



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

April 3, 2013

Docket No. 03036120  
Control No. 580254

License No. 19-30771-01

Charles Sabatos  
Deputy Executive Officer  
Department of Health & Human Services  
Food and Drug Administration  
Harvey W. Wiley Building HFS-657  
5100 Paint Branch Parkway  
College Park, MD 20740

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, LICENSE AMENDMENT,  
CONTROL NO. 580254

Dear Mr. Sabatos:

This refers to your license amendment request. Enclosed with this letter is the amended license.

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 notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

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

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits**, see our **toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

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/regulatory/enforcement/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.

C. Sabatos

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Thank you for your cooperation.

Sincerely,

***Original signed by Dennis R. Lawyer***

Dennis R. Lawyer  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 11

cc:  
Michael Spady, Radiation Safety Officer

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**SUNSI Review Complete: DLawyer**

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