



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

March 30, 2011

Docket No. 03034162

License No. 29-30308-01

Mark A. Smith  
Vice President, Radiation Services  
Sterigenics International, Inc.  
Rockaway, New Jersey Site  
108 Lake Denmark Road  
Rockaway, NJ 07866

SUBJECT: NRC INSPECTION NO. 03034162/2011001, STERIGENICS INTERNATIONAL, INC., ROCKAWAY, NEW JERSEY SITE, AND NOTICE OF VIOLATION

Dear Mr. Smith:

On March 1, 2011, Mr. Robert Temps, Senior Inspector, NRC Headquarters Spent Fuel Storage and Transportation, and Randolph C. Ragland, Jr., of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was also observed by Dennis Zannoni, Supervising Nuclear Engineer, New Jersey Department of Environmental Protection. The inspection was limited to a review of international shipments made by the Rockaway, NJ facility to MDS Nordion in 2008 and 2009. The findings of the inspection were discussed with you and Stanley Yap, Radiation Safety Officer of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation (Notice) is enclosed and is categorized as a Severity Level IV violation in accordance with the NRC Enforcement Policy. The violation involved the failure to have a general license for the delivery of licensed material in a package for transport by a carrier, due to a failure to comply with the conditions of the MDS Nordion F-168 Certificate of Compliance (CoC), as endorsed by a Department of Transportation revalidation. The violation is cited in the enclosed Notice because the violation was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration, review the NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," at the NRC website at [www.nrc.gov](http://www.nrc.gov); select **Electronic Reading Room; Document Collections; Generic Communication**; then **Information Notices**. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at

M. Smith

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<http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC; Regulation; Enforcement**; then **Enforcement Policy**. 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Randolph Ragland at 610-337-5083 if you have any questions regarding this matter.

Sincerely,

**/RA/**

Blake D. Welling, Chief  
Security and Industrial Branch  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

cc:  
Stanley Yap, Radiation Safety Officer  
State of New Jersey

M. Smith

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Blake D. Welling, Chief  
Security and Industrial Branch  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

cc:  
Stanley Yap, Radiation Safety Officer  
State of New Jersey

Distribution:  
D. J. Holody, RI

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L29-30308-01.2011001.doc

**SUNSI Review Complete:** RRagland

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OFFICE	DNMS/RI	N	NMSS/SFST		DNMS/RI		
NAME	RRagland RCR		RTemps RRT		BWelling BDW		
DATE	3/29/2011		3/29/11		3/30/11		

OFFICIAL RECORD COPY

## **NOTICE OF VIOLATION**

Sterigenics International, Inc.  
Rockaway, NJ

Docket No. 03034162  
License No. 29-30308-01

During an NRC inspection conducted on March 1, 2011, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 71.3 states, in part, except as authorized in a general license or specific license issued by the Commission, no licensee may – (a) Deliver licensed material to a carrier for transport; or (b) Transport licensed material.

10 CFR 71.21(d) states, in part, that the general license in 10 CFR 71.21 applies only to a licensee who complies with the terms and conditions of the certificate and revalidation issued by DOT.

Contrary to the above, on or about April 1, 2008, October 29, 2008, and August 5, 2009, Sterigenics International, Inc., an NRC licensee pursuant to Part 30, delivered for transport licensed material in violation of its general license because Sterigenics International, Inc. did not comply with DOT Certificate USA/6306/B(U) and USA/0617/B(U)-96. Specifically, Sterigenics International, Inc. did not comply with the conditions of the MDS Nordion F-168 certificate as endorsed by the DOT revalidation.

This is a Severity Level IV violation (Section 6.8.d).

Pursuant to the provisions of 10 CFR 2.201, Sterigenics International, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Notice of Violation  
Sterigenics International, Inc.

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Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 30th day of March 2011