U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-19025/85002(DRSS)

Docket No. 030-19025

Licensee: Radiation Sterilizers, Inc.
3000 Sand Hill Road 2-190
Menlo Park, CA 94025

Inspection At: 711 E. Cooper Court
Schaumburg, IL

Inspectors: C. C. Casey
Radiation Specialist — Date: 5/30/85

J. L. Lynch
Radiation Specialist — Date: 5/29/85

Approved By: D. G. Wiedeman, Chief
Nuclear Materials Safety
Section 1 — Date: 5/31/85

Special Inspection Summary

Inspection on May 13, 1985 (Report No. 030-19025/85002(DRSS))
Areas Inspected: This was an unannounced special safety inspection initiated by five allegations received by telephone on April 17 and 18, 1985. The inspection included a review of operating procedures, facility tour and interviews with personnel.
Results: One of the allegations was substantiated and one violation was identified.

DETAILS

1. Persons Contacted

*Thomas Hurley, General Manager
*Pete Robles, Production Manager
James Freiberg, Operator
Paul Wingfield, Operator
Jeff Babor, Operator

*Attended exit interview.

2. Purpose of Inspection

This was an unannounced special inspection for review of allegations concerning the radiation safety program at Radiation Sterilizers, Inc. (RSI). RSI utilizes approximately 1.3 million curies of cobalt-60 in a walk-in type irradiator.

3. Specific Allegations and NRC Findings

Allegation: The irradiator is not always operated with two employees in attendance as required.

Findings: License Condition No. 20 (April 18, 1983 letter) states that the irradiator is operated on a continuous schedule with at least two persons monitoring the process, one of which is a user-operator.

A review of the operation log maintained in the control room identified one instance of the irradiator being operated with less than two persons in attendance.

On March 24, 1985, the irradiator was run by an operator for a period of approximately two hours without another person in attendance. According to the operator, Jeff Babor, the other scheduled individual did not show up for work at midnight and rather than delay production, he began solo operation of the irradiator. About two hours later, Babor became ill and went home after powering the unit down. The irradiator was restarted six hours later when the next shift came on duty. No abnormal situations occurred during the single operator shift.

Babor stated that he operated the irradiator alone because he was concerned that if production ceased, RSI management would blame him for the down time. Interviews with other employees did not show similar concerns. This issue was discussed with RSI management at the conclusion of the inspection. The inspectors were told that RSI policy states that two individuals are to be present during irradiator operation and that employees would not be punished for following policy. This point will be affirmed during future employee safety meetings and incorporated into written procedures.

This appears to be an isolated incident of a failure to follow license requirements. This constitutes noncompliance with License Condition No. 20.

The allegation was substantiated, one violation was identified.

Allegation: The ventilation exhaust fan in the irradiator cell is not working, thus allowing ozone levels to attain high levels.

Findings: The exhaust fan was functioning during the inspection (as it was during the March 1985 inspection). No evidence of high ozone concentrations was apparent. The facility is equipped with two 4,000 cfm fans, one in a backup capacity. The General Manager indicated that a fan has stopped working in the past but when noticed (smell and eye discomfort from increased ozone concentration), the backup fan was initiated. RSI was cited during the March inspection for failure to check the air system for proper operation on a monthly basis. This check was performed as required since the inspection. The licensee management plans to purchase an instrument to measure ozone concentrations in air to address employee concerns in the future.

The allegation was not substantiated, no violations were identified.

Allegation: RSI compromises system safety when they place products close to the source racks.

Findings: In order to deliver high doses to products in a relatively short period of time, they are placed in positions around the source cage. None of these set positions are inside the source cage plane or present an increased possibility of collision with the source racks.

The allegation was not substantiated, no violations were identified.

Allegation: The flashing warning beacon located at the maze entrance is not functional. Other warning lights are also inoperational.

Findings: The nonfunctional warning beacon was cited as a violation during the March 14, 1985 inspection. It was repaired the next day according to licensee records. The beacon was operating normally during this inspection. All other warning lights were functioning properly during both inspections. The employees that were interviewed verified that repair records were accurate.

The allegation was not substantiated, no violations were identified.

Allegation: Warning horn indicating source raising does not work at all times.

Findings: The warning horn functioned properly through repeated testing during both inspections. Although some tone distortion was noted at times, the horn was definitely adequate to warn people of the source raising. Interviews with employees indicated that the horn has been functional as required.

This allegation was not substantiated, no violations were identified.

4. Exit Interview

At the conclusion of this special inspection, an exit interview was held with Messrs. Hurley and Robles, to discuss the allegations and NRC findings.