 03036120  
Mail Control No. 594437

Enclosure:  
Amendment No. 16

cc: Charles Watts, Radiation Safety Officer

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Thank you for your cooperation.

Sincerely,

*/RA/*

John Miller, Health Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Nuclear Materials Safety  
Region I

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SUNSI Review Complete: John Miller

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