



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 9, 2005

Docket No. 03036120

License No. 19-30771-01

Janice Oliver  
Deputy Center Director, CFSAN  
Department of Health and Human Services  
Food and Drug Administration  
Harvey K. Wiley Building, HFS 003  
5100 Paint Branch Parkway  
College Park, MD 20740

**SUBJECT:** INSPECTION 03036120/2005001, DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, COLLEGE PARK, MARYLAND AND MUIRKIRK ROAD COMPLEX, LAUREL, MARYLAND

Dear Ms. Oliver:

On April 20, 2005, Todd Jackson and Robert Prince of this office conducted a safety inspection at the above address and the Muirkirk Road Complex, Laurel, Maryland of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in communications from April 20 through May 14, 2005, between Constance Rosser of your organization and this office, was also examined as part of the inspection. The preliminary findings of the inspection were discussed with you, Denise Knox Riley, Theodore Chambers, Constance Rosser, and Ronald Wright at the conclusion of the onsite inspection.

Within the scope of this inspection, no violations were identified. At the exit meeting the inspector noted that there has been significant progress in implementing your actions to correct violations identified during the previous NRC inspection. While there was some difficulty in immediately finding receipt survey records, all requested records were eventually located. Additionally, each laboratory inspected had the necessary local records organized and immediately available in the lab. The contractor providing technical support for liquid scintillation detectors and other instruments has been helpful, and has provided needed expertise while you address the training needs of your staff. Continued development of in-house technical capabilities remains a priority.

Current NRC regulations and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

J. Oliver  
Department of Health and Human Services

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No reply to this letter is required. Your cooperation with us is appreciated.

Sincerely,

***Original signed by James P. Dwyer***

James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Constance S. Rosser, Radiation Safety Officer  
State of Maryland

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**SISP Review Complete: (JPD)**

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