

INDUSTRIAL - ACADEMIC INSPECTION REPORTInspection Report No. 82-01

Licensee (Name and Address)

Radiation Sterilizers, Inc.  
1401 Morgan Circle  
Tustin, CA 92680For use at:  
711 E. Cooper Court  
Schaumburg, IL 60172Licensee Contact: Tom Hurley, RSO/Gen. Mgt.Telephone No. 312-843-0999License No. 04-19644-01Docket No. 30-19025Last Amendment No. (Orig. Lic.)Date of Admendment: 7/2/81Category: EPriority: IVDate of Inspection: 12/21/82Type of Inspection: ☒ Announced  
( ) Unannounced☒ Initial  
( ) Special  
( ) Reinspection

## Summary of Findings and Action:

- ( ) No Noncompliance, Clear 591 issued ( ) Action on Previous N/C  
( ) Noncompliance, 591 issued ( ) Regional Action  
☒ Noncompliance, Appendix ( ) HQ Action

Inspector: C. G. Dierg  
(Signature)12/21/82  
(Date Signed)Approved: J. D. F.  
(Signature)12/27/82  
(Date Signed)

INDUSTRIAL - ACADEMIC INSPECTION REPORT

Licensee: Production Services, Inc Lic. No. 04-19664-01 Amendment No. N/A  
 Date of Inspection: 12/21/82 E IV 30-19025 orig Lic. 7/2/81

1. INSPECTION HISTORY

a. Items of noncompliance or safety items noted during last inspection conducted on N/A Initial Insp. Yes      No     

b. Requirement      Corrected      Not Corrected     

c. If any items of noncompliance or safety items noted during the last inspection were not corrected, explain:     

2. ORGANIZATION

a. Organizational structure as described in application or letter

Dated 1/24/81, Or     

b. List primary licensee contact: Mr. Tom Hurley, RSO & Gen Mgr. Telephone No.: 312-843-0999

c. Comment:     

Individuals delineated in Lic. Cond. #12 are located in California. Tom Hurley RSO & Gen Mgr. and Dean Knight, Production Mgr. at the site.

**NE** License Condition No. 12 states: material shall be used by or under the supervision and in the physical presence of, Allan Chin, Bruce C. Meyer, or Steven Smith. Contrary to this, none of these individuals are located in the Chicago area and thus the material is not used in their physical presence.

3. SUMMARY OF LICENSED PROGRAM (Kind of program, number of people, rate of use or quantities on hand, places and frequency of use, type, quantity and use as authorized).

This is a  $^{60}\text{Co}$  irradiator facility of about 835,000 Curies. The facility is operated by about 11 people, 3 shifts/day on a 5 day week basis. The irradiator was loaded during Oct. 1981 and began operation as a sterilizer unit about the first of November 1981. The irradiator will be used for sterilization of medical devices and the health care industry and for material effects studies on materials, equipment, electronics and gemstones. Based upon the initial sampling material appears to be used as authorized.

Category and priority of this license is appropriate: Yes ☒ No ☐

If "No" state new Category \_\_\_\_\_ Priority \_\_\_\_\_.

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by L/C or application: Yes ☒ No ☐ If "Yes":

1) By whom RSO (local)

2) Frequency Continuing Announced: \_\_\_\_\_ Unannounced: ☒

3) Scope Overview and overall review of program and basic safety.

4) Records maintained: Yes ☒ No ☐

5) Records reviewed: Yes ☒ No ☐

6) Period Reviewed: 1982

b. Comment (responsibility of auditor or committee, management control): Audit

insp by RSO/Gen Manager who also performs monthly safety report; copy attached as Exhibit A



5. TRAINING RETRAINING AND INSTRUCTION TO WORKERS

a. Training program specified in L/C or application: Yes ☒ No ☐

b. If training program is required, describe scope of program: Basic Orientation, intermediate, and advanced training in Radiation Hazard Protection and OTJ Operations (See Attached Exhibit B).

c. Retraining required: Yes ☐ No ☒

If "Yes" is retraining: Complete ☐ Incomplete ☐

1) Are tests and/or examinations required: Yes ☐ No ☐

2) If "Yes" are records available: Yes ☐ No ☐

3) Reviewed test results: Yes ☐ No ☐

4) Period reviewed: \_\_\_\_\_

5) Comment (per cent completed, test results, etc.): \_\_\_\_\_

d. Training provided, but not covered above: Monthly safety meeting and periodic review ~~of~~ on Rad. Safety (2/82, 3/82, 4/11/82). Other SOPs

e. Instructions to workers in accord with 10CFR 19.12: Yes ☒ No ☐

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Operating and emergency procedures

- 1) Required by L/C or application: Yes ☒ No ☐
- 2) Provided, but not required by L/C or application: Yes ☒ No ☐
- 3) Procedures reviewed: Yes ☒ No ☐
- 4) Appeared Adequate: Yes ☒ No ☐
- 5) Comments (personnel's understanding of procedures):  
Understanding was adequate.

b. Changes in procedures since last inspection: Yes ☐ No ☒

- 1) Were changes authorized: Yes ☐ No ☐
- 2) Comments:

7. INSTRUMENTATION

a. Type(s) of radiation survey instruments on hand as per L/C, application or equivalent: Yes ☒ No ☐

- 1) If "No" list changes:

b. Capability of radiation survey instruments adequate for program:

Yes ☒ No ☐

c. Calibration of instruments required: Yes ☒ No ☐

d. If "Yes" instruments calibrated in accord with requirements:

Yes ☒ No ☐

e. Comment: All instr inside XETEX model 415 A chipers  
Calibrated on a 6 mo. frequency by XETEX Corp.

## B. MATERIALS

a. Radioactive material secured to prevent unauthorized removal from:

1) Restricted area: Yes ☒ No ☐

2) Unrestricted area (20.207): Yes ☒ No ☐

b. Method of control appears adequate: Yes ☒ No ☐

c. Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## FACILITIES

a. Facilities described in letter or application: Yes ☒ No ☐

b. Facilities inspected: Yes ☒ No ☐

c. Comment: As specified. Very well engineered & designed  
Minimal possibility of system failures. Have  
installed motion sensors and IR sensors in  
addition to other controls outlined & specified.



POSTING AND LABELING

a. Posting and labeling in accord with 10CFR 20.203: Yes ☒ No ☐

b. Comment: \_\_\_\_\_

RECEIPT AND TRANSFER OF MATERIAL

a. Procedures for picking up and receiving packages (10CFR 20.205 (b)(c)):

Yes ☒ No ☐

1) Incoming shipments monitored: Yes ☒ No ☐

2) Records of monitoring maintained (10CFR 20.401(b)): Yes ☒ No ☐

3) Records reviewed by NRC inspector: Yes ☒ No ☐

4) Period reviewed: 10/82

b. Procedures for opening packages (10CFR 20.205(d)): Yes ☒ No ☐

c. Comment: Original loading of <sup>60</sup>Co sources came in  
✓ two casks from HEC during September 1981.

Casks were unloaded and sources were transferred  
in water pool (23' x 23' deep) to modules and  
put into irradiator configuration holder during  
October 1981. ~~But~~ Written procedures were  
instituted and implemented for this work.

d. Records of receipt and transfer of material available (30.51(a); 40.61(a);

70.51(b)(1)): Yes ☒ No ☐

1) If "Yes" review of records was made by inspector: Yes ☒ No ☐

2) Period Reviewed: Sept. Oct, 1981

3) Comments: \_\_\_\_\_

e. Packages on hand meet labelling requirements (49CFR 173.399):

Yes ☐ No ☒

Comments: \_\_\_\_\_

f. Reports to commission required by L/C or regulation submitted:

Yes ☒ No ☐

Comments: \_\_\_\_\_

PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD badge supplier Landauer & Sons Inc / Rad. Det. Co. Calif.

b. Badge exchange frequency Monthly film badges / Wallit 720 Card

c. Reports reviewed by RSO

e. Records reviewed for period '81 to present by NRC inspector

f. NRC forms or equivalent

1) NRC-4 (20.102(b)): Yes ☐ No ☒ Complete: Yes ☐ No ☐

2) NRC-3 (20.401(a)): Yes ☒ No ☐ Complete: Yes ☒ No ☐

Maximum whole body quarterly exposure: m

Maximum extremity quarterly exposure: (NA - not used)



- 3) Comment: To date, personnel have received no significant exposure in excess of the "minimal" specified by ~~Landauer~~. Licensee has exposed area badges to assure Braccner can detect exposure. See attached Exhibit C, the exposure was determined to be 350 mrem
- g. Pocket dosimeters used: Yes ☒ No ☐
- 1) Type used: XETEX 415 A Chirper & read out
- 2) Frequency of recharging: as necessary
- 3) Frequency of reading: every time used
- 4) Comment: These are not the same as the pencil type pocket dosimeters.
- h. Direct radiation surveys of restricted and/or unrestricted areas being made: Yes ☒ No ☐
- 1) Records of surveys being maintained: Yes ☒ No ☐
- 2) Records of surveys reviewed: Yes ☒ No ☐
- 3) Period reviewed: the '81 fwd
- 4) Comments: \_\_\_\_\_

PERSONNEL RADIATION PROTECTION - INTERNAL

- a. Potential for exposure of individuals to airborne radioactive materials exists: Yes \_\_\_\_\_ No ☒ Not Applicable
- 1) If "Yes" does program for monitoring and control exist: Yes \_\_\_\_\_ No \_\_\_\_\_
- 2) Program for monitoring and control appears adequate: Yes \_\_\_\_\_ No \_\_\_\_\_
- b. Comments: \_\_\_\_\_

c. Respiratory protection program required by L/C or application:

Yes \_\_\_\_\_ No ☒

1) If "Yes" were respiratory protection procedures reviewed:

Yes \_\_\_\_\_ No \_\_\_\_\_

2) Respiratory protection procedures appear adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

3) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

d. Bioassay program required: Yes \_\_\_\_\_ No ☒

1) If "Yes" was bioassay program reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

2) Bioassay program appear adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

3) Comments:

*Only initial pre employment physical  
✓ as a base for possible future requirement  
as the result of some incident*

e. Smears and air samples

1) Monitoring for airborne radioactivity is conducted (20.103):

Yes \_\_\_\_\_ No ☒

a. Records of monitoring reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

b. Period reviewed: \_\_\_\_\_

c. Records of monitoring appears adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

2) Smear surveys being conducted (20.201, b): Yes \_\_\_\_\_ No ☒

a. Records of smear surveys reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

b. Period reviewed: \_\_\_\_\_

c. Records appeared adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

3) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

LEAK TESTS

- a. Leak tests required: Yes ☒ No ☐
- b. If "Yes" leak tests conducted: Yes ☒ No ☐
- c. Records of leak tests maintained: Yes ☒ No ☐
- d. Leak tests records reviewed: Yes ☒ No ☐
- e. Period reviewed: '81 fund
- f. Records of leak tests appear adequate: Yes ☒ No ☐
- g. Comments: Leak test performed by analysis  
performed on grab samples of the fuel  
water.

RADIOACTIVE EFFLUENT CONTROL AND WASTE DISPOSAL

- a. Byproduct material released to atmosphere and/or sewer (20.106 and 20.303):  
Yes ☐ No ☒
- b. Records of releases or radioactive effluents maintained (20.401):  
Yes ☐ No ☒
- 1) Period reviewed: \_\_\_\_\_
- 2) Records appear adequate: Yes ☐ No ☐
- c. Solid waste disposal method: Material will be returned to supplier (AECI)
- 1) Records of disposal maintained (30.51): Yes ☐ No ☒ NA
- 2) Surveys of waste prior to disposal made (20.201): Yes ☐ No ☐
- 3) Period reviewed: \_\_\_\_\_
- 4) Records of surveys appear adequate (20.401): Yes ☐ No ☐
- d. Comments: Do not anticipate any returns to supplier  
for several years.



16. SHIPPING INCIDENTS

a. Have any shipping incidents occurred since (date) None since Sept, 1987

1) Was incident documented: Yes \_\_\_\_\_ No \_\_\_\_\_

2) If "Yes" documentation appears adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

b. Comments (reports to DOT, etc.): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10CFR 19.13 (reports to individuals):

Yes ☒ No \_\_\_\_\_

b. Licensee in compliance with 10CFR 20.405 (over exposures):

Yes ☒ No \_\_\_\_\_

c. Licensee in compliance with 10CFR 20.403 (incidents):

Yes ☒ No \_\_\_\_\_

d. Licensee in compliance with 10CFR 20.402 (theft or loss):

Yes ☒ No \_\_\_\_\_

e. Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

*Not applicable  
at this time*

POSTING OF NOTICES

a. Licensee in compliance with 10CFR 19.11(a) or (b): Yes ☒ No ☐

b. Licensee in compliance with 10CFR 19.11(c): Yes ☒ No ☐

c. Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

ENVIRONMENTAL MONITORING PROGRAM

a. Environmental Monitoring Program required: Yes \_\_\_\_\_ No ☒

b. If "Yes" records reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

c. Period reviewed: \_\_\_\_\_

d. Records appeared adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

e. If Environmental Program is not required, briefly describe any existing program: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

CONFIRMATORY MEASUREMENTS

a. Independent measurements made by inspector: Yes ☒ No ☐

b. Comments (describe type, results, comparison with licensee results): \_\_\_\_\_

E-520 #9570 MPC w/ End window GM. Calib 10/5/82 and

XETEX NRE #8369 Model 305B Calib 11/20/82.

With the exception of the licensee's check source, no measurements were significantly greater than background (0.02-0.04 mR/hr).

INDEPENDENT INSPECTION EFFORT

- a. Comment on type of independent inspection effort conducted: Toured the facilities and discussed the operation with personnel.  
General Manager stated he would be ~~glad~~ happy to provide a tour for NRC inspectors at the facility. Please let him ~~know~~ (Tom Hurley) when to expect the group. ©

CONTINUATION FROM PREVIOUS PARAGRAPHS - USE BACK OF PAGE IF NECESSARY



**RADIATION  
STERILIZERS  
INCORPORATED**

**PROCEDURES MANUAL**

Procedure #80

Date: 09/09/82  
Supersedes: 1

**EQUIPMENT MAINTENANCE**

Issue: 2  
Page: 1 Of: 1

It is part of every employee's responsibility to promptly report abnormal performance, operation, wear or damage of equipment to the Maintenance Manager, Production Manager or General Manager.

The Maintenance Manager has the responsibility for administering the preventive and corrective maintenance program. The program must include specific elements of inspection and servicing, frequency and proper materials for:

- Conveyor Systems
- Source Hoists
- Detectors
- Water Treatment
- Ventilation System
- Air Compressors
- Air Actuated Systems
- Product Carriers and Totes

Maintenance activities must be recorded in a permanent log.

Authorized by:

*Dean A. Knight*

Authorized by:

*J. W. Huley*

# Exhibit C

**RADIATION  
STERILIZERS  
INCORPORATED**

February 10, 1982

MEMO TO FILE

REGARDING: TEST, RADIATION EXPOSURE  
AREA MONITOR

Maze Entry Area Film Badge was placed in maze at maze radiation detector. This area is monitored by the maze radiation detector and is exposed to 300 to 500 mR/hour.

Film badge was placed on February 10, 1982 at 09:51. It was removed on February 10, 1982 at 11:01. Source downtime during this period was 4 minutes; therefore, total exposure time was 65 minutes.

Identification of Film Badge is as follows:

0927850  
V40213-00007  
AREA #1 MAZE NT G9  
V40213-00007

By: Dean A. Knight Date 2-10-82

Witnessed By: Richard H. Winkler Date 2-10-82

Witnessed By: Paul Winkler Date 2-10-82

EtL  
12/21/82