



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

November 1, 2000

Docket No. 03034162

License No. 29-30308-01

Stanley Yap
General Manager
Sterigenics International
108 Lake Denmark Road
Rockaway, NJ 07866

SUBJECT: INSPECTION 03034162/2000001, STERIGENICS INTERNATIONAL,
ROCKAWAY, NEW JERSEY SITE

Dear Mr. Yap:

On September 13 and 14, 2000, Dick Ladun and Sattar Lodhi of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of facilities, equipment and instrumentation, training, and management over site. The findings of the inspection were discussed with you and other members of your staff of your organization at the conclusion of the inspection.

As part of our inspection on September 14, 2000, a water sample was taken from the irradiator pool. The sample was analyzed at the Region 1 laboratory for cobalt-60 (Co-60) using gamma spectroscopy techniques. The results of our analysis indicate a Co-60 concentration less than the minimum detectable activity (MDA) for the counting system of 8.0×10^{-9} microcuries per milliliter.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

Original signed by John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

cc:
State of New Jersey

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	Rladun JDK		Slodhi JDK	Jkinneman JDK		
DATE	11/1/00		11/1/00	11/1/00		

OFFICIAL RECORD COPY

APPENDIX A IRRADIATOR INSPECTION RECORD (IP 87112)									
REGION 1									
Insp. Report #	00-001	License #	29-30308-01			Docket #	030-34162		
Licensee Name	Sterigenics International								
Street Address	108 Lake Road								
City, State, Zip	Rockaway, New Jersey 07866								
Location (Authorized Site) Being Inspected	Rockaway, New Jersey								
Licensee Contact Name	Stanley Yap, Plant Manager, RSO				Phone #	973 625 8400			
Priority	1	Program Code	03521		Description	Industrial Irradiator			
Date of Last Inspection:	5-13-99			Date of This Inspection	9/ 13, 14/00				
Type of Insp.	Announced		Routine	x	Initial				
	Unannounced	x	Special						
Next Insp. Date	10-2001	Normal	x	Reduced		Extended			
Justification for change in normal inspection frequency:									
Summary of Findings and Actions									
No violations, Clear 591 or letter issued			x	Non-cited violations					
Violation(s), 591 issued		Violation(s), letter issued							
Follow up on previous violations:	None								
Inspector - Printed Name	Richard H. Ladun <i>/RA/</i> Sattar Lodhi <i>/RA/</i>								
Signature	-					Date	10/23/00		
Approved - Printed Name	John D. Kinneman								

Signature	-	<i>/RA/</i>	Date	11/1/00
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PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY		
1.	AMENDMENTS AND PROGRAM CHANGES	
License amendments issued since last inspection, or program changes noted in the license.		
AMENDMENT #	DATE	SUBJECT
01	10-99	RSO change
2.	INSPECTION AND ENFORCEMENT HISTORY	
Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.		
Disposal of Strontium 90 calibration sources.		
3.	INCIDENT/EVENT HISTORY	
List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.		
Discussions with RSO and a review of the license file reflect no incidents or events have been reported to the NRC since the last inspection.		
PART II - INSPECTION DOCUMENTATION		
NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87112, "Appendix B, Irradiator Inspection References."		

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1.	ORGANIZATION AND SCOPE OF PROGRAM
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Management organizational structure; authorized location of use; type and quantity of byproduct material used; staff size.

Management organizational structure is as described in the license application and there is no change in management since the last inspection. The RSO is also the plant manager and reports to Director (John Gilbert) who is at the corporate office in Ottawa. The licensee operates a batch pool, Co-60 irradiator. Staffing size is approximately 12, with 3 shifts. Current inventory is over 1,000,000 curies, a source loading is scheduled for October 2000. The licensee also has Sr-90 sealed source in storage. Inspectors discussed licensee's plans to dispose of the sources in storage. The licensee will try to dispose of these sources soon.

2.	MANAGEMENT OVERSIGHT
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Management support to radiation safety; Radiation Safety Officer (RSO); and program audits, including as low as is reasonably achievable (ALARA) reviews.

Management appears to provide direct support to the radiation program. The RSO is also the Plant Manager. During the course of the inspection, the facility was the subject of a announced corporate audit. The audit team consisted of 5 members, including the team leader. The inspector observed portions of the audit and interviewed the team leader and the auditor who was assigned the examination of the radiation safety program. Both auditors were familiar with NRC regulations and requirements of the license. The audit appeared very detailed and according to the team leader the radiation program was a priority.

3.	FACILITIES
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Facilities as described; design, construction monitoring, and acceptance testing requirements; uses; control of access; shielding; fire protection; conveyor system; engineering controls; and compliance with public dose limits.

The inspector determined after tour of the facility that no changes had taken place since the last inspection. Access control was maintained by personnel . All required engineering controls to include shielding and fire protection were in place.

4. EQUIPMENT AND INSTRUMENTATION

Survey instruments; 10 CFR Part 21 procedures; interlocks; alarm systems; area and process monitors; conductivity instrumentation; maintenance; 10 CFR 36.61 requirements.

The inspector determined by observation and record reviews that all required survey instruments including the remote area radiation monitor were in calibration and operable. The inspector observed the license perform an alarm and interlock test. All systems appeared to work as designed. Conductivity instrumentation was calibrated on a yearly basis.

5. MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material; source handling procedures; source integrity; irradiated materials handling.

Discussions with the RSO and observations by the inspector determined that the materials and uses is as authorized, Security and control of licensed material is maintained by personnel. Procedures for the receipt and transfer of RAM and associated source handling procedures should be reviewed and implemented during the next source loading in October.

6. OPERATING AND EMERGENCY PROCEDURES

Procedures development and availability; manufacturer's instructions; emergency/abnormal event procedures; assistance arrangements with outside agencies

Inspector determined by discussions with RSO that Operating and Emergency procedures were current and that assistance arrangements with outside agencies have been up dated.

7. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses.

Inspector review leak test and inventory records for 1999 and 2000. All records were complete and up to date,

8. TRAINING AND INSTRUCTIONS TO WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations.

<p>Inspector reviewed training records for 1999 and 2000. The licensee was unable to provide documentation for the annual refresher training of two operators . Discussions with the RSO indicated that this required training was administered but the records could not be located at this time. The Inspector advised the audit team of this finding and ask that they pursue it since the necessary records may be in their possession. The NRC would review there findings during the next inspection.</p>	
9.	RADIATION PROTECTION
<p>Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications.</p>	
<p>The inspector reviewed dosimetry records for 1999 and 2000. All readings were well below NRC allowable limits and most were minimal. The RSO advised that NRC bulletins and generic communications are periodically discussed with workers.</p>	
10.	RADIOACTIVE WASTE MANAGEMENT
<p>Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; records.</p>	
<p>N/A</p>	
11.	DECOMMISSIONING
<p>Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.</p>	
<p>Not inspected</p>	
12.	TRANSPORTATION
<p>Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.</p>	
<p>N/A</p>	
13.	POSTING AND LABELING
<p>Reporting and follow up of theft; loss; incidents; overexposures; change in RSO, authorized user; and radiation exposure reports to individuals.</p>	
<p>Discussions with RSO and record reviews indicated that no incidents reported to the NRC with the exception of a change of RSO since the last reporting period.</p>	

14.	POSTING AND LABELING				
Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material.					
Tour of the facility by the inspector determined that all required posting and labeling was in place to include NRC Form 593.					
15.	INDEPENDENT AND CONFIRMATORY MEASUREMENTS				
Areas surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date.					
A pool water sample was taken and analyzed in the Regional laboratory for Cobalt-60. The analysis indicated a Co-60 concentration was less than 8.0×10^{-9} microcurie per milliliter (the MDA of the counting system). It is well within NRC allowable limits.					
16.	VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:				
State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.					
None					
17.	PERSONNEL CONTACTED				
Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone). Use # to indicate individual present at entrance meeting. Use * to indicate individual present at exit meeting.					
	Name	Title	Phone No.	In Person or By phone	
	S. Yap	RSO	973-625-8400	##	
	J. Roper	Q.A. Manager		#	
	R.Keim	Production Supervisor		#	
	R. Smith	Q. A. Manager		#	
	A. Morrison	Operations Manager		#	
18.	PERFORMANCE EVALUATION FACTORS (PEFs)				
	A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.	Y	N	x
	B.	RSO too busy with other assignments.	Y	N	x
	C.	Insufficient staffing.	Y	N	x

	D.	Radiation Safety Committee fails to meet or functions inadequately.	N/A	x	Y		N	
	E.	Inadequate consulting services or inadequate audits conducted.	N/A		Y		N	x
REMARKS: (Consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program.)								
Very good audit program								
19.	SPECIAL CONDITIONS OR ISSUES							
Special license conditions; year-2000 effects of computer software and embedded systems.								
None								
PART III - POST- INSPECTION ACTIVITIES								
1.	REGIONAL FOLLOWUP ON PEFs							
Not Applicable								
2.	DEBRIEF WITH REGIONAL STAFF							
Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.								
Discussed inspection results with supervisor								
3.	YEAR-2000 ISSUES							
Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.								
None								

END