Robert

FIRST INTERIM REPORT

OF

THE RSI INCIDENT EVALUATION TASK FORCE

DECEMBER, 1988

9004060071 900315
PDR FOIA
GILBERT90-29 PDR

5/86

OBJECTIVE - 3

This section addresses the licensing history, and radiation safety procedures for the R.S.I. Facility relative to the license conditions in License No. GA. 868-1, and Georgia Department of Human Resources, Rules and Regulations for Radioactive Materials, Chapter 290-5-23.

LICENSING HISTORY

On March 19, 1984, R.S.I. submitted an application to the Georgia Department of Human Resources for a radioactive material license to use either Cobalt-60 or Cesium-137 for sterilization purposes in a Category IV Gamma Irradiator.

The application was reviewed by personnel from D.H.R.'s Radiological Health Section and Nuclear Regulatory Commission (N.R.C.) Staff. The criteria used to evaluate this application included N.R.C. Guide for the Preparation of Applications for Licenses for the use of Gamma Irradiators (Proposed Revision-I to Regulatory Guide 10.9 dated April, 1982); N.R.C. Guide for the Preparation of Applications for

Licenses for the use of Gamma Irradiators; A.N.S.I. Standard N 43.10 - 1984 Safe Design and Use of Gamma Irradiators; N.R.C. Guide for Review of Applications for use of Gamma Irradiators; and Georgia Department of Human Resources, Radioactive Materials Rules and Regulations, Chapter 290-5-23, effective date of July 12, 1982.

After corresponding with R.S.I. Management for six months regarding R.S.I.'s license application, the Georgia Department of Human Resources, under the statuatory authority of the Georgia Radiation Control Act and pursuant to an Agreement between the U.S. Nuclear Regulatory Commission and the State of Georgia, issued R.S.I. a Georgia Radioactive Materials license on December 7, 1984.

The original Georgia Radioactive Material License No. GA 868-1 was issued to R.S.I. for the possession and storage of 500,000 curies of Cobalt-60 in R.S.I.'s storage pool. The request to use the WESF Cesium-137 capsules was not approved because these sources had not been approved by the N.R.C. for use in wet storage Gamma Irradiator Facilities at that time.

Amendment #1 issued on January 24, 1985 authorized the licensee to load the radioactive material into the source modules and source rack for purposes of performing shielding surveys and dosimetry studies.

Amendment #2 issued on February 8, 1985 authorized the licensee to use the Category IV Gamma Irradiator for the irradiation of single use medical devices and other items.

Amendment #3 issued on March 18, 1985 added a R.S.I. employee to License Condition 12A as a user for transferring radioactive material from the AECL shipping container into the source racks.

Amendment #4 issued on June 12, 1985 deleted License Condition 21B, thus allowing the licensee to perform a biological shielding survey with product carriers in the gamma irradiation cell.

Amendment #4 CORRECTED COPY, issued June 18, 1985 corrected the reference in License Condition 21 by changing 290-5-23-.03(2)(c) to 290-5-23-.03(2)(e).

Amendment #5 issued on June 18, 1985 authorized the licensee to possess 1,500,000 curies of Cobalt-60, an increase of 1,000,000 curies above the initial possession limit of 500,000 curies.

Amendment #6 issued on August 15, 1985 changed License Condition 12A by authorizing the licensee to use NRC approved shipping containers, (G.E. 1500 or AECL).

Amendment #7 issued on January 6, 1986 authorized the licensee to possess 12,300,000 curies of Cesium-137. Also added License Condition 32 which states that Cs-137 sources shall not be used until a temperature monitoring system is installed. The temperature sensor shall be installed in the source racks as close as possible to the surface of the capsule.

Amendment #7, CORRECTED COPY, issued on March 12, 1986 removed requirements of License Condition 32 based on the letter dated October 21, 1985 from N.R.C. to the Department of Energy (DOE) Office of Defense Waste and By-Product Management.

Amendment #8 issued on February 4, 1986 deleted one R.S.I. employee and added two additional employees to License Condition 12A as users for transferring radioactive material from NRC approved shipping containers into the source racks.

Amendment #9 issued on February 2, 1987 changed License Condition 19 which added the letter dated January 16, 1987 and attachments which removed the HEPA Filtration System and backup exhaust fan commitments from the original license application dated March 19, 1984.

Amendment #10 issued on May 15, 1987 changed License Condition 19 which added the letter dated April 30, 1987 concerning the key control policy relative to R.S.I. personnel.

Amendment #11 issued on November 11, 1987, changed License Condition 19 which added the letters and attachments dated March 19, 1987, September 10, 1987, September 25, 1987 and November 11, 1987, concerning the addition of the wall in the area above the cell and over the sliding doors in the machinery area; and requiring new procedures for gaining entrance through the Mezzanine Door above the cell, and a revision to the key control policy for the facility; and revising the General Operating Procedures to reflect only "Radiation Employees" are required to wear film badges; and amending the Original Emergency Power Procedure to reflect a Manual Source Lowering Procedure.

Amendment #12, changed License Condition 19 which added the letter dated November 24, 1987 which reclassified the area in the machinery room as an unrestricted area.

Amendment #13 issued June 7, 1988 changed License Condition 19 which added the letter dated June 6, 1988 to stop the product irradiation due to the leaking radioactive source.

Amendment #14 issued on August 16, 1988 required the following:

1. No product would be processed until all decontamination activities are complete. Product shall not be processed until authorized by the Georgia Department of Human Resources.
2. No actions other than those necessary to determine and maintain the safety of the plant, environment, public, and onsite personnel shall continue.
3. Submitting a detailed plan of implementation and receiving approval from the Department of Human Resources before starting any decontamination of the source storage pool and/or identification and removal of any leaking source or sources.

Amendment #15 issued June 10, 1988, required the following:

1. No product would be processed until all decontamination activities are complete. Product shall not be processed until authorized by the Georgia Department of Human Resources.

Amendment #15 (continued)

2. No actions other than those necessary to determine and maintain the safety of the plant, environment, public, and onsite personnel shall continue.

3. Submitting a detailed plan of implementation and receiving approval from the Department of Human Resources before starting any decontamination of the source storage pool and/or identification and removal of any leaking source and sources.

4. R.S.I. to ship WESF Cesium-137 Capsules which were identified by the Department of Energy to Oak Ridge National Laboratory (ORNL) in accordance with Onsite Revision 2, Packaging and Transportation Procedures dated August 11, 1988.

RADIATION SAFETY PROCEDURES

These topics address the procedures and hardware used at the facility as related to radiation safety.

Search/Security System

The irradiation cell area and control room are equipped with sequentially activated key switches. Also, the irradiation cell has emergency trip cables, and the control room has an emergency stop button.

The key switches activate various interlock systems to prevent cell entry during the sterilization process. When the key switches are closed in sequential order the following systems are activated: 1) visual and audible warning signals; 2) maze photocells; 3) pressure mats at the maze entrance; and 4) close the maze doors. When the final key switch is activated in the control room, the radioactive sources may be raised and lowered from the storage pool.

This system can be deactivated automatically by an individual performing any of the following measures: 1) tripping an emergency cable in the cell; 2) pushing the emergency stop button in the control room; 3) tripping the photocells or pressure mats at the entrance to the maze; or 4) removing the key in the control consol from the "on" position.

Also, the cell has a one way door which allows an individual egress at anytime.

Health Physics Instrumentation

The licensee possesses two Geiger-Muller Survey Instruments which are used for surveying the irradiation cell during and after each source loading, and upon routine entrances into the cell. These instruments are scheduled to be calibrated at six months intervals. Also, operational checks are to be performed with a check source daily prior to using the instruments.

The licensee has two Gamma Radiation Area Monitors inside the cell. One is used to detect the presence of radiation levels above ambient background when the sources are in the storage pool. The other monitor measures radiation levels inside the maze area of the cell when the sources are raised above the storage pool.

Also, the licensee has a Digital Area Radiation Monitor located adjacent to the ion exchange columns for continuously monitoring radiation levels on the water recirculation system in the event of a cesium source capsule leak.

Personnel Training Requirements

The license requires each employee dependent upon the individual's job title to successfully complete certain aspects of an in-house radiation and operational safety training program. (See Attachment A) The radiation safety officer, and co-radiation safety officer; licensed users; and shift supervisor (i.e. independent users) are required to complete more of the training program than a materials (product) handler.

The radiation safety officer and co-radiation safety officer must complete the entire training course or equivalent. Also, these individuals must complete a one week University level course in radiation protection. In addition, the employee must be knowledgeable of all radiation safety procedures and record requirements for the facility.

The licensed users (i.e. source handlers) must complete the basic level of the in-house training program plus the on-the-job training involving radioactive source rods/capsules manipulation.

The shift supervisor (i.e. independent users) receives a minimum of 40 hours of training which includes 20 hours of orientation/basic training. The other 20 hours of training include: a) Care, operation and maintenance of the system; b) General understanding of the safety

system operation; c) General operating procedures; d) General radiation safety rules; e) Record keeping; and f) Dosimetry calculations and methods.

All plant personnel are required to complete the Basic/Orientation level of the in-house training program.

Written tests are required for each employee and maintained on file. The minimum passing score is 80% and employees are re-instructed in subjects where difficulty is encountered.

Attachment - A

Levels of Training

Basic / Orientation	20 Hours
Intermediate Training	20 Hours
Advanced Training	20 Hours and continuing on-the-job training

Summary of Training Course Content

Basic Training:

1) Training on plant operations, functions of the various alarms (sounds and meanings).

2) Each employee received orientation relative to Chapter 290-5-23-.07 of the Georgia Rules and Regulations for Radioactive Material.

3) Specific basic radiation subjects covered are.

   a) Atomic structure and particles

   b) Radioactivity and radiation

   c) Interaction of Radiation with matter

   d) Units of radioactivity and radiation dose

e) Hazards of excessive exposure to radiation

f) Radiation effects on man

g) Methods of controlling radiation exposures - (time, distance, shielding)

h) Legal limits on radiation exposure

i) Radiation detection instruments and their application, operation, calibration, and limitations.

j) Radiation survey techniques

k) Characteristics of personnel monitoring equipment, film badges, pocket dosimeters, alarming dosimeters.

Intermediate Training

Completion of basic training, plus knowledge of conveyor operation, safety system, general operating procedures, emergency procedures, and radiation safety rules.

Advanced Training

Completion of basic and intermediate training, radiation dose evaluation, basic shielding evaluation, theory and practice of radiation protection, basic mathematical formulas for radiation protection, instrument/detector theory and applications.

On-the-job training during source loading and source handling operations: Requiring an individual to evaluate changes in survey meter readings during manipulation of source rods/capsules, and to assess possible hazardous situations. Requiring physical and manual dexterity to safely manipulate source rods/capsules. Attending and participating in job related seminars and courses.

Instructors

The Radiation Safety Officer performs the radiological safety aspects of the course. The Operations Manager performs the facility and operations portions of the training.

Personnel Monitoring Equipment

The licensee possesses three types of personnel monitoring equipment which is worn or carried for determining an individual's radiation exposure. The three types of personnel monitoring equipment are film badges, thermoluminescent dosimeters (TLDs), and pocket dosimeters. The radiation workers are provided a film badge and thermoluminescent dosimeter, and visitors are supplied with a pocket dosimeter.

The film badges are evaluated on a monthly basis. These film badges are capable of detecting and estimating beta, x-ray, gamma radiation exposures. The TLDs are evaluated on an annual basis unless a suspected exposure is encountered on the film badge. Finally, the pocket dosimeters are read immediately after being worn by a visitor.

Emergency Procedures

A) General

The safety system is designed to automatically lower the radioactive sources to the bottom of the storage pool and to stop the conveyor if any of the following detectors are activated:

1) Emergency cable in cell
2) Emergency stop button at the console in the control room
3) Maze pressure mats
4) Maze photocells
5) Smoke or fire alarm
6) Conveyor system malfunction
7) Pool water level alarm
8) Maze area radiation monitor

If the safety system is violated, the cause is displayed at the control station. The shift supervisor performs a preliminary investigation to determine the cause carrying an operable radiation survey meter at all times when entering the cell. If, after a thorough check of the safety system, there is nothing obviously wrong or the problem is identified and corrected, the system may be re-started.

If the safety system continues to indicate a violation, the shift supervisor should stop operations and notify the Radiation Safety Officer or his alternate. A current call list is posted at all times in the control room, indicating the call sequence.

B) Suspected Radiation Incident

Any indication of abnormal radiation levels at the entrance to the maze after the system has been shutdown should be treated as a suspected radiation incident and the following actions taken by the shift supervisor:

1. Confirm the presence of radiation with a second operable survey meter and note levels.
2. Makes no attempts to enter the cell.
3. Notify the Radiation Safety Officer of the incident.
4. Close and lock the doors at the entrance to the maze.
5. Shut off ventilation fans and water circulation pumps.
6. Leave the radiation area with the radiation survey meter.
7. Maintain surveillance and prevent entrance to the radiation area until the Radiation Safety Officer arrives.
8. Upon arrival the Radiation Safety Officer will assume total responsibility for any further investigations and notifications of the incident.

C) Suspected Radiation Exposure

All cases of suspected overexposure in excess of the quarterly limit of 1.25 rem for radiation workers (but less than 25 rem levels) must be reported at once to the Radiation Safety Officer.

When incidents which involve actual or suspected radiation exposure of 25 rem or more to any part of the body occur the following steps will be taken:

1. The individual will be dispatched to the Emergency Room of the specified hospital with an accompanying form letter which provides general information to the hospital attendant relative to the type of radiation accident.
2. Prior to dispatching the employee to the hospital, the film badge and TLD wallet dosimetry should be retrieved so it may be sent for processing.
3. The Radiation Safety Officer shall be notified as soon as possible.
4. All pertinent information will be documented concerning the exposure, in the event the incident has to be re-constructed. Also, additional information will be obtained from all involved employees.
5. The Radiation Safety Officer will be responsible for coordinating the investigation and providing any notifications of the incident.

NOTE: All employees at the facility are given a pre-employment physical which includes a complete blood count. This establishes a baseline for any suspected radiation overexposure.

D) Suspected Radioactive Source Capsule Failure

The licensee committed to installing a Digital Area Radiation Monitor or equivalent meter adjacent to the resin tanks for continuously monitoring radiation levels on the resin tanks (Ion Exchange Columns). The monitor would be set to provide an audible alarm between 0.1 and 0.2 millirems per hour. This alarm would alert the operator to shutoff the water recirculating system and initiate the following emergency actions:

1) The operator would confirm the radiation levels with at least two operable survey meters after shutting off the recirculating pump.

2) If the radiation levels are not confirmed, the incident would be treated as a false alarm, and operations resumed after resetting the radiation monitor.

3) If the radiation levels are confirmed, the operator would shutdown the system, evacuate all personnel from the plant, and notify the Radiation Safety Officer. The Radiation Safety Officer would be responsible for the subsequent emergency actions based on the radiation levels present inside the gamma cell.

Capsule Failure Scenarios and Facility Actions

In the event the radioactive source(s) leak generates r diation levels of 0.1 to 0.2 millirem per hour on the Digital A ea Radiation Monitor, personnel should have access to the cell for limited periods of time. Thus, the ion exchange columns encased in concrete in the cell would be used to continuously remove the radioactivity from the circulated pool water. Concurrently the leaking radioactivity source(s) would be identified using equipment developed by the Department of Energy Office at Hanford, Washington. The equipment consists of a closed loop system which includes a container in which a cesium capsule may be inserted. The radioactivity of the water in the closed loop would be monitored and increased radioactivity results would be used to indicate the leaking source(s).

In the event of a catastrophic capsule failure resulting in radiation levels above the storage pool which would prevent access by personnel. Concrete shielded resin columns would be used to lower the pool radioactivity levels to permit access by personnel. Once this level is reached. the leaking source and clean up procedure would be as described above.

The leaking source(s) would be sealed inside a container then loaded into shipping cask for return to Hanford for inspection and/or disposition.

The concrete shielded resin columns would be used for final removal of the residual radioactivity from the pool.

The contaminated concrete shielded resin columns would be disposed of via shipment to a commercial waste disposal site.

E) Manual Lowering of Source Racks

In the event of a power outage the following procedures are implemented if the power is not restored within one minute.

1) No individual shall attempt to enter the cell.
2) The Radiation Safety Officer or other designated individuals must be contacted if at all possible.
3) After an attempt to contact one of these individuals the lead operator will implement the following procedure in two steps:

a) Shielding the sources by going to the roof and locating the manual brake release on the first source hoist. Then pulling the manual release arm back and allowing the source racks to lower two or three feet then releasing the manual brake arm. Again repeating this action until the racks have been lowered approximately seven feet. This process is then repeated for source racks two through four. Also, no individual shall enter the cell.

b) The racks are then continuely lowered one at a time as described above until completely lowered to the storage position in the pool. The system is then secured by locking the conveyor room doors. The entrance to the cell is monitored until the Radiation Safety Officer or his designee arrives, or power is restored.

Once power is restored normal restart procedures are initiated.

Audible and Visual Alarms/Indicators

The facility is equipped with various audible alarms and visual indicators for warning the personnel of conditions within the cell.

The following indicators and alarms are located inside the control room.

1) Source Position Display
   - sources in the up position - Red Indicator
   - sources in the down position - Green Indicator
   - sources neither up or down - Amber or Yellow Indicator
2) Water Level Indicator for Storage Pool
   - High
   - Low
   - Normal
3) Cell Emergency Cable Indicator
4) Maze Entrance Photocell Indicator
5) Maze Pressure Mats Indicator
6) Audible Alarm for Radiation Monitor in Maze
7) Conveyor Jam/Malfunction Indicator
8) Emergency Stop Button Indicator
9) Loss of Electrical/Power Indicator
10) Smoke or Fire Alarm

11) Seismic Alarm

12) Indicator for in Cell Radiation Monitor

13) Audible Alarm for Radiation Detector for Resin Tanks (Ion Exchange Columns)

The alarms and visual signals described below are located either within or immediately adjacent to the cell.

1) A bell and warning light for warning all personnel that the gamma cell safety security system will be activated.
2) A steady horn tone for indicating when the sources are being raised from their storage position in the pool.
3) A pulsating horn tone for indicating when the sources are being lowered to their storage position.
4) A red flashing light in the maze entrance for indicating when the radioactive sources are not down; or above normal radiation levels exist in the cell.
5) Lighted signs at the maze entrance displaying either "Entry Permitted" or "No Entry" depending on cell status.

Safety System Operational Checks

The licensee performs operational checks monthly of the following components of the safety system.

1. Emergency Cable inside the gamma cell.
2. Emergency Stop Buttons relative to the position of the radioactive sources in the gamma cell.
3. Key switches which activate the gamma cell.
4. Pressure Mats at the entrance to the gamma cell.
5. Area Radiation Monitor inside the gamma cell.
6. Area Radiation Monitor inside the maze.
7. Photocells inside the maze.
8. Smoke and Fire Alarm including temperature alarm.
9. Water Level Indicator.
10. Status Lights and Warning Signs relative to gamma cell status.
11. Audible alarms relative to gamma cell conditions.
12. Status Printer for the Radioactive sources.

Note: Operational checks of the pressure mats and maze photocells are performed prior to starting the gamma cell system after each overnight shutdown.

ATTACHMENT - B

Copies

of

Radiation Sterilizer, Inc.'s

Radioactive Material License

and

Amendments

Georgia Department of Human Resources
Radiological Health Section

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Georgia Radiation Control Act No. 936 (H. B. 162) 1964 and the Georgia Department of Human Resources Rules and Regulations, C Chapter 290-5-23, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued a such licensee to transfer, receive, possess, and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) a piece(s) designated below. This license is subject to all applicable rules and regulations of the Georgia Department of Human Resources and orders of t logical Health Section, now or hereafter in effect and to any conditions specified below.

License (1. Name and 2. Address)	3. License Number	GA. 868-1
Radiation Sterilizers, Inc. 300 Sand Hill Road #2-190 Menlo Park, California 94025	4. Expiration Date	December 31, 1989
	5. Area Code / Telephone No.	404 / 981-4077

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess a one time
A. Cobalt 60	A. Sealed sources (AECL Model C-188, Types 1,2, 3, or 4)	A. 500,000 curies (No single source to exceed 12,000 Curies

9. Authorized Use

A. For possession and storage in RSI's source storage pool located at 2300 Mellon Court Decatur, Georgia. The sources shall be stored in and not removed from the AECL Model F 234 shipping cages.

Conditions

10. Radioactive material may be used only at Radiation Sterilizers Inc., 2300 Mellon Court, Decatur, Georgia 30035.

11. The licensee shall comply with the provisions of Georgia Department of Human Resou Rule 290-5-23-.03, "Standards for Protection Against Radiation," and Rule 290-5-23 "Notices, Instructions and Reports to Workers; Inspections."

Page of Pages

Date December 7, 1984

For the Georgia Department of Human Res

BY

Form 3851 (Rev. 3-82)

CONDITIONS (Continued)

12. Radioactive Material in the AECL Model F 234 shipping cages shall be removed from the shipping cast and placed in storage by, or under the supervision and in the physical presence of Allan Chin, Bruce C. Meyer, Thomas W. Hurley, or Barry P. Fairand.

13. The Radiation Safety Officer in this program shall be Mr. Tom Fisher.

14. This license does not authorize the loading of the radioactive sources into the source modules or the source racks.

15. Sealed sources oontaining radioactive material shall not be opened by the licens

16. A.
Each sealed source containing radioactive material shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be put into use until tested.

B.
The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Alternately, the test shall be capable of detecting the presence of 4×10^{-8} microcuries per milliliter of radioactive material in the test sampl The test sample shall be taken from the source storage pool or from a sampling tap immediately prior to the particulate filters. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.

C.
If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed sources from use and shall cause them to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within 5 days of the test with the Radiological Health Section, Georgia Department of Human Resources, Atlanta, Georgia, describing the equipment involved, the test results, and the corrective action taken.

D.
Analysis of tests for leakage and/or contamination shall be performed by Helegson Nuclear Services or by other persons specifically authorized by this Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE December 7, 1984

BY _____

CONDITIONS (Continued)

17. Safety features of the irradiator (which includes but is not limited to entry control devices, intrusion detection devices, warning systems, and controller logic which governs any safety device or system) shall not be altered, modified, replaced or in any way changed without written approval of the Department. The licensee shall immediately report to the Department by telephone or telegraph the failure of any safety feature (device, system, or circuit) of the irradiator. A written report of such failure shall be filed with the Department within 10 days after the failure, describing the failure, conditions under which the failure occured, the suspected cause (s) of the failure, and action taken or proposed to correct the failure and prevent recurrence.

18. The irradiator cell and maze shall be checked using a physical radiation detection instrument to assure that prior to the first individual's entry into these areas, the radiation level from the source in these areas is below that at which it would be possible for an individual to receive a dose in excess of 100 millirem in any one hour.

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in;

    A. Application dated March 9, 1984 and signed by Allan Chin, President;

    B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

    C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President; and

    D. Letters dated November 1, 1984 and December 3 , 1984 and signed by Tom Fisher, General Manager.

    The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE December 7, 1984

BY _____

Georgia Department of Human Resources

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTARY SHEET

LICENSE NUMBER GA.

AMENDMENT NO. .0

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated January 10, 1985 and signed by Mr. Tom Fisher for Allan Chin, President, Radioactive Material License GA. 868-1 is amended as follows:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
A. Cobalt 60	A. Sealed Sources (AECL Model C-188, Types 1, 2, 3, or 4.)	A. 500,000 Curies (No single source to exceed 12,000 curies

9. Authorized Use

For installation of the sealed sources into the source modules and the source modules into the source racks at RSI's Category IV Gamma Irradiator located at 2300 Melon Court, Decatur, Gerogia; for performance of radiation surveys with the source racks in their up, operating position to determine the maximum radiation levels in each area adjoining the irradiation cell and maze; and for the performance of dosimetry surveys.

Conditions

(Continued)

DATE January 24, 1985

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCE

BY [signature]

DPH/EHS(5)—4

CONDITIONS (Continued)

CONDITION 12. IS AMENDED TO READ:

12. A. Radioactive Material shall be removed from the AECL Model F 234 shipping cages and placed into the source modules and the source modules placed into the source racks by or under the supervision and in the physical presence of Allan Chin, Bruce C. Meyer, Thomas W. Hurley, or Barry P. Fairand.

B. Radioactive material shall be used by or under the direct supervision of Tom Fisher, Radiation Safety Officer, or other individuals designated by him who have completed the basic and intermediate training and the ninety-days (90) on-the-job training program described in; Section 9 of attachments to application dated March 19, 1984, letter dated August 21, 1984 and letter dated January 10, 1985. Direct supervision shall be exercised by the individual's physical presence at the plant facility.

CONDITION 14 IS DELETED:

14. (Deleted)

CONDITION 19. IS AMENDED TO READ:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in;

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated November 1, 1984 and December 3, 1984 and signed by Tom Fisher, General Manager; and

E. Letter dated January 10, 1985 and signed by Tom Fisher for Allan Chin, President.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE January 24, 1985

BY Bobby H. Whitley

Form 7854

CONDITIONS (Continued)

20. The following condition was described and submitted by you for approval in letter dated January 10, 1984 wherein you requested that ANSI NO. 43.10 be utilized as the procedure for performing biological shield surveys.

After installation of sealed sources in the irradiator, a radiation survey shall be conducted in accordance with ANSI NO. 43.10 with the source racks loaded and in their up operating position to determine the maximum radiation levels in each area adjoining the radiation shield.

21. To demonstrate compliance with the Rules and Regulations for Radioactive Material Chapter 290-5-23-.03 (2) (c) the biological shield surveys shall be conducted:

a) prior to the initiation of any irradiation of materials after the initial loading of the source racks and after each increase in the total curie loading of the source racks;

b) without product carriers, products, or any other material in the irradiate cell or maze which would add to the inherent shielding of the permanent physical structures of the irradiator.

In compliance with the requirements of the Rules and Regulations for Radioactive Materials Chapter 290-5-23-.02 (12) (b) 2. A report of the results of the above surveys and test shall be sent to the Director, Radiological Health Section, Georgia Department of Human Resources, Atlanta, Georgia, not later than thirty (30 days following each installation of sources in the source racks.

22. The following condition was described by you and submitted for approval in your original application and subsequently amended by letters dated October 31, 1984 and January 10, 1985 submitted thereafter and by oral assurances.

The irradiator shall be maintained such that all entry control devices, all intrusion detection devices and all information and warning devices must be functioning properly to initiate any operation utilizing the radiation sources. No operation shall be initiated or continued unless these devices are functioning properly except those operations necessary to place the sources in a safe condition or to repair the malfunctioning device(s).

23. The following condition was described and submitted by you for approval in your original application and subsequently amended by letters dated January 10, 1985, Item 1 and January 17, 1985, Item 1 to reflect the following: The restricted area for the purposes of this license is to be defined as the area beyond the floor to ceiling wall as per your modification.

The irradiator shall be operated in accordance with 10CFR, Part 20, Section

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE January 24, 1985

BY Bobby H. Dillehay

Form 7854

CONDITIONS (Continued)

23. Continued.

20.203 (c) (6) (i) and (ii). Entrance and/or exit doors to/from the defined restricted area shall remain closed at all times when the source racks are not in their shielded storage position in the source storage pool. Entrance into the defined restricted area shall be obtained only after a device has been activated that shall cause the radiation level within one meter of the sealed radioactive sources to be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 millirems in one hour.

24. The following condition was described and submitted by you for approval in your original application and subsequently amended by letter dated August 22, 1984 to reflect the following:

The building roof hatch access to the roof of the Gamma cell shall be kept locked except during shielded cask handling operations or during roof maintenance.

25. The following condition was described and submitted by you for approval in your original application and subsequently amended by letter dated October 31, 1984 to reflect the following:

In the event of the activation of the seismic detector, the high level radiation alarm in the maze, or any water alarm, the source racks shall be returned to their fully shielded position in the source storage pool.

In your original application which was subsequently amended by letter dated October 31, 1984, you submitted for approval a procedure whereby activation of the emergency stop button would cause the source racks to be returned to their fully shielded position in the source storage pool. Upon inspection it was determined that activation of the emergency stop button would not result in the return of the sources to the fully shielded position. It is highly recommended that you institute the procedure described in letter dated October 31, 1984.

26. The following condition was described and submitted by you for approval in your original application and subsequently amended by letter dated October 31, 1984 to reflect the following:

Before removing the source racks from the fully shielded position in the source storage pool the following visual signals shall be operational such that:

(a) Entry status lights at entrance to the maze area indicate, "No Entry," when

(1) Console key switch is set;

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE January 24, 1985

BY Teddy A. Taylor

CONDITIONS (Continued)

26. (a) (2) Continued.

(2) Source racks are not completely down; and

(3) Radiation is detected in the cell or maze regardless of whether key switches are set;

(b) There is a visual display at the control station of the source rack position. Sources up - red display, Sources down - green display, Sources neither up or down - amber or yellow display.

In your original application which was subsequently amended by letter dated October 31, 1984 you submitted for approval a description of the Radiation Detection System and the Gamma Cell Safety System whereby a visual display at the control station would show the radiation present in the cell and/or in the maze, as appropriate. Upon inspection it was determined that the radiation present in the cell or maze would not be displayed at the control station. It is recommended that you install the display as described in the letter dated October 31, 1984.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY [signature]

DATE January 24, 1985

Georgia Department of Human Resources

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTARY SHEET

PAGE 1 OF 2 PAGES

LICENSE NUMBER GA. 868-1

AMENDMENT NO. 03

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated January 17, 1985 and signed by Mr. Tom Fisher for Allan Chin, President, Radioactive Material License GA. 868-1 is amended as follows:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
A. Cobalt 60	A. Sealed Sources (AECL Model C-188, Types 1, 2, 3, or 4.)	A. 500,000 curies (no single source to exceed 12,000 curies.

9. Authorized Use

For use in RSI's Category IV Gamma Irradintor located at 2300 Mellon Court, Decatur, Georgia; for irradiation of single use medical devices and other items. No flammable, corrosive or explosive substance are to be irradiated.

Conditions

CONDITION 19. IS AMENDED TO READ:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

(See Page Two)

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Thomas E. Reid

DATE February 8, 1985

DPH/EMS(5)-4

CONDITIONS (Continued)

19. A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

CONDITIONS 27., 28., 29., 30., and 31. ARE ADDED:

27. The following condition was described and submitted by you for approval in your original application and subsequently amended by letter dated October 31, 1984 to reflect the following:

The irradiator cell and maze shall be visually checked by the operator and controlled by any additional administrative procedures that are necessary to assure that these areas are cleared of personnel prior to each use of the source.

28. General operating procedures contained in Section 6 of the application as modified by letters dated October 31, 1984, January 11, 1985 and January 17, 1985 and Emergency Procedures contained in Section 12 of the application modified by letter dated October 31, 1984 shall be followed. A copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall be submitted to Department of Human Resources, Radiological Health Section as an amendment request to Radioactive Material License GA. 868-1.

29. The following condition was described and submitted by you for approval in your letter dated January 17, 1985 to reflect the following:

The programmer shall be used only by the General Manager or his designee under the direction of the Corporate Director of Engineering or his designee for troubleshooting problems within the irradiator.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE February 8, 1985

BY Thomas E. Fisher

1854

CONDITIONS (Continued)

30. In accordance with the Rules and Regulations for Radioactive Material Chapter 290-5-23-.02 (12):

A. Any proposed change to the safety system software program shall be submitted to the Georgia Department of Human Resources, Radiological Health Section as an amendment request to Radioactive Materials License GA. 868-1.

B. Proposed modifications in procedures and/or the facility affecting radiation safety shall be submitted to the Department of Human Resources, Radiological Health Section as an amendment request to Radioactive Material License GA. 868-1. A written analysis may be required by the Department of Human Resources, Radiological Health Section to determine the amendment's compliance with appropriate statutes, rules and regulations.

31. The following condition was described by you and submitted for approval in your original application and subsequently amended thereafter by letter dated October 31, 1984 and by oral assurances.

The irradiator shall be operated only in modes where the product entrance and exit doors remain closed or are blocked by product carriers to prevent entry when the radioactive sources are not in their shielded storage position.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE February 8, 1985

BY Thomas E. Idell

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-1

AMENDMENT NO. .03

CORRECTED COPY

Radiation Sterilizers, Inc.
300 Sand Hill Road, # 2-190
Menlo Park, California 94025

In accordance with letter dated February 25, 1985 and signed by Tom Fisher, General Manager, License No. GA. 868-1 is amended as follows:

Condition 12, is amended to read:

12. A. Radioactive Material shall be transferred from the AECL shipping container into the source racks by or under the supervision and in the physical presence of Allan Chin, Bruce C. Meyer, Thomas W. Hurley, Barry P. Fairand or Tom Fisher.

B. Radioactive Material shall be used by or under the direct supervision of Tom Fisher, Radiation Safety Officer, or other individuals designated by him who have completed the basic and intermediate training and the ninety-days (90) on-the-job training program described in; Section 9 of attachments to application dated March 19, 1984, letter dated August 21, 1984 and letter dated January 10, 1985. Direct supervision shall be exercised by the individual's physical presence at the plant facility.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE April 8, 1985

BY Thomas C. Fisher

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868

AMENDMENT NO. .04

CORRECTED COPY

Radiation Sterilizers, Incorporated
300 Sand Hill Road, # 2-190
Menlo Park, California 94025

In accordance with letter dated April 25, 1985 and signed by Tom Fisher, General Manager, License No. GA. 868-1 is amended as follows:

Condition 21. is amended to read:

21. To demonstrate compliance with the Rules and Regulations for Radioactive Material Chapter 290-5-23-.03 (2) (e) the biological shield surveys shall be conducted prior to the initiation of any irradiation of materials after the initial loading of the source racks and after each increase in the total curie loading of the source racks.

In compliance with the requirements of the Rules and Regulations for Radioactive Materials Chapter 290-5-23-.02 (12) (b) 2. A report of the results of the above surveys and test shall be sent to the Director, Radiological Health Section, Georgia Department of Human Resources, Atlanta, Georgia, not later than thirty (30) days following each installation of sources in the source racks.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE June 18, 1985

BY Thomas E. Hill

Form 3854

RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE ___ OF ___ PAGES

LICENSE NUMBER GA. 868-.

AMENDMENT NO. .05

Radiation Sterilizers, Incorporated
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated June 17, 1985 and signed by Tom Fisher, General Manager, License No. Ga. 868-1 is amended as follows:

Item 8.A. is amended to read:

8.A. 1,500,000 Curies (no single source to exceed 12,000 Curies).

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE June 18, 1985

BY Thomas E. Hill

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA.868-1

Amendment No. .06

Radiation Sterilizers, Inc.
300 Sand Hill Road, # 2-190
Menlo Park, California 94025

In accordance with letter dated August 12, 1985 and signed by Tom Fisher, General Manager, License No. GA.868-1 is amended as follows:

Condition 12, is amended to read:

12. A. Radioactive Material shall be transferred from NRC approved shipping containers into the source racks by or under the supervision and in the physical presence of Allan Chin, Bruce C. Meyer, Thomas W. Hurley, Barry P. Fairand or Tom Fisher.

B. Radioactive Material shall be used by or under the direct supervision of Tom Fisher, Radiation Safety Officer, or other individuals designated by him who have completed the basic and intermediate training and the ninety-days (90) on-the-job training program described in; Section 9 of attachments to application dated March 19, 1984, letter dated August 21, 1984 and letter dated January 10, 1985. Direct supervision shall be exercised by individual's physical presence at the plant facility.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Thomas E. Hill

DATE August 15, 1985

Form 3854

Georgia Department of Human Resources

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-1

AMENDMENT NO. 07

Radiation Sterilizers, Incorporated
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated August 16, 1985 and signed by Allan Chin, President, Radioactive Material License GA. 868-1 is amended as follows:

To add:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
B. Cesium 137	B. Sealed Sources (DOE WESF)	B. 12,300,000 curies Each source not to exceed 150,000 curies

9. Authorized Use

B. For use in RSI's Category IV Gamma Irradiator located at 2300 Mellon Court, Decatur, Georgia; for irradiation of single use medical devices and other items. No flammable, corrosive or explosive substance are to be irradiated.

Conditions

Condition 19. (See Page 2)

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Thomas E. Hill

DATE January 6, 1986

DPH/EMS(5)—4

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA 868-1

AMENDMENT NO. 07

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President; and

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

Condition 32. is added:

32. The licensee shall not use any cesium-137 sources until a temperature monitoring system is installed. The temperature sensor shall be installed in the source racks as close as possible to the surface of the capsule estimated to reach the highest temperature.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Thomas E. Hill

DATE January 6, 1986

Form 3854

'eorgia Department of Human Resource
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 2

LICENSE NUMBER 1

AMENDMENT NO. 10

CORRECTED COPY

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated August 16, 1985 and signed by Allan Chin, President, Radioactive Material License No. GA. 868-1 is amended as follows:

To Add:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
B. Cesium 137	B. Sealed Source (DOE WESF)	B. 12,300,000 curies Each source not to exceed 150,000 curies

9. Authorized Use

B. For use in RSI's Category IV Gamma Irradiator located at 2300 Mellon Court, Decatur, ~~Georgia~~ for irradiation of single use medical devices and other items. No flammable, corrosive or explosive substance are to be irradiated.

Conditions

Condition 19. (See Page 2)

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOU

BY Thomas E. Hill

DATE March 12, 1986

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-

AMENDMENT NO. .07

CORRECTED COPY

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President; and

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE March 12, 1986

BY Thomas E. Hill

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 868-

Amendment No. .08

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated January 9, 1986 and signed by Tom Fisher, General Manager, License No. GA. 868-1 is amended as follows:

Condition 12, is amended to read:

12. A. Radioactive Material shall be transferred from NRC approved shipping containers into the source racks by or under the supervision and in the physical presence of Allan Chin, Bruce C. Meyer, Barry P. Fairand, Tom Fisher, Adam Clipson, or Bob Ramsey.

B. Radioactive Material shall be used by or under the direct supervision of Tom Fisher, Radiation Safety Officer, or other individuals designated by him who have completed the basic and intermediate training and the ninety-days (90) on-the-job training program described in; Section 9 of attachments to application dated March 19, 1984, letter dated August 21, 1984 and letter dated January 10, 1985. Direct supervision shall be exercised by individual's physical presence at the plant facility.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE February 4, 1986

BY Thomas E. Hill

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 868-1

AMENDMENT NO. .09

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated January 16, 1987 and signed by Tom Fisher, General Manager, Radioactive Material License No. GA. 868-1 is amended as follows:

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President:

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President:

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President;

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President; and

G. Letter dated January 16, 1987 and signed by Tom Fisher, General Manager.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE February 2, 1987

BY Wilford D. Ingram

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 868-1

AMENDMENT NO. 10

Radiation Sterilizers, Inc.
300 Sand Hill Road, ~~#2-190~~ 4-245
Menlo Park, California 94025

In accordance with letter dated April 30, 1987 and signed by Tom Fisher, General Manager, Radioactive Material License No. GA. 868-1 is amended as follows:

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letter dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and Janurary 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President;

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President;

G. Letter dated January 16, 1987 and signed by Tom Fisher, General Manager; and

H. Letter dated April 30, 1987 and signed by Tom Fisher, General Manager.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE May 15, 1987

BY Willard D. Ingram

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-1
Amendment No. 11

Radiation Sterilizers, Inc.
300 San Hill Road, #4-245
Menlo Park, California 94025

In accordance with letters dated March 19, 1987, September 10, 1987, September 25, 1987, and November 11, 1987, all signed by Tom Fisher, Vice President of Operations, Radioactive Material License No. GA. 868-1 is amended as follows:

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letter dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President;

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President;

G. Letter dated January 16, 1987 and signed by Tom Fisher, General Manager;

H. Letter dated April 30, 1987 and signed by Tom Fisher, General Manager; and

I. Letters dated March 19, 1987, September 10, 1987, September 25, 1987, and November 11, 1987 all signed by Tom Fisher, Vice President of Operations.

The Georgia Department of Human Resources' Rules and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statement are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

BY Willard H. Ingram

DATE November 19, 1987

Form 3854

Georgia Department of Human Resources
RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-1

Amendment No. 12

Radiation Sterilizers, Inc.
300 San Hill Road, #4-245
Menlo Park, California 94025

In accordance with letters dated March 19, 1987, September 10, 1987, September 25, 1987, and November 11, 1987, all signed by Tom Fisher, Vice President of Operations, Radioactive Material License No. GA. 868-1 is amended as follows:

Condition 19. is amended to read:

19. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in:

A. Application dated March 9, 1984 and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984 and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984 and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985 and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985 and signed by Allan Chin, President;

F. Letter with attachment dated December 10, 1985 and signed by Allan Chin, President;

G. Letter dated January 16, 1987 and signed by Tom Fisher, General Manager;

H. Letter dated April 30, 1987 and signed by Tom Fisher, General Manager;

I. Letters dated March 19, 1987, September 10, 1987, September 25, 1987, and November 11, 1987 all signed by Tom Fisher, Vice President of Operations ; and

J. Letter dated November 24, 1987 and signed by Tom Fisher, Vice President of Operations.

The Georgia Department of Human Resources' Rule and Regulations for Radioactive Materials, Chapter 290-5-23 shall govern the licensee's statements in applications or letters, unless the statement are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE _____

BY Willard D. Ingram

Georgia Department of Human Resources

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 868-1

Amendment No. 13

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated June 6, 1988, and signed by Tom Fisher, Vice President, Quality Assurance and Regulatory Affairs, Radioactive Material License No. GA. 868-1 is amended as follows:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
A. Cobalt 60	A. Sealed Source (AECL Model C-188, Types 1, 2, 3, or 4)	A. 1,500,000 curies (No single source to exceed 12,000 curies)
B. Cesium 137	B. Sealed Source (DOE WESF)	B. 12,300,000 curies each source not to exceed 150,000 curies

9. Authorized Use

A. and B. For use in Radiation Sterilizers, Inc. Category IV Gamma Irradiator located at 2300 Mellon Court, Decatur, Georgia for storage only and activities related to decontamination, identification and removal of leaking source or sources. Product is not to be processed until all decontamination activities are complete. Product shall not be processed until authorized by the Georgia Department of Human Resources.

Conditions

Condition 19. (See Page 2)

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE June 7, 1988

BY Thomas E. Hill

3839 (4-86)

CONDITION (Continued)

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the documents including any enclosures, listed below:

A. Application dated March 9, 1984, and signed by Allan Chin, President;

B. Letter with attachments dated August 21, 1984, and signed by Allan Chin, President;

C. Letters dated October 4, 1984 and October 31, 1984, and signed by Allan Chin, President;

D. Letters dated January 10, 1985 and January 17, 1985, and signed by Tom Fisher for Allan Chin, President;

E. Letter dated August 16, 1985, and signed by Allan Chin, President;

F. Letter with attachment dated December 10, 1985, and signed by Allan Chin, President;

G. Letter dated January 16, 1987, and signed by Tom Fisher, General Manager;

H. Letter dated April 30, 1987, and signed by Tom Fisher, General Manager;

I. Letters dated March 19, 1987, September 10, 1987, September 25, 1987, and November 11, 1987, all signed by Tom Fisher, Vice President of Operations;

J. Letter dated November 24, 1987, and signed by Tom Fisher, Vice President of Operations; and

K. Letter dated June 6, 1988, and signed by Tom Fisher, Vice President, Quality Assurance and Regulatory Affairs.

The Georgia Department of Human Resources' regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE June 7, 1988

BY Thomas E. Hill

3854

RADIATION STERILIZERS INCORPORATED

November 24, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Department Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

Per our phone conversation on November 20, 1987, I am requesting that the area beyond the floor to ceiling, machinery room, be reclassified as an unrestricted area.

The request is being made because of the addition of the walled in area above the cell and over the sliding doors.

If you have any questions, please contact me.

Sincerely,

Tom Fisher
Vice President of Operations

TDF/cc

RECEIVED
DEC 1 1987
RADIOLOGICAL HEALTH UNIT

RADIATION STERILIZERS INCORPORATED

June 6 1988

Memo to: Mr Tom Hill
From: Mr Tom Fisher
Subject: Leaking Cesium Source and cleanup
Re: License number GA-868-1

Dear Tom,

Due to the leaking source and cleanup at Radiation Sterilizers Inc., no product will be processed until the leaking source and cleanup is completed.

Sincerely,

Tom Fisher

Radiation Sterilizers Incorporated, 2300 Melion Court, Decatur, Georgia 30035/Telephone: (404)981-4077

Georgia Department of Human Resources

RADIOACTIVE MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

LICENSE NUMBER GA. 86

Amendment .14

diation Sterilizers, Inc.
..0 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated June 6, 1988, and signed by Tom Fisher, Vice President, Quality Assurance and Regulatory Affairs, and discussions held in RSI's offices on June 9, 1988, Radioactive Material License No. GA. 868-1 is amended as follows:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
A. Cobalt 60	A. Sealed Source (AECL Model C-188, Types 1, 2, 3, or 4)	A. 1,500,000 curies (No single source to exceed 12,000 curies)
B. Cesium 137	B. Sealed Source (DOE WESF)	B. 12,300,000 curies each source not to exceed 150,000 curies

9. Authorized Use

A. and B.

1. For use in Radiation Sterilizers, Inc. Category IV Gamma Irradiator locate at 2300 Mellon Court, Decatur, GA for storage only. Product is not to be processed until all decontamination activities are complete. Product shal not be processed until authorized by the Georgia Department of Human Resources.
2. No actions other than these necessary to determine and maintain the safety of the plant, environment, public, and onsite personnel shall continue.
3. Prior to starting any decontamination of the source storage pool and/or identification and removal of any leaking source or sources, RSI shall submit a detailed plan of implementation and receive approval from the Department of Human Resources.

Conditions

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOURCES

DATE June 10, 1988

BY Thomas E. Hill

rm 3839 (4-86)

RADIOACTIVE MATERIALS LICENSE SUPPLEMENTARY SHEET

LICENSE NUMBER GA. 86
Amendment No. 15

Radiation Sterilizers, Inc.
300 Sand Hill Road, #2-190
Menlo Park, California 94025

In accordance with letter dated August 9, 1988, and signed by Allan Chin, President, Radioactive Material License No. GA. 868-1 is amended as follows:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may possess at any one time
A. Cobalt 60	A. Sealed Source (AECL Model C-188, Types 1, 2, 3, or 4)	A. 1,500,000 curies (No sin source to exceed 12,000 curies)
B. Cesium 137	B. Sealed Source (DOE WESF)	B. 12,300,000 curies each source not to exceed 150,000 curies

9. Authorized Use

A. and B.

1. For use in Radiation Sterilizers, Inc. (RSI) Category IV Gamma Irradiator located at 2 Mellon Court, Decatur, GA for storage only. Product is not to be processed until all decontamination activities are complete. Product shall not be processed until authoriz by the Georgia Department of Human Resources.
2. No actions other than those necessary to determine and maintain the safety of the plan environment, public, and onsite personnel shall continue.
3. Prior to starting any decontamination of the source storage pool and/or identification removal of any leaking source or sources, RSI shall submit a detailed plan of implementation and receive approval from the Department of Human Resources.
4. Removal of capsules identified by Department of Energy for testing purposes shall be shipped by RSI to Oak Ridge National Laboratory (ORNL) in accordance with Onsite Revis 2, Packaging and Transportation Procedures dated August 14, 1988.

Conditions

FOR THE GEORGIA DEPARTMENT OF HUMAN RESOUR(

BY Thomas E. Hill

DATE August 16, 1988

RADIATION STERILIZERS INCORPORATED

November 11, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Dept. Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

With the addition of the walled in area above the cell and over the sliding doors in the machinery our key control policy has been revised plus a new procedure for gaining entrance through the mezzanine door has been established.

We hope the above information meets with your approval and that the non-compliance issue, of February 18, 1985 can now be found in compliance.

If you have any questions please contact me.

Sincerely,

Tom Fisher
Vice President of Operations

TDF/dp

Enclosures

RECEIVED
NOV 13 1987
RADIOLOGICAL
HEALTH UNIT

RADIATION STERILIZERS INCORPORATED

Procedure for Using Mezzanine Door on Top of Cell

1. Before access through the mezzanine door on top of cell can be accomplished, the following procedure must be completed.

2. Mezzanine Door Entrance Procedure: Entrance through the mezzanine door on top of cell will be gained by lowering the sources, turning the console key to off, removing it, and then placing the console key in safety enumerator panel and actuating. Entry through the mezzanine cell door can then be made carrying an operable survey meter.

3. Once work has been accomplished the cell mezzanine door will be locked and normal start up procedures used.

#30

KEYS

a. Console Key
b. Roof Latch Key
c. Machinery Room Keys
d. (3) Item Machinery Room
e. Mezzanine Door Key

Only authorized personnel, production manager, shift supervisors and any material handler who has satisfactorily completed the supervisors requirements, will have access to keys that would allow entry into restricted areas of the building.

a. There will be only one console key available for operating the control console at ant time during a 24 hour period. The RSO will have the other console key locked in his desk. If at any time the building is not operational the console key will be returned to the RSO.

b. The roof latch keys will also be locked up in the RSO desk and will only be issued to authorized personnel upon loading/unloading radiation sources or to do maintenance on the roof of the building. When loading/unloading of radiation sources or maintenance on the roof is completed the key will be returned to tne RSO.

c. The two doors leading to the tote transfer room will have one key issued to each shift supervisor and production manager.

d. The three console panels in the tote transfer room, programable controller, electrical and safety annumerator panel, will have one key issued to the production manager who in turn will stage the key in the console room so that each shift supervisor will have access to the key in order to perform maintenance on the system.

e. There will be only one mezzanine door key issued and it will be to the maintenance manager. The spare keys will be locked up in the RSO desk.

RADIATION STERILIZERS INCORPORATED

September 25, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Department of Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

Per our phone conversation on September 16, 1987, concerning our request to require only "Radiation Employees" to wear film badges while working. The changes in section #6 item #8 of our license. If you have any questions please contact me.

Sincerely,

Tom Fisher
Vice President of Operations

TDF/DP

RECEIVED
SEP 19 1987
RADIOLOGICAL HEALTH UNIT

Radiation Sterilizers Incorporated, 2300 Mellon Court, Decatur, Georgia 30035/Telephone: (404)981-4077

Section No. 6

General Operating Procedures

Standing Orders

1. The Radiation Safety Officer (RSO) will have total responsibility for all aspects of the operation pertaining to radiation.

2. The RSO will authorize specific personnel to load and unload isotope based on training and experience. Unauthorized personnel are not permitted to move the sources, however, they may assist when under the direct supervision of an authorized person.

3. The RSO will authorize personnel to be shift supervisors based on training and experience. This will include the proper use of the control console to raise and lower the conveyors.

4. Unauthorized persons will not be permitted in the building.

5. The building will be locked at all times when unoccupied.

6. All entries into the radiation cell will be logged into the entry log.

7. The RSO will designate those personnel who will have access to the radiation cell.

8. Only "radiation employees" will wear radiation film badges at all times within the facility.

9. There will be no smoking permitted in the building except in designated areas.

10. Personnel will not attempt to ride on a moving conveyor.

11. Personnel will not alter or modify the control and safety system.

12. Visitors to the gamma cell will sign the visitors log and be issued a digital type dosimeter to be carried during the period of their visit. Initial and final dosimeter readings will be recorded with name, date, and affiliation.

STERILIZERS INCORPORATED

September 10, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Department of Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

Per our phone conversation on September 4, 1987, concerning our request to increase the 30 second delay time to 45 seconds. This increase in time will allow more time to visually assure that everyone is out of the cell prior to setting the safety system up for operation.

The change is in section No. 3, "Gamma Cell Safety System", of our license.

If you have any questions please contact me.

Sincerely,

Tom Fisher
Vice President of Operations

TDF/cc

RECEIVED
SEP 11 1987
RADIOLOGICAL HEALTH UNIT

Radiation Sterilizers Incorporated, 2300 Mellon Court, Decatur, Georgia 30035/Telephone: (404)981-4077

RADIATION STERILIZERS INCORPORATED

RECEIVED
MAY 1 1987
RADIOLOGICAL HEALTH UNIT

April 30, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Department of Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

I would like to amend our key control policy that was submitted in our license, GA-868-1, to the state on January 15, 1985 to read as follows:

Keys

a. Console Key
b. Roof Latch Key
c. Machinery Room Keys
d. Machinery Room Panel Keys
e. Electrical Box Keys

Only authorized personnel, production manager, shift supervisors and any material handler who has satisfactorily completed the supervisors requirements, will have access to keys that would allow entry into restricted areas of the building.

a. There will be only one console key available for operating the control console at any time during a 24 hour period. The RSO will have the other console key locked in his desk. If at any time the building is not operational the console key will be returned to the RSO or his designee.

b. The roof latch keys will also be locked up in the RSO's desk and will only be issued to authorized personnel upon loading/unloading radiation sources or to do maintenance on the roof of the building. When loading/unloading of radiation sources or maintenance on the roof is completed the key will be returned to the RSO.

c. The two doors leading to the tote transfer room will have one key staged so that it will be accessible to all shift supervisors.

Radiation Sterilizers Incorporated, 2300 Melion Court, Decatur, Georgia 30035/Telephone: (404)981-4077

d. The three console panels in the tote transfer room, programmable controller, electrical and safety annumerator panel, will have one key issued to the production manager who in turn will stage the key in the console room so that each shift supervisor will have access to the key in order to perform maintenance on the system.

e. The electrical panel boxes on top of the cell will be kept locked and the key will be staged in the control console room along with keys in item #d.

f. All keys not issued in items a-e will be locked up in the General Manager's office.

If you have any questions please contact me.

Sincerely,

Tom Fisher
General Manager

TDF/cc

RADIATION STERILIZERS INCORPORATED

December 10, 1985

Mr. Thomas E. Hill, Chief
Radioactive Materials Unit
Radiological Health Section, Suite 600
Georgia Department of Human Resources
878 Peachtree Street, NE
Atlanta, GA 30309

Reference: License Number GA.868-1

Dear Mr. Hill:

The following information is provided in response to the requests outlined in your December 2, 1985 letter.

1. A model 501A Digital Area Monitor (or equivalent meter) will be installed adjacent to the resin tanks for continuous monitoring. The monitor will be set to provide an audible alarm between 0.1 and 0.2mr/hr. This alarm will alert the operator to shut off the recirculating system and to initiate emergency actions.

2. Two types of capsule failure are possible. The first is a small leak due to a weld failure or pin hole. In this situation leakage rates will be very low and personnel would have access to the cell for limited periods of time where the radiation levels are 0.1 to 0.2 mr/hr.

Ion exchange columns encased in concrete will be used to continuously remove the activity from the circulated pool water. Concurrently the leaky source will be located using the equipment developed by the DOE at Hanford, or similar. This equipment consists of a closed loop system which includes a container into which a cesium capsule may be loaded. The activity of the water in the closed loop is monitored. The leaky source will be indicated by an increase in activity with time.

The leaky source will be sealed into a container, which in turn will be loaded into a shipping cask for return to Hanford for inspection and/or disposition.

The concrete shielded resin columns will be used for final removal of the residual cesium from the pool water.

The second type of capsule failure would be termed catastrophic and result in radiation levels above the storage pool which would prevent personal access. This type of failure is highly unlikely.

In this event, concrete shielded resin columns would be used to lower the pool activity to levels where personnel access to the pool is permitted. Once this level is reached, the clean up procedure would be as described above.

3. The contaminated concrete shielded resin columns will be disposed of via shipment for burial to a commercial waste disposal site.

4. Any alarm of the radiation monitor located adjacent to resin columns will be treated as a suspected radiation incident. The operator will confirm the radiation levels with at least two (2) operating survey meters after shutting off the recirculating pump.

If the levels are not confirmed, the incident will be treated as false alarm, and operations resumed after resetting the radiation monitor.

If the levels are confirmed, the operator will shut down the system, evacuate all personnel from the plant, and notify the RSO. The RSO will be responsible for any and all subsequent emergency responses based upon the specific conditions existing.

The basic clean up procedures outlined above in item 2 will be followed under the RSO's direct supervision. The assistance of your office and DOE experts will be solicited throughout this operation.

5. A copy of the DOE lease agreement is included. This lease covers the first 12MCi increment of RSI's allotment. We have taken delivery of 9MCi of this amount, which has been installed in our Westerville plant.

The DOE's revised allocation quantities were scheduled for announcement on December 6, 1985. We have as yet not been notified of our new allocation. As a minimum, we expect to be allocated an additional 9MCi. We would like to install these 9MCi plus 3MCi remaining on our current lease into the Decatur facility.

This lease is representative of the future DOE leases.

These monitoring and cleanup procedures have been accepted by the NRC prior to granting us license to load and use cesium in Westerville.

As soon as our allocation is made known to us, I will call you to inform you. I trust this information will permit you to approve our request to load and use the WESF capsules in our Decatur facility. We would like to initiate action to do this as soon as our allocation is made known to us.

Sincerely,

Allan Chin

Allan Chin
President

AC/tk

Enclosure

cc: Mr. Tom Fisher

RADIATION STERILIZERS INCORPORATED

RECEIVED
AUG 19 1985
RADIOLOGICAL HEALTH UNIT

August 16, 1985

Mr. Thomas E. Hill, Chief
Radioactive Materials Unit
Radiologic Health Section
Georgia Department of Human Resources
878 Peachtree Street N.E.
Atlanta, GA 30309

Dear Mr. Hill:

Please amend our license No. GA868-1 to add the nuclide cesium 137 to the list of licensed radioactive materials.

Nuclide: Cesium 137

Physical Form: Waste Encapsulation Storage Facility (WESF) Capsules. Double encapsulated in stainless steel.

Possession Limit: 21 MCi

RSI has been negotiating with the DOE and NRC for the past two years to approve the use of WESF capsules in wet storage category IV panoramic irradiators. We have been successful in our efforts and the NRC has licensed out Westerville, OH facility to use cesium capsules. The Westerville facility has been designated as the demonstration facility for this type of application, and as such will be monitored by the DOE to assure that no unforeseen problems may arise during the use of the WESF capsules. A capsule will be periodically removed from the Westerville plant and destructively analyzed.

Approximately seven (7) cesium 137 curies are equivalent to one (1) cobalt 60 curie using these sources because of the lower photon energy and self absorption of the WESF capsules.

The current shortage of cobalt 60 has had severe economic impact on RSI, and the use of this alternate gamma source will greatly alleviate this problem. The DOE is also encouraging industry to utilize this material for beneficial uses.

The NRC will still maintain control over the use of cesium in industrial facilities. Their current position is that additional facilities should not be loaded with WESF capsules until the first sample has been evaluated, which will be about 12 months from our first loading in Westerville. This loading took place on August 5, 1985.

Both DOE and RSI are petitioning that this 12 month wait period be reduced because there is no technical basis for it. We expect the NRC to permit an earlier second loading and are therefore requesting amendment to our license to use the WESF capsules contingent upon NRC approval.

It is important that this amendment be approved in order to prevent further delays in the shipment of this material to our facility. Ideally we would like to begin shipments into the Decatur plant next month. However we realize that the NRC may not act on this matter to meet this schedule. In any event we would like to be able to move on this as soon as a decision is made.

Thank you for your cooperation. Please call me if you have any questions.

Sincerely,

Allan Chin

Allan Chin
President

AC/tk

RADIATION STERILIZERS INCORPORATED

RECEIVED
JAN 18 1985
RADIOLOGICAL HEALTH UNIT

January 17, 1985

Mr. Thomas E. Hill
Radiological Health
878 Peachtree Street
Room 600
Atlanta, GA 30309

Dear Mr. Hill:

This letter provides additional responses to the specific items listed in your December 26, 1984 letter which were not covered in my January 10, 1985 letter. The specific items covered in my January 10, 1985 letter are so indicated.

1. Reference January 10, 1985 letter.

2. Reference January 10, 1985 letter.

3. Reference January 10, 1985 letter.

4. Reference January 10, 1985 letter.

5. Reference January 10, 1985 letter.

6. Reference January 10, 1985 letter.

7. Reference January 10, 1985 letter.

8. RSI administrative procedures and personnel training instruct all RSI personnel in the purpose, use and location of the emergency cable in the cell. Because RSI considers this to be a critical device, it has installed a second redundant cable on its own initiative.

All non-RSI personnel are always accompanied by a trained RSI employee whenever they are in the cell. The RSI employee is always the last person to leave the cell. After the last non-RSI person has left the radiation cell, the trained RSI employee is required to walk completely around the cell to assure that no one is hiding or unconscious in the cell area. During this traverse of the cell, he must actuate each segment of the emergency cable which automatically assures its working status and allows the system to be subsequently armed. This requirement to actuate each segment of the emergency cable assures that the trained RSI employee has in fact traversed and inspected the cell.

Radiation Sterilizers Incorporated, 2300 Mellon Court, Decatur, Georgia 30035/Telephone: (404)981-4077

A further requirement of the trained RSI employee is that he must audibly announce that the cell should be clear because the sources are about to be raised.

As an alternate action to assure that non-RSI personnel entering the cell are aware of the location and function of the emergency cable, RSI will post a notice to this effect in the area of the sliding access door which all non-RSI personnel will be asked to read prior to entering.

9. RSI has defined that the area beyond the floor to ceiling conveyor room door will be a controlled restricted area. This wall is a full physical barrier.

Additionally RSI will install protective covers on critical detection devices which might be subject to damage or disruption.

10. Administrative procedures and personnel training instruct RSI employees to verify that an unsafe radiation condition, in fact exists whenever there is a trip of the safety system. This is performed by the trained RSI employee using an operating survey meter. If an unsafe radiation situation is verified, the employee has been trained to secure all areas beyond the conveyor room, and to notify the RSO and/or the general manager. They are trained to not attempt to identify the cause and to remain on site to prevent any other entry beyond the conveyor room until the RSO and/or general manager arrives on site. This is absolutely the fastest and most reliable action that can be taken.

There may be many reasons that the safety system will trip, i.e. power failure, component failure, or accidental trip of the system. In the absence of an unsafe radiation safety situation, the trained RSI employees are fully capable of correcting the problem and re-starting the system. Unnecessary calls to the RSO are avoided.

RSI operates on a 24 hour schedule and an RSI employee will always be on site during operation to take proper corrective action. During non-operating periods, the sources are stored at the bottom of the pool and the facility and building secured. The single operating key is kept under lock.

We do not believe that a third party notification system is an improvement over the existing procedure.

11. Reference January 10, 1985 letter.

12. RSI frequently has the need to move heavy items through the maze. Permanent installation of the pressure mats would cause unnecessary damage. Our current design incorporates a rug-like covering over the eight (8) pressure mats to keep them in place. This design permits temporary removal when heavy traffic conditions occur. The trained RSI employees are responsible for the replacement of the mats prior to re-starting the system.

13. Reference January 10, 1985 letter.

14. Reference January 10, 1985 letter.

15. A summary of the pool water testing procedure is included.

16. RSI's designs are company proprietary and the result of many years of design and development effort. We estimate their value to be several million dollars if they got into the wrong hands. The designs integrate both the mechanical and safety systems, and therefore are not independent entities. Changes are continually being made to the mechanical system which do not affect the safety system. We are very concerned over allowing this information out of RSI. It also constitues a substantial potential liability to Georgia. Alternately, we will supply the state a copy of the flow or logic diagram for the safety system which will demonstrate how we meet the regulations. We will deviate from this only after prior discussion with the state.

17. The requested drawings will be provided and it is emphasized they entail a substantial liability to the state to maintain their secrecy and confidentialility. Additional information will be provided upon specific request.

18. This item is related to item 4. Since we feel that the cell monitor is proper for its application, and does meet the Federal regulations according to industry wide practice, there is no reason to move it.

19. This interlock has been installed.

20. We do not understand how this bears on radiation safety. The lights have been carefully located to provide maximum light and minimum probability of damage. It is inconceivable to envision that they can be damaged by either the conveyor system or the source handling tools.

Any light cover will reduce the amount of light emitted which would increase the probability of an accident in the cell.

Plastic or glass covers will darken and/or embrittle under the influence of radiation.

For safety reasons we prefer not to shield these light fixtures.

21. Reference January 10, 1985 letter.

22. A sumary of this procedure is included.

23. Reference January 10, 1985 letter.

24. All components used in the safety chain are designed by the manufacturers to be fail safe. The only item not meeting this criteria are the pressure mats. By their mode of operation they cannot be designed to be fail safe. RSI has accounted for this through design redundancy. Eight (8) individual 2' x 3' mats are used in a two wide four long array. At least four of these must fail before the system is potentially inoperative.

25. A summary of this procedure is attached.

26. Reference January 10, 1985 letter.

27. a.) The only possible means of failure of the source rack or modules is through corrosion. Since all components in the pool and source rack system are 300 series stainless steel, and the water is maintained at non-corrosive levels, a corrosive failure cannot be envisioned.

b.) A source rack lifting cable failure will permit the source rack to fall to a safe position at the bottom of the pool. The guide cables will aid in controlling and slowing its decent.

The sources will be removed, a new cable attached, and the rack raised for inspection and repair as required.

A single guide cable failure would not cause the rack to be misaligned since the other guide cable in conjunction with the lifting cable will maintain the rack aligned. During routine cell entries, RSI employees are trained to check the guide cables for failures and to repair or replace them as required.

Simultaneous failure of both guide cables would not prevent a serious problem since the rack will always be contained within the protective cage and guided into the water.

c.) The safety margins on the supporting track and trollies are

large enough to presuppose this happening. Additionally there is a support grating beneath the carriers and over the pool which will prevent carriers from falling into it.

d.) Over-rated cranes are always used to lift the casks. The likelihood of crane cable breakage is remote since crane operators are required to inspect and maintain their equipment. If a sling breaks, the second sling will still support the cask from a free fall. To guard against the improbability of both slings breaking, a half inch reinforcing plate of stainless steel is welded to the tank bottom beneath the cask loading area.

e.) The building is designed such that the cask must move laterally several feet beyond its normal loading position. Physically the necessary movement required to hit the source rack is not attainable.

f.) These monitors, when saturated, are fail safe.

g.) A ventilation fan failure will shut the system down. A belt failure will not shut the system down, but will cause ozone to diffuse into the operating area to warn the trained RSI personnel. They will shut the system down and replace the belt. A belt failure will not impose a radiation safety hazard.

h.) Anytime grates are moved, they are secured by ropes or other attachments to prevent their falling into the pool.

i.) RSI racks are designed to prevent this occurrence. However, if it does happen, they will fall into the pool where they can be retrieved.

j.) The water treatment system consists of filtration, de-ionization and make-up. All of these components are routinely checked and maintained well within the period of time that any potential problem could develop.

k.) All handling and disposal of contaminated demineralized resins will be per Georgia or Federal guidelines.

28. A summary of this procedure is included.

29. Reference January 10, 1985 letter.

30. Reference January 10, 1985 letter.

31. Reference January 10, 1985 letter.

32. Reference January 10, 1985 letter.

33. A summary of this procedure is included.

34. Reference January 10, 1985 letter.

35. A summary of this procedure is included.

36. A summary of this procedure is included.

37. A summary of this procedure is included.

The final form of all RSI procedures will be kept on hand at the Decatur facility for review and reference as required.

I certainly hope that this review will be the last prior to the issuance of our license. Your rapid response to this letter will be greatly appreciated.

Sincerely,

Tom Tiahn
for

Al Chin
President

AC/cc

Enclosures

#15 a.) A one (1) gallon sample of pool water will be taken one (1) foot below the surface of the water.

b.) The action level that will require the collection of additional samples will be > 2.25×10^{-8} uci/cc.

c.) The minimum detectable level at Georgia Tech is ~2.25×10^{-9} uci/cc for a 2000 cc sample. The minimum detectable level at Helgeson Nuclear is 6×10^{-10} uci/cc for a 500cc sample.

d.) The turnaround time from sample collection to receiving test results for Georgia Tech would be ~1 day and ~1 week for Helgeson Nuclear.

MANAGEMENT CONTROL OF PROGRAMMER

The programmer will be under the control of the General Manager and can be used only by him or his designee when directed by the Corporate Director of Engineering or his designee. The programmer will be used for troubleshooting problems within the irradiator.

If work is necessary on the roof of the cell it will first have to be authorized by either the production manager or general manager.

The shift supervisor and production manager are the only employees authorized to work on any equipment on the roof of the cell.

If contract employees are needed to do any work on the roof of the cell they will first have to check in with the shift supervisor or production manager who will escort them to the work area. When work is completed all contract employees will have to check out with either the shift supervisor or production manager. The shift supervisor will also verify by making all personnel have left the area.

#33 a.) When resins in RSI's deionizers need regenerating Continental Water Systems will either bring out new deionization tanks or just replace resins.

b.) RSI will dispose of any used resins after first checking to make sure they are not contaminated with radiation.

c.) Testing of the resins will either be done by Georgia Tech or some other approved radiation testing facility.

d.) Resins to be tested will be poured into a bucket, stirred and ~ 1000 gm sample taken.

e.) Sensitivity of the radioanalysis procedure at Georgia Tech will be determined during the first replacement of our deionization resins. In conversation with B. Boyd at Georgia Tech, he will need ~1000 gms of resins and will put them under a gamma analayzer and report radiation levels in uci/gm of resin.

f.) See attacned letter from Continential Water Systems.

MILLIPORE Continental Water Systems

P.O. Box 968 Roswell, Georgia 30077 404-992-4400

January 10, 1985

TO: Luther Pratt

FROM: Bill Reynolds

RE: RSI

This memo is to inform you about the procedure for handling RSI, a new account established in December 1984.

RSI is located at 2300 Mellon Court, Decatur, Georgia 30035. We have sold exchange deionization equipment to this Company. This consists of 4 Catalog No. 2051 Deionization Tanks, 1 Catalog No. 3258 20" Filter Housing, Installation Parts and Manifold. We will NOT provide normal service for this equipment. The nature of their business is such that we do not want to intergrate the resins in those tanks back into our plant. At the time these tanks are exhausted, we will discuss their disposal of old resins and the purchase of new resins.

Please alert me when RSI calls regarding any type service.

Thank you very much.

Bill Reynolds

Bill Reynolds

BR:lkm

CC: ~~Tom Morgan, RSI~~ TOM FISHER FYF, JM
CC: Katherine McGee, CWS
CC: Stewart Ford, CWS

#35

As mentioned in item #26 the RSO will delegate or authorize, based on training and experience persons, the responsibility to manage and use radiation safety procedures and equipment.

The persons authorized by the RSO will be the production manager, shift supervisor and any material handler who has completed all requirements for being a shift supervisor.

#36

Informal surveys for radiation will be done on the following locations:

1. Water treatment area - film badge - monthly plus monitoring with radiation detector monthly.

2. Air system - checked monthly with radiation detector - only exhaust air.

3. Cell is monitored upon each cell entrance by shift supervisor.

#37

Corporate Radiation Safety Inspections will be conducted by the Corporate RSO or his designee on an unscheduled basis.

The following items will be reviewed during the inspection:

a. maintenance records
b. safety records
c. training records
d. equipment calibration records
e. any external radiation surveys since last inspection
f. general inspection of building and sterilization process
g. downtime logbook
h. cell visitor logbok
i. personnel expsure reports
j. leak test records.

Any discrepencies found during the inspection will be reviewed with the general manager and a time schedule for correction of discripenses will be set up.

The general manager will inform the Corporate RSO in writing when all discrepenses have been completed.

RADIATION
STERILIZERS
INCORPORATED

January 16, 1987

Mr. Will Ingram
Radiological Health Section
Georgia Department of Human Resources
878 Peachtree Street, NE
Atlanta, Georgia 30309

Dear Mr. Ingram:

Attached are the revisions to our Radioactive Material License number GA-868-1, that you and I discussed on December 29, 1986.

If you have any questions, please contact me.

Sincerely,

Tom Fisher
General Manager

TDF/cc

Enclosures

RECEIVED
JAN 27 1987
RADIOLOGICAL
HEALTH UNIT

RADIATION STERILIZERS INCORPORATED

January 10, 1985

Mr. Thomas E. Hill
Radiological Health Section
G.M.H.I. Room 425 South
1256 Briarcliff Rd. N.E.
Atlanta, GA 30306-2694

Dear Mr. Hill:

This letter referen[illegible] your letter dated December 26, 1984 concerning our applic[illegible] for licensing our Decatur Facility.

Specifically addressed are items 1, 2, 3, 4, 5, 6, 7, 11, 13, 14, 21, 23, 26, 29, 30, 31, 32 and 34 for which you required responses prior to amending our application to permit loading of the sources into our source racks and performing radiation surveys and dosimetry studies. Responses to the remaining 37 items will be forthcoming prior to final license issuance.

1. RSI will define the area beyond the floor to ceiling wall to be a restricted area for the purpose of this license. As such we believe that we will comply to section 20.203 (c), (6), (i), (a).

2. The electrically operated lock defined in this item will not permit operation of the RSI system since it will shut the system down every time we attempt to run product into the cell. As our discussion of this item revealed, there was an obvious misunderstanding of how our system operates. Since this lock was redundant, no action is planned.

3. Re-definition of the restricted area should satisfy this requirement in conjunction with the installation of the safety railing along the roof of the cell.

4. The cell monitor which is set to alarm at 100 MR/hr or less is specifically installed to warn personnel in the cell of a potential radiation problem. This monitor is wired to be activated after all four source racks have tripped their down limit switch. Therefore any subsequent attempt to raise the sources will be detected and alarm the safety system.

A continuous monitoring of the field would result in a alarm and system shutdown every time the sources are attempted to be raised. This would prevent operation of the system.

The current design meets the regulations and is consistent with industry practice for this type of system. No change is deemed to be required.

5. The visual and audible alarms are indicators only of system operation. Failure of any of these devices will not affect system operation.

RSI personnel training requires all employees to take cognizance of all visual and audible indicators and to repair or replace them as required.

Incorporation of redundant, logical systems are not considered to be necessary and would be difficult and expensive to install. They would also create additional potential maintenance problems.

We believe that our current personnel training will assure constant working of all visual and audible indicators.

6. RSI will install an additional warning light(s) to assure that one of them will be visible from all location in the cell.

7. RSI did not install an automatic door closer on the personnel emergency door because of safety reasons. Our concern was that such a device could injure a second person from exiting by closing on him. The door is wired such that whenever it is open, it is a safety system violation and will shut the system down. We believe that the system is safer without such a device.

11. We intend to survey the total shield area per the ANSI N43:10 document. Locations and specific radiation levels ~~exceeding 0.25 MR/hr will be documented and physically marked~~. The surveys can only be conducted after the amendment requested in this letter is granted.

We do not understand how radiation levels are expected to increase when additional shielding (in the form of product and carriers) is added.

13. The installation of such a stand pipe would cause severe damage to all of the electrical equipment in the sump because they could become submerged. We would propose a trap on the pool drain line whose open end terminates 10" above the gamma cell floor. Additionally a water detector will be installed in the trap to provide early warning of an overflow condition and still contain the water from discharging to the sewer prior to evaluation for contamination.

We beieve this will serve the same purpose as the stand pipe.

14. This meter has been installed and helps control water conductivity below 10 microsiemens per cm.

21. a.) A video display failure has no effect on the safety system. When the screen goes blank, the operator will shut the system down and replace or repair the unit. The system is then re-started in the normal manner.

b.) All of the safety system controls are in industrial units which are designed to preclude transient problems. As an additional precaution an uninterruptable power supply conditions all line voltage.

c.) A computer malfunction will not affect the safety system. It is merely an operator interface. If it fails, the operator will shut the system down and replace or repair the unit. The system can then be started in the normal manner.

23. Program re-entry is always by disc. After a disc is read into CCU memory, a compare program verifies all data. No errors are accepted. When transfer is complete, a system test of all sensing devices verfies accuracy of the program.

26. A summary of this procedure is included.

29. A summary of this procedure is included.

30. A summary of this procedure is included.

31. The one inch stainless steel pool level cortrol line is not susceptible to clogging from corrosion. The water is filtered and deionized. It is also located 12" below the normal pool water level. It is therefore highly unlikely that it will plug.

However, if it is assumed to happen, the level control will indicate a full pool. Normal evaporation will cause the level to slowly drop. RSI employees normally enter the cell several times a week and would notice the drop.

If they don't, the level will continue to drop until the level of water above the sources in the down position will alarm the 100 MR.hr monitor. At this time the low water level will be detected and protective action taken.

32. A summary of this procedure is included.

34. Attached are copies of the documention that will be used at the RSI Decatur facility. All training approvals will be signed off by the general manager.

Sincerely,

Al Chin
President

AC/chc

Enclosures

RADIATION STERILIZERS INCORPORATED

October 31, 1984

RECEIVED
NOV 2 1984
RADIOLOGICAL HEALTH UNIT

Mr. Thomas E. Hill
Environmental Radiation Specialist, Sr.
Radiological Health Section
Georgia Department of Human Resources
G.M.H.I. Room 425-South
1256 Briarcliff Rd., N.E.
Atlanta, GA 30306-2694

Dear Mr. Hill:

Attached are my responses to your questions listed in your letter of October 18, 1984. Several of the comments you made were the result of proof reading omissions on my part. For simplicity, I have corrected my October 4, 1984 letter to incorporate my responses to your latest questions. [redacted] This info has been incorporated into the original Applicat

Enclosed also is a letter which I finally received from the NRC regarding the use of cesium in my facilities. RSI's intention has always been to make the Atlanta facility the initial site for using cesium as you have been made aware by Mr. Tom Fisher.

Since the use of cesium has special considerations, which the NRC should rightfully evaluate, we have been workign directly with the NRC to obtain licensing for the RSI facilities. Since two of our facilities are in NRC regulated states (Illinois and Ohio), the use of cesium was petitioned from the NRC via an amendment application to those licenses.

As soon as this amendment is approved, we would like to incorporate the use of cesium into the Georgia license. I am in the process of responding to the NRC letter which I plan to submit next week. I will send you a copy of my response at that time so that you will be kept fully informed.

The Georgia application will be the first commercial application of a dry irradiation wet storage facility. The first application of a dry irradiation, dry storage facility will be in Denver, Colorado. Iotech is building this facility, and, since Colorado is an agreement state, licensing is being accomplished jointly between the State of Colorado and the NRC.

I hope to have approval of the NRC within two to three weeks which will coincide with our planned start of isotope loading into Atlanta around the first of December. Please let me know if you anticipate any problems in meeting this licensing schedule.

Sincerely,

Allan Chin

Allan Chin
President

AC:ck

Enclosures

RADIATION STERILIZERS INCORPORATED

October 31, 1984

Mr. Thomas E. Hill
Environmental Radiation Specialist, Sr.
Radioactive Materials Unit
Radiological Health Section
Georgia Department of Human Resources
G.M.H.I. Room 425-South
1256 Briarcliff Road N.E.
Atlanta, GA 30306-2694

Dear Mr. Hill:

I have received your September 26, 1984 and October 18, 1984 requests for additional information. My responses have been sequentially keyed to your questions.

A1. The Co-Radiation Safety officer will be required to have completed the RSI training course or equivalent. Additionally he will be required to have successfully completed a nominal one week long course in radiation protection given at the University level. He will be knowledgeable of all radiation procedures, record requirements and energency responses. A minimum six month on the job training period will also be required.

A2. In addition to the previously supplied training information, new employees will be provided with written copies of Chapter 290-5-23-07 of the Georgia Rules and Regulations for Radioactive Materials. The information contained in this chapter will be reviewed to respond to any questions which the employee may have.

A3. Each cell entry is documented to include the following information:

a. Date
b. Time of entrance
c. Time of exit
d. Name

e. Affiliation
f. Initial dosimeter reading
g. Final dosimeter reading
h. Dosimeter number
i. Reason for entry

A4. Under normal conditions of source storage, the cobalt will all be under 15 feet of water. The depth of water is equivalent to 15 x 62.4/138 or 81.4" of 138# concrete. By reference the ceiling of the cell is only 73" of 138# concrete.

Measurements at the pool surface and roof surface have confirmed that no detectable levels of radiation exist at the four RSI systems currently in operation using similar shielding.

A5. No.

A6. Yes, the alarm system is active whenever the sources are not in the completely down position.

A7. All make up water lines are above the pool water level and valves are installed to prevent back siphonage.

A8. Pool samples are taken by grab sampling at a depth of 12-24" from the pool. The recirculating water pump mixes the water sufficiently (20gpm) to assure that the sample is reasonably representative.

ANSI Section 3.3

1. Yes. All of the interlocks and detectors in the safety system are designed such that failure of any item will not permit system operation until it is returned to the designed operational condition.

ANSI Section 5

1. All of the information outlined in Section 5.4 is contained in the RSI survey report.

2. The following contamination test will be run at RSI:

a. Source leaks are monitored by checking the pool water. These tests will be performed by Helgeson Nuclear as indicated in Section 11 of the application.

b. Shipping cask interiors as per Section 8.

c. Shipping cask exteriors as per Section 8.

d. Irradiator wipe tests-similar to "c" above. The data outlined in Section 5.5 will be contained in the contamination test report.

ANSI Section 7

1. Yes

ANSI Section 8

1. Yes

2. Yes

3. Yes

4. Yes

5. Yes

6. The cell roof plug weighs about 15 tons and is not readily removed. Interlocks on this plug are not necessary. The roof plug is contained within the building. A locked roof hatch, monitors access to it. The source loading procedures include checks to assure the roof plug is in place after each loading sequence. There are no other removable plugs in the shield.

7. A stainless steel grate over the open end of the pool prevents personnel from falling into the source pool.

8. The allowable level for ozone is 0.1ppm. At .05ppm concentrations, the ozone irritates the eyes and nose to the extent that it becomes unbearable. Actual attempts at measuring ozone during periods when the source is raised is difficult since it must be done remotely. Samples must be withdrawn through long lengths of tubing during which it rapidly dissociates, and gives erroneous readings. The irritation to eyes and throats is still the best determinant of proper ventilation. RSI ventilation rates are generally 2-3 times as much as other facility designs. Because of this, very little evidence of ozone, which is very pungent, can be detected in RSI cells even upon immediate entrance after the sources are lowered. Redendant exhaust fans are

also used to assure noxious gases are maintained below threshold limit values.

9. Electrical disconnects are installed on each source winch which are required to be used during maintenance and source loadings.

10. Yes

ANSI Section 10

1. Yes

2. No

3. The 10 microsiemens/cm figure is arbitrary, and RSI has selected to use a figure of 20 microsiemens per cm because many stainless steel experts have stated that high purity water is more corrosive to stainless steels. Moderate levels of control are necessary to prevent highly acid or basic solutions from being used. We intend to operate in the 10-20 microsiemen/cm range.

There is a definite hazard in the ANSI spec of not specifying a minimum value of conductance because of the possibility of creating a potentailly hazardous corrosive condition. If you require us to meet the 10 microsiemer/cm limit, we will. Also please specify a minimum level. We feel that the 20 microsiemen/cm limit is safer for the sources.

4. RSI systems employ contracted water de-ionization services. Prior to exchanging the ion exchange columns, they will be checked with survey meters for levels above background. When excessive levels of irradiation are detected on the resin beds, the facility will be shutdown. The resin beds will be placed in shielding casks or otherwise shielded and removed for commercial waste disposal. Standard methods generally following 18.2 and 18.3 for identifying and removing the leaky source will be employed.

5. RSI typically uses swimming pool type filters for removing accumulated dirt and debris from the bottom of the pool. The filters shall be constantly surveyed for any increased radiation levels during vacuum cleaning operations.

All vacuuming tools will be immersed and filled with water prior to hooking up to the pump. Upon removal they are checked with a survey meter for excess radiation.

ANSI Section 11

1. Yes

ANSI Section 12

1. Yes

ANSI Section 13

1. Yes

ANSI Section 14

1. Yes, except for the following:

   a. RSI facilties are never operated while unattended. When not in operation, the source is lowered to the bottom of the pool and the area and building are secured.

   b. The following information is not pertinent and is stored in the office administrative area and not in the control room.

      * name and address of irradiator manufacturer (RSI)

      * model and serial number of irradiator (RSI design)

      * ANSI Compliance designation "N43.10-1984"-Georgia. License confirms compliance

      * name and address of source manufacturer(s)

      * model and serial numbers of all sources

      * type of radionucleide involved and total activity with date of measurement.

      * maximum design activity (nominal capacity) of the irradiator

2. Yes

3. Yes

4. Yes

ANSI Section 15

1. Yes

ANSI Section 16

1. Yes

2. Yes. An external wipe test of the external surface of the shipping container will be performed to detect gross contamination.

3. The procedure in Appendix A is followed. No survey meter will detect 0.005 uCi. They will however indicate a low level leak. RSI uses a counting method in conjunction with the survey meter which is a more accurate technique. The Xetex meter or any other will probable detect the presence of about 0.5 uCi.

These checks are secondary checks on the supplier who certifies the absence of contaminent (-0.005 uCi) on the sources.

4. Yes

5. Historically contamination wipe test have not been required in this type of facility where only doubly encapsulated sealed sources are employed. The dispersibility of radioactive materials out of these forms has been accepted to be highly unlikely by regulatory bodies, and contamination wipe tests have not been required. Semi-annual test are conducted on the pool water to check for leaky sources.

ANSI Section 17

1. Yes — check list formal list

2. Yes

3. Yes

4. Yes

ANSI Section 18

1. The procedures of 18.2 will be generally followed for removal of a damaged, leaking or suspected leaking source.

2. The procedures of 18.3 will be generally followed for disposal of contaminated material.

I expect to receive a letter shortly from the NRC confirming the conditions under which the Cesium-137 WESF capsules may be used in RSI facilities. I will forward a copy to you upon receipt.

I trust that this information will be sufficient to permit the issuance of a license to the Decatur facility. If you have any further questions, please do not hesitate to call me.

Our facility is nearing completion, and we expect to begin shipment of isotope into it early in November. If you foresee any difficulty in this schedule, I would appreciate an immediate phone call.

Sincerely,

Allan Chin
President

AC/tb

cc: Tom Fisher
Radiation Sterilizers, Inc.
2300 Mellon Court
Decatur, GA 30035

RADIATION STERILIZERS INCORPORATED

RECEIVED
OCT 11 1984
RADIOLOGIC
HEALTH UNIT

October 4, 1984

Mr. Thomas E. Hill
Environmental Radiation Specialist, Sr.
Radioactive Materials Unit
Radiological Health Section
Georgia Department of Human Resources
G.M.H.I. Room 425-South
1256 Briarcliff Road N.E.
Atlanta, GA 30306-2694

Dear Mr. Hill:

I have received your September 26, 1984 request for additional information. My responses have been sequentially keyed to your questions.

A1. The Co-Radiation Safety officer will be required to have completed the RSI training course or equivalent. Additionally he will be required to have successfully completed a nominal one week long course in radiation protection given at the University level. He will be knowledgeable of all radiation procedures, record requirements and energency responses. A minimum six month on the job training period will also be required.

A2. In addition to the previously supplied training information, new employees will be provided with written copies of Chapter 290-5-23-07 of the Georgia Rules and Regulations for Radioactive Materials. The information contained in this chapter will be reviewed to respond to any questions which the employee may have.

A3. Each cell entry is documented to include the following information:

a. Date
b. Time of entrance
c. Time of exit
d. Name

Radiation Sterilizers, Inc., 3000 Sand Hill Road, Bldg. #4-245, Menlo Park, CA 94025 (415) 854-2800

e. Affiliation
f. Initial dosimeter reading
g. Final dosimeter reading
h. Dosimeter number
i. Reason for entry

A4. Under normal conditions of source storage, the cobalt will all be under 15 feet of water. The depth of water is equivalent to 15 x 62.4/138 or 81.4" of 138# concrete. By reference the ceiling of the cell is only 73" of 138# concrete.

Measurements at the pool surface and roof surface have confirmed that no detectable levels of radiation exist at the four RSI systems currently in operation using similar shielding.

A5. No.

A6. Yes, the alarm system is active whenever the sources are not in the completely down position.

A7. All make up water lines are above the pool waters level and check valves are installed to prevent back siphonage.

A8. Pool samples are taken by grab sampling at a depth of 18-24" from the pool. The recirculating water pump mixes the water sufficiently (20gpm) to assure that the sample is reasonably representative.

ANSI Section 3.3

1. Yes. All of the interlocks and detectors in the safety system are designed such that failure of any item will not permit system operation until it is returned to the designed operational condition.

ANSI Section 5

2. Only approved sealed sources or special form materials will be used in this facility. These sources are mechanically contained within a source rack in the radiation cell. Generally, once they are loaded they are seldom moved, and there is virtually no possibility of low level contamination in the facility. Therefore there does not appear to be a reason to routinely run wipe tests to determine contamination within the facility. Leak tests on

the pool water monitor the sources for leakage. If a leaky source occurs, contamination test will be run per 5.5.

ANSI Section 7

1. Yes

ANSI Section 8

1. Yes

2. Yes

3. Yes

4. Yes

5. Yes

6. The cell roof plug weighs about 15 tons and is not readily removed. Interlocks on this plug are not necessary. The roof plug is contained within the building. A locked roof hatch, monitors access to it. The source loading procedures include checks to assure the roof plug is in place after each loading sequence. There are no other removable plugs in the shield.

7. A stainless steel grate over the open end of the pool prevents personnel from falling into the source pool.

8. The allowable level for ozone is 0.1ppm. At .05ppm concentrations, the ozone irritates the eyes and nose to the extent that it becomes unbearable. Actual attempts at measuring ozone during periods when the source is raised is difficult since it must be done remotely. Samples must be withdrawn through long lengths of tubing during which it rapidly dissociates, and gives erroneous readings. The irritation to eyes and throats is still the best determinant of proper ventilation. RSI ventilation rates are generally 2-3 times as much as other facility designs. Because of this, very little evidence of ozone, which is very pungent, can be detected in RSI cells even upon immediate entrance after the sources are lowered. Redendant exhaust fans are also used to assure noxious gases are maintained below threshold limit values.

9. Electrical disconnects are installed on each source winch which are required to be used during maintenance and source loadings.

10. Yes

ANSI Section 10

1. Yes

2. No

3. The 10 microsiemens/cm figure is arbitrary, and RSI has selected to use a figure of 20 microsiemens per cm becaure many stainless steel experts have stated that high purity water is more corrosive to stainless steels. Moderate levels of control are necessary to prevent highly acid or basic solutions from being used. We intend to operate in the 10-20 microsiemen/cm range.

There is a definite hazard in the ANSI spec of not specifying a minimum value of conductance because of the possibility of creating a potentailly hazardous corrosive condition. If you require us to meet the 10 microsiemen/cm limit, we will. Also please specify a minimum level. We feel that the 20 microsiemen/cm limit is safer for the sources.

4. RSI systems employ contracted water de-ionization services. Prior to exchanging the ion exchange columns, they will be checked with survey meters for levels above background.

5. RSI typically uses swimming pool type filters for removing accumulated dirt and debris from the bottom of the pool. The filters shall be constantly surveyed for any increased radiation levels during vacuum cleaning operations.

All vacuuming tools will be immersed and filled with water prior to hooking up to the pump. Upon removal they are checked with a survey meter for excess radiation.

ANSI Section 11

1. Yes

ANSI Section 12

1. Yes

ANSI Section 13

1. Yes

ANSI Section 14

1. Yes, except for the following:

a. RSI facilties are never operated while unattended. When not in operation, the source is lowered to the bottom of the pool and the area and building are secured.

b. The following information is not pertinent and is stored in the office administrative area and not in the control room.

* name and address of irradiator manufacturer (RSI)

* model and serial number of irradiator (RSI design)

* ANSI Compliance designation "N43.10-1984"-Georgia. License confirms compliance

* name and address of source manufacturer(s)

* model and serial numbers of all sources

* type of radionucleide involved and total activity with date of measurement.

* maximum design activity (nominal capacity) of the irradiator

ANSI Section 15

1. Yes

ANSI Section 16

1. Yes

2. No. These tests are performed at the shippers facility prior to shipping. There is no necessity to repeat this test unless the shipping cask is received in a damaged condition. In these instances the shipper is notified immediately for disposition and subsequent handling.

3. The procedure in Appendix A is followed. No survey meter will detect 0.005 uCi. They will however indicate a low level leak. RSI uses a counting method in conjunction with the survey meter which is a more accurate technique. The Xetex meter or any other will probable detect the presence of about 0.5 uCi.

These checks are secondary checks on the supplier who certifies the absences of contaminent (~0.005 uCi) on the sources.

4. Yes

5. Historically contamination wipe test have not been required in this type of facility where only doubly encapsulated sealed sources are employed. The dispersibility of radioactive materials out of these forms has been accepted to be highly unlikely by regulatory bodies, and contamination wipe tests have not been required. Semi-annual test are conducted on the pool water to check for leaky sources.

ANSI Section 17

1. Yes

2. Yes

3. Yes

4. Yes

ANSI Section 18

1. The procedures of 18.2 will be generally followed for removal of a damaged, leaking or suspected leaking source.

2. The procedures of 18.3 will be generally followed for disposal of contaminated material.

I expect to receive a letter shortly from the NRC confirming the conditions under which the Cesium-137 WESF capsules may be used in RSI facilities. I will forward a copy to you upon receipt.

I trust that this information will be sufficient to permit the issuance of a license to the Decatur facility.

If you have any further questions, please do not hesitate to call me.

Our facility is nearing completion, and we expect to begin shipment of isotope into it early in November. If you foresee any difficulty in this schedule, I would appreciate an immediate phone call.

Sincerely,

Allan Chin
President

AC/tb

cc: Tom Fisher
Radiation Sterilizers, Inc.
2300 Mellon Court
Decatur, GA 30035

RADIATION STERILIZERS INCORPORATED

RECEIVED
AUG 20 1984
RADIOLOGICAL HEALTH UNIT

August 21, 1984

Mr. Thomas E. Hill
Environmental Radiation Specialist, Sr.
Radioactive Materials Unit
Radiological Health Section
G.M.H.I. Room 425-South
1256 Briarcliff Rd., N.E.
Atlanta, GA 30306-2694

Dear Mr. Hill:

Thank you for your comprehensive review of our license application. For simplicity and clarity, I will use respond to your comments sequentially as presented in your June 19, 1984 letter.

Source Approva

1. The NPI sources were approved for use in category IV type irradiators by the Maryland Department of Health and Menta Hygiene. A copy of the registration is included for your references as EXHIBIT A.

2. The WESF cesium capsule has been verbally approved on August 14, 1984. Mr. Bernie Singer, Head of the NRC licensing Branch, notified me of this in a telecon, which will be confirmed in writing. Mr. Singer's phone number is 301-427-4211. Usage of these sources will be contingent upon the establishment of a research protocol whereby the DOE will periodically remove a WESF capsule from one of RSI's facilities and destructively test it for corrosion or other potencial failure modes.

The DOE has been committed to perform this testing program.

The test program will be applied to one RSI facility, and will be used to monitor the use of cesium in all other RSI facilities. Due to current schedules, it is quite likely that Atlanta will be the first facility to utilize cesium on a commercial basis. DOE monitoring will therefore be performed at this location.

A. General

1. The attachments referencing Items 5a, 6, 8, 9, 10, and 11 apply to the Georgia Department of Human Resources Application for Radioactive Material License.

Item 12 of the application was responded to through reference to Regulatory Guide 10.9 as recommended in your letter of November 29, 1983. Items 13 to 17 of the Regulatory Guide 10.9 respond to item 12 of the application.

2. The facility shielding has been designed to meet the requirements of an un-restricted area for all areas in and around the building excluding the interior of the radiation cell during normal operation. When the sources are in the raised or operating position the maze and cell are controlled as a restricted area. The roof of the radiation cell will be treated as a controlled or restricted area since the spruce winches are accessible in that area.

3. All entrances to the RSI building are provided with locks to secure and control access. The normal mode of operation will be seven days, round the clock. During early startup, five-day operation may be followed. The facility will be locked on weekends. Additionally internal locked doors will prevent access to the maze entrance from within the building.

   Access to the roof can only be attained from inside the building. A locked roof hatch maintains security against building access from the roof. The hatch is opened only during isotope loading or roof maintenance periods.

4. Following our discussion on this subject, I contracted the contractor, and he provided me with a written explanation which is included for your review as EXHIBIT B.

B. Application Item 4. Radiation Program Personnel

1. Mr. Tom Fisher has been hired to be the general manager and full-time Radiation Safety Officer for the Decator facility. A summary of his qualifications is included for your review.

   Mr. Fisher has been responsible for the total operation and maintenance of the Becton-Dickinson gamma facility in Sumter, SC for the past three years. This facility is similar to the Decatur facility in size and complexity. Background and experience information for Tom Fisher is shown in EXHIBIT C.

2. With the exception of the last sentence in item 15c, the duties outlined are the responsibility of the facility RSO. The Corporate RSO will audit the facility to assure that the facility RSO is operating in compliance with the license.

The corporate RSO may delegate the auditing function to other officers of the corporation.

The facility RSO may designate alternate or co-Radiation Safety Officers to act in his behalf from his staff providing that they are adequately trained and instructed to carry out these duties.

3. The initial isotope loading into the Decatur facility will be performed by either Allan Chin, Bruce Meyer, Thomas Hurley, Barry Fairand, or Bob Ramsey. Authorization under USNRC license 04-19644-01 is included for reference as EXHIBIT D.

   Mr. Fisher and members of his staff will be instructed in the isotope loading procedures, and will be qualified to install isotope during future loadings.

4. The material handlers receive a minimum of 20 hours of basic training and orientation. During this period, the material outlined in Section 9 of the Appendix is covered. Additionally, training in first aid and worker safety are provided.

   The shift supervisors receive a minimum of 40 hours of training which includes the 20 hours of basic training and orientation provided to the material handlers. An additional 20 hours of training is provided which includes:

   a. Care, operation and maintenance of the conveyor system
   b. General understanding of the safety system operation
   c. General operating procedures
   d. Emergency procedures
   e. General radiation safety rules
   f. Record keeping
   g. Dosimetry calculations and methods.

   Written tests are required for each employee and are kept on file. The minimum passing score is 80% and employees are re-instructed in subjects where difficulty is encountered.

   Samples of training texts and tests are included as EXHIBIT E.

5. The terms "independent user" and "shift supervisor" are used interchangeably. These employees are authorized to operate the mechanical conveyor system in order to process the material to be sterilized. They are trained to operate the pre-programmed control console which includes starting and stopping the conveyor, and raising and lowering of the sources. These are considered to be normal operations.

In the event of an abnormal occurrence relating to radiation levels in the maze or cell, they are instructed to prevent personnel entrance to the maze, maintain surveillance with a survey meter, and to alert the Radiation Safety Officer. These personnel are not automatically authorized to move individual sources into or within the rack.

A licensed user is a person who has been trained in the proper procedures for handling and moving individual sources. Sources are handled during any loading operation, and less frequently when sources are shifted around within the source rack.

The licensed users generally include the plant general manager, the production supervisor, and possibly one or more of the senior shift supervisors.

Shift supervisors or independent users generally receive three months on the job training although shorter periods of training are adequate depending upon prior education and experience.

6. The general manager will maintain the training and experience records for all employees in his facility.

7. A copy of the list of these pamphlets is included as EXHIBIT F.

8. The Radiation Safety Officer of the plant is required to have a sound background in radiation safety.

9. The line of authority at each plant flows from the plant manager to the production supervisor to the shift supervisors to the material handlers during normal operations. During emergency operations, the Radiation Safety Officer will assume the position of highest authority.

(10) Copies of Chapter 290-5-23-.07 of the Georgia Rules and Regulations for Radioactive Materials (July 12, 1982) will be given to and discussed with each new employee.

The posting requirement option of 4(b) will be employed.

This training and instruction will be in addition to RSI's normal training schedule. Much of the material covered by 290-5-23-.03 is included in our normal training course.

C. Application 5.A. Attachment

1. In the other RSI facilities, the weight of the cobalt sources and the racks were such that when the power failed, the source rack would lower by gravity in a controlled manner. The variation between an empty and full cobalt rack was about 2 to 1.

When cesium is used, the variation is much higher (5 to 1) and a more controlled rack descent is required. An auxiliary power supply will be used to accomplish this, and this statement should apply to item 13d.

D. Application Item 6 Health Physics Instrumentation

1. Model 305A survey meter is certified by Xetex Corp. to operate continuously in 100R/hr fields. Additionally it is normally checked up to 1000 R/hr fields after manufacture as an acceptance test. A specification sheet for the 305A meter is included as EXHIBIT G.

2. Xetex was contacted in reference to an approval as a calibration lab. Their response was that they are licensed to possess and use the calibration sources by the State of California. They are also traceable to NBS standards. Xetex routinely calibrates meters for NRC. NRC has accepted Xetex's calibration procedures which were submitted as part of the RSI license application. NRC does not approve calibration labs, but accepts them based upon procedural review.

Pertinent sections of the Xetex Licensee are included in EXHIBIT H.

E. Application Item 7, General Instrumentation

1. Model 501A Xetex area monitors are used to monitor cell and maze dosage levels. One detector is located on the wall of the radiation cell perpendicular to the plane of the source rack. This detector is designed to alarm at 100 mR/hr whenever the sources are at the bottom of the pool. When the sources are in the raised position the meter is switched off because of the high (25,000 R/hr +) dose rates at that location which would prematurely damage the G-M tube.

The second detector is located in the maze and operates continuously to monitor the exiting carriers for potential isotope carry out. This detector will alarm and stop the conveyor at 1R/hr levels.

A specification sheet for the 501A area monitor is included as EXHIBIT I.

2. A diagram showing the general location of the detectors and warning signals is included as EXHIBIT J. The operating console and readouts are located in the control room. Referencing EXHIBIT K, the control room is the corner office closest to the conveyor room entrance.

F. Application Item 9, Area Monitoring

1. The daily radiation area surveys are performed each time entrance is made to the radiation cell. These are unscheduled events and can occur several times during a shift or not at all.

Documentation is kept of each cell entry. No reference is made of normal radiation levels during these entries.

G. Appendix Section 3, Gamma Cell Safety System

1. The general manager maintains control over the duplicate master keys for the system operation. During normal operations, the key is captive in the control console and under the control of the shift supervisor. During periods of extended shutdown, the key is secured in a lock box.

2. Personnel access to the maze and cell during normal operations is restricted in several ways. First the conveyor room access is controlled via locked doors (reference EXHIBIT K sheet A2). All tote loading and tote shifting on the carriers is performed within the controlled access conveyor room.

A second barrier wall controls access to the maze and cell. This wall contains two sliding doors which open and close on signal to permit entry and exit of product carriers. They are designed to prevent personnel passage with the carrier. This wall also contains a personnel door which will always allow exit to the conveyor room and the building.

Additionally the maze entrance is monitored by photocells and floor pressure mats. If either the photocells or pressure mats are triggered, the sources will be automatically lowered and alarms activated.

3. The pre-set time for correcting malfunctions of the conveyor system varies depending upon the isotope loading and dose requirements.

The conveyor motion through the radiation cell is of an indexing nature. Dosage is controlled by controlling the index cycle or pre-set time. For example, if the index cycle time is three minutes, any malfunction which can be corrected within that period will not affect the dosage delivered to the product. If the malfunction cannot be corrected within the three minute cycle, the sources will be lowered to prevent overdosing the product.

H. Appendix 5, Biological Shielding Calculations

1. Shielding calculations for pool:

pool depth = 24 feet water
rack height = 13 feet
Assume all cobalt under 15 feet water (middle 5 feet of rack)
Self-absorption factor = 1/4
TVL water = 13.9 inches
15 feet water = 13 TVL
= 81.4 inches of 138 pounds/cubic feet concrete
For reference, the ceiling is 73 inches of concrete.
Shielding requirements for cesium are diminished by approximately 30 percent from cobalt because of lower energy gammas.

I. Appendix Section 7, Design Safety Analysis

1. The pressure mats are each 3 feet long. The total 6 foot span is beyond the normal step.

2. The sliding doors are interlocked with the conveyor system and open and close to permit entrance only of the product carrier. Any forced opening of the doors will alarm and shut the system down.

3. The emergency exit door in the wall adjacent to the sliding doors is designed to permit exit at all times via a push bar lock on the door. Entrance cannot be normally made through this door.

4. Alarms are actuated and the sources lowered whenever the photocells or pressure mats are violated when the sources are in the raised position. Unscheduled opening of the sliding doors will also shut the system down.

J. Appendix Section 8, Source Control System

1. The leak test on the cask is performed by RSI. Upon receipt of the shipping cask, the bottom drain and top vent plugs are removed. A baseline count is made on a container of distilled water which is subsequently used to fill the cask cavity. Filling is from the bottom drain hole.

   After 30 minutes the water is allowed to drain from the cask through a paper filter. A count is then made on both the filter and the water. If measurable differences in counts are observed, from the baseline, the cask is resealed and returned to the vendor.

   If the counts show no change from the control, the loading process continues. The 304A or 305A survey meters equipped with an ear jack are used to measure the radiation counts.

2. Three basic tools are used to load the cobalt source modules. One is designed to remove individual source rods from the shipping cage containing the sources and to place them into the modules. A second tool is designed to hold the source module in place beneath a funnel to assist loading the sources into the module. A third tool is used to transfer the modules from the module holder to the source rack.

   When cesium capsules are used, each capsule is transferred directly from the shipping container into the source racks.

K. Appendix Section 11, Radiation Safety Maintenance Program

1. The cell and maze detectors are Xetex model 501A area monitors. The detectors are halogen quenched GM tubes located in the cell and maze. The monitor electronics are located in the control room.

   These units are checked by lowering the alarm limit to a level which can be triggered by the small cesium check source.

   The unit is also equipped with a "Test" button which will insert a signal into the system which permits the logic circuit to be tested for proper response.

2. The Georgia limit of 0.005 uCi of activity per source will be the basis for determining leakage from the sources.

L. Appendix 12, Emergency Procedures:

1. The primary emergency procedure to protect any personnel from radiation exposure is to prevent access to the cell. The use of NRC approved sealed sources, protective modules and metal cages assure that the sources will not be mechanically or thermally damaged.

   Heat and smoke sensors will detect fire in the cell and cause the sources to be lowered. No smoking restrictions apply within the plant to eliminate the possibility of carrying live flames into the cell. The materials processed are not spontaneously combustible. Combustible materials are not processed.

   If a fire does ignite, the sources will be lowered, the ventilation fans shut off, and the overhead sprinklers turned on. After the fire is extinguished the system will be cleared using normal precautions for monitoring for radiation.

M. Appendix Section 15, Water Treatment System:

1. The makeup water line is monitored for "on" time. Any excessive "on" time indicates a possible pool leak.

2. No openings in the pool wall are below 18" of the top which limits the minimum height of the water in the pool to 22.5 feet of water.

3. The pool water samples are taken under the supervision of the RSO. The samples are taken directly from the pool at a depth of 18" to 24". Since the pool water is being re-circulated, the sample is representative. The samples are then sent to Helgeson Nuclear Services for counting and measurement.

4. Helgeson's license is California 1378-59.

5. The pump discharge pressure is used to monitor filter changes. Filters are changed when outlet pump pressures indicate that the filters are becoming clogged. If a filter is found to be slightly contaminated, a commercial nuclear disposal service will be enlisted to dispose of it. Additional pool tests will be performed to check for the source of contamination.

6. The conductivity of the output from the de-ionizers is monitored to 20 umhos/cm. Commercial de-ionizer companies will service the units.

7. City sewer

N. Appendix Section 16, Ventilation System:

1. The major amount of cell contamination is paper fibers which are collected on the roughing filter preceding the HEPA filter. These filters are checked quarterly for dirt and dust accumulation which could restrict the flow and replaced as required.

   Proper care and replacement of the pre-filters will normally eliminate the need to replace the HEPA filters.

I trust that this information is responsive to your request for additional information, and that the license approval for the Decatur facility will be issued soon. Construction of the facility is proceeding rapidly, and if you would like a tour of the facility during this period, I am sure that Tom Fisher will be glad to oblige you. Our scheduled completion date is around October 1, 1984.

Sincerely,

Allan Chin

Allan Chin
President

AC:ck

ROUTING AND TRANSMITTAL SLIP Date 6/13/89

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Joel Lubenau		
2.		
3.		
4.		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

PSI Meeting
6/13/89
Minutes will be provided later by Court Reporter

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Rdlw	Phone No.

5041-102 * U.S. GPO: 1988—481-247/60003

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

6/88

RSI CAPSULE AND SITE RECOVERY INFORMATION MEETING

ATTENDENCE LIST

JUNE 13, 1989

NUMBER	NAME	ORGANIZATION
01	W. KELLY DAGENHART	MMES
02	J. B. CLENDENEN	MMES
03	BRYAN D. WALKER	DOE
04	SYLVIA JANE WOLFE	DOE
05	RICHARD B. CHITWOOD	DOE HDQTRS
06	MARK P. ELLIOTT	NRC II
07	ALLAN CHIN	RSI
08	JAMES L. SETZER	DNR
09	JAMES C. HARDEMAN	DNR
10	THOMAS E. HILL	DHR
11	CHARLES L. WAKAMO	EPA IV
12	JOHN A. CHRISTIAN	CNSI
13	LAWRENCE F. SEARS	CNSI
14	EUGENE NEWMAN	ORNL
15	WILLIAM W. BOWEN	WESF
16	E. DEWEY ROBBINS	WESF
17	RICHARD L. WOODRUFF	NRC II

Topics to be Addressed at the
RSI CAPSULE AND SITE RECOVERY INFORMATION MEETING
June 13, 1989

1. When will the ORNL hot cells be available for evaluation of capsule 1502? **DOE.**
2. A review of all of the data to date generated by ORNL on the capsules returned to ORNL. **ORNL**
3. Agreement of acceptable contamination levels on the RSI model 1500 casks to be used for WESF shipments. **WHC**
4. Review status of definition of special and nor special form capsules. **WHC**
5. Review of shipping schedule from Decatur concerning recent WESF failures of the visual, clunk and size inspections. **WHC**
6. Review of Westerville shipping schedule. **WHC**
7. Status of Hultgren report - when issued? **DOE**
8. Review of the Decatur cleanup plan and schedule. **DOE**
9. NRC limitations on Westerville license. **NRC III**
10. Georgia requirements for Decatur startup. **GA**
11. Capsule overpack contract for use with model 1500 casks. Review schedule. **WHC**
12. Capsule overpack contract for fabrication of GE 600 overpacks. NRC approval of changes? **WHC**
13. Status of Georgia Governor's Task Force. **GA**
14. Review of action approval process. Who? **DOE**
15. Need permanent on-site project manager to assure continuity. **DOE**
16. Consensus on inside out failure mechanism. **ORNL**
17. RSI equipment design, fabrication, and installation schedule. **RSI**
18. Agreement on acceptable levels of cleanup within the facility. **GA**
19. Identification of a specific individual who will have the responsibility of making decisions affecting this project. **DOE**
20. Establish an accountable cleanup schedule to be reviewed at each monthly meeting. **DOE**

RSI PROJECT INFORMATION MEETING

RSI DECATUR SITE PROCEDURES, PROGRESS, AND RECLAMATION PLANS

JUNE 13, 1989

W. K. DAGENHART

DOE SITE MANAGER AND MMES TECHNICAL MONITOR FOR THE CNSI CONTRACT

STATUS OF RSI RECOVERY PROJECT DECONTAMINATION OPERATIONS

June 13, 1989

Chem-Nuclear Systems, Inc. (CNSI), Columbia, South Carolina has been contracted by Martin Marietta Energy Systems (MMES) to provide decontamination, radiological controls, waste treatment, waste packaging, and project management services for the Radiation Sterilizers, Inc. (RSI) Recovery Project, Decatur, Georgia. In addition, CNSI will support the shipping activities for the cesium sources being removed from the facility. The status of this project as of June 13, 1989 is summarized below:

1. Approximately 14,000 square feet of the Radiation Sterilizers, Inc. (RSI) facility has been released for use by RSI. The released area of the facility includes the aerosol line, a portion of the warehouse area, the Shipping and Receiving Office and the administrative areas. The released areas have been isolated from the contaminated areas by a temporary wall installed in the warehouse area and by a locked door between the Control Room and the administrative areas.

2. Approximately 12,000 square feet of the RSI facility remain to be released. This area includes the remaining portion of the warehouse, Maze, Irradiation Cell, and the Cell Mezzanine. The Equipment Room and Pit, the Maze Entrance and a major portion of the warehouse area have been decontaminated and released for restricted use. Confirmatory surveys have not been completed.

3. The equipment used to load and unload and move the product through the Irradiation Cell has been disassembled and removed from the Warehouse and Machine Room. The removed equipment was decontaminated and released to RSI for reuse or salvage when RSI indicated a desire for it and when economically feasible. The remainder of the equipment was disposed of as radwaste.

4. Most of the conveyor track has been removed and shipped off-site for disposal. The remaining track has been used to support the ion exchange operation and to get heavy equipment into and out of the Irradiation Cell.

5. Routine surveys in the warehouse have indicated the presence of cesium contamination well within the established release limits. Surveys of the Cell Mezzanine have shown similar levels of contamination in general. However, the source rack lifting devices, the HEPA System, and the Irradiation Cell plug are know to be severely contaminated.

6. The routine surveys of the Maze and Irradiation Cell have indicated that the general contamination ranges from several hundred dpm/100 cm^2 to several thousand dpm/100 cm^2. However hot spots of up to several hundred thousand dpm/100 cm^2 have been found.

7. The contamination levels in the storage pool have been reduced to as low as 1.26E-7 (+/- 4.22E-8) uCi/ml. The ion exchange system is operated continuously except for scheduled periods for desorption studies to maintain the activity of the water at acceptable levels. The pool walls, floor and source storage racks have been vacuumed to further reduce residual contamination.

8. Special form and normal form source shipments will be made based on the shipping schedule provided by Westinghouse Hanford Company. All personnel on site will be required to support source shipments. No large scale decontamination operations will be conducted concurrent with the source shipments. Minor decontamination may be conducted between shipments or tasks to maximize personnel utilization. Accordingly, the site release schedule is highly dependent on the source shipping schedule.

In summary, the most highly contaminated material has been removed from the facility. The next major task is to remove the remaining sources. Decontamination of the Irradiation Cell and storage pool will follow source removal. Based on the current shipping schedule provided by Westinghouse, the following milestone estimates are provided:

Normal Form Shipments Complete (11)	9-6-89
Special Form Shipments Complete (161)	9-28-89
Overpacked Special Form Shipments Complete (75)	1-19-90
Site Decontamination Complete	4-19-90
Site Release	6-15-90
Final Report Submitted	7-30-90

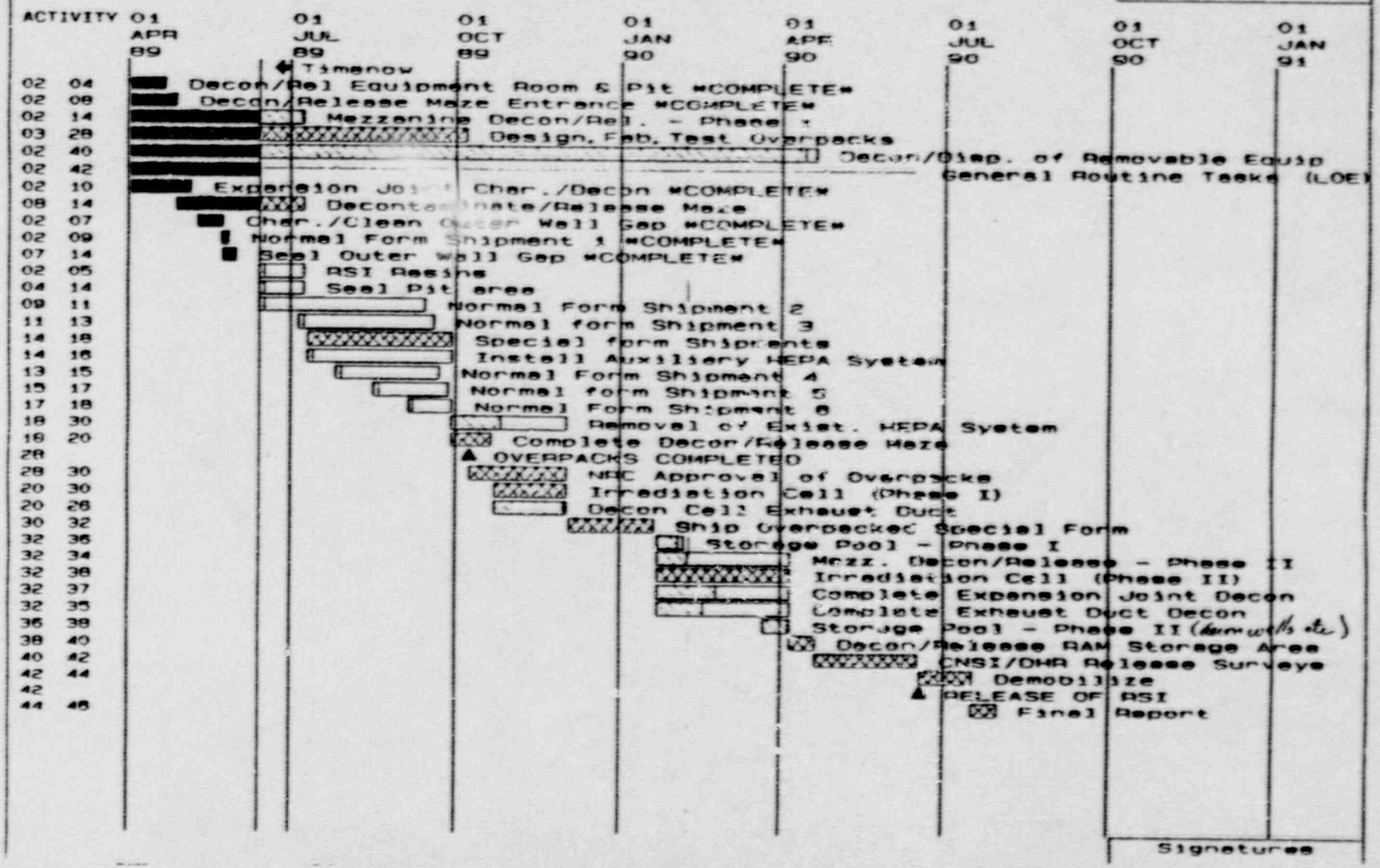
Alternative decontamination techniques and employment of advanced technologies are being investigated as possible means to reduce the time and cost necessary for site release. Attached is an estimated schedule detailing remaining tasks required for project completion.

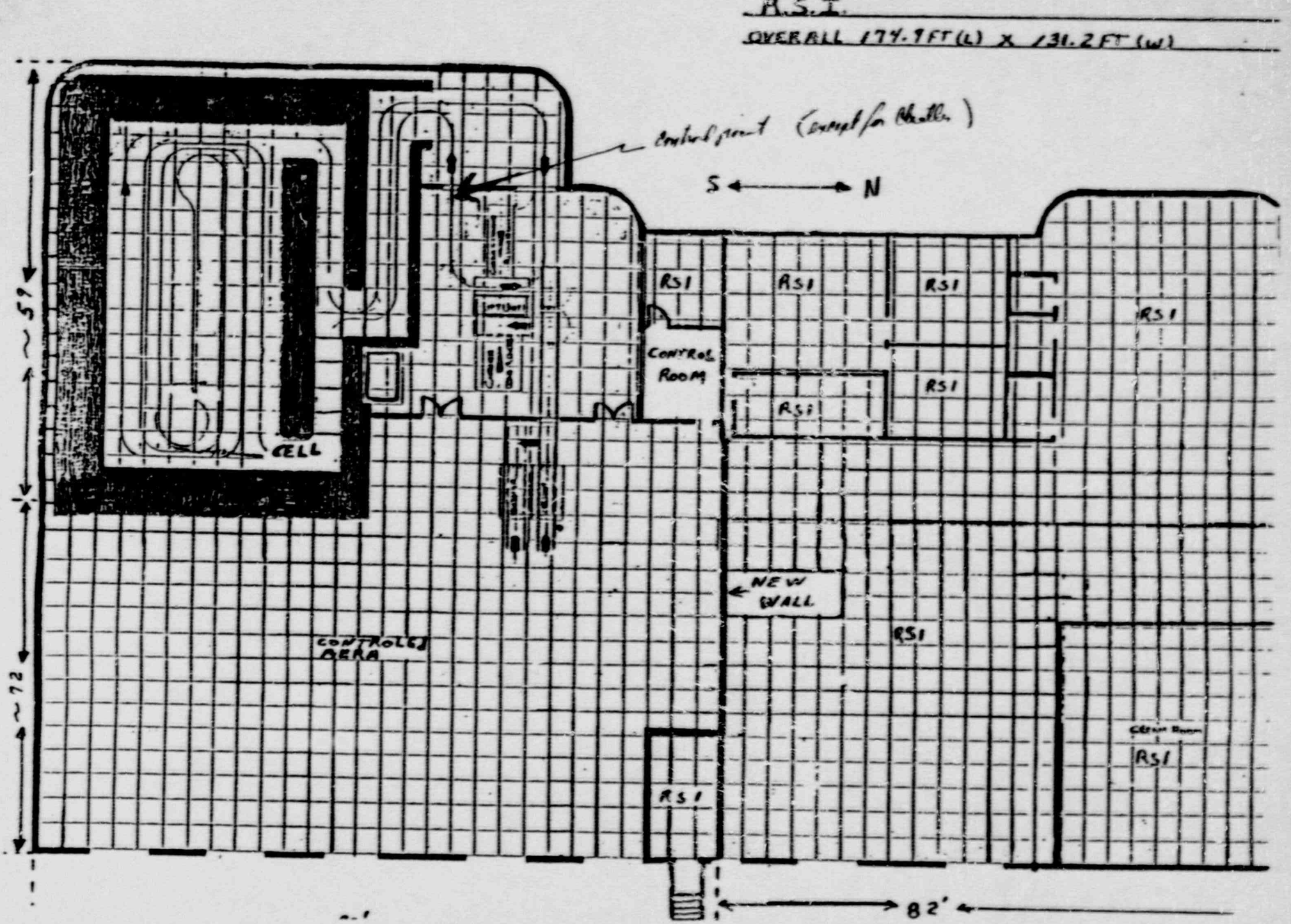
CHEM-NUCLEAR SYSTEMS, INCORPORATED

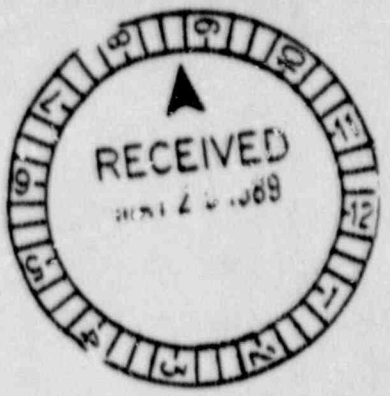
Decontaminate & Release RSI Facility

MASTER SCHEDULE REPORT page 1

CNSI Proj. # 92205
Filename : RSI_REV8
Time Now: 13:49:00
Report Date: 03/08/89




R.S.I.
OVERALL 174.9FT (L) X 131.2FT (W)
Control point (except for Shuttle)
S
N
~ 51'
~ 72'
CELL
CONTROL ROOM
RSI
RSI
RSI
RSI
RSI
RSI
NEW WALL
CONTROLLED AREA
RSI
RSI
82'



RSI RECOVERY ACTIVITY
Document and Procedure
Approval/Concurrence Form
Source Identification Task

Document/Procedure Title:

Packaging and Transportation Procedure: RSI-WHC-008, Rev A-0

Operation:

Capsule Screening Techniques

Approval:

W K Dagenhart — DOE Site Manager — Date: 5/24/89 — Time: 10:12

Concurrence:

Angus Robinson — Chem Nuclear Systems, Inc. — Date: 5/24/89 — Time: 10:45 P.

[signature] — Radiation Sterilizers, Inc. — Date: 5/25/89 — Time: 0700

Bill Slaunwhite — Georgia Department of Human Resources — Date: 5/24/89 — Time: 2247

James C. Hardeman — Georgia Department of Natural Resources — Date: 5/24/89 — Time: 2246

WHC SUPPORT PROCEDURE APPROVAL FORM

CESIUM CAPSULE RECOVERY ACTIVITY AT RSI, DECATUR, GA

DOCUMENT/PROCEDURE NO: RSI - WHC - 009

TITLE: RADIATION SHIELDING, INC (RSI) CESIUM SOURCE RECOVERY PACKAGING AND TRANSPORTATION PROCEDURE FOR GE 6,600 CURIE OVERPACK LOADING AND CASK DECONTAMINATION

PREPARED BY: E. D. Miller F. B. PERKINS DATE: 24 MAY 1989

IMPACT LEVEL: II

APPROVAL:

E. D. Miller 5/24/89
Engineering

DATE: 5/24/89
Operations

DATE: 5/24/89
Quality Assurance

DATE: 05/24/89
Safety

CAPSULE EXAMINATION

SUMMARY

June 13, 1989

E. Newman
ORNL

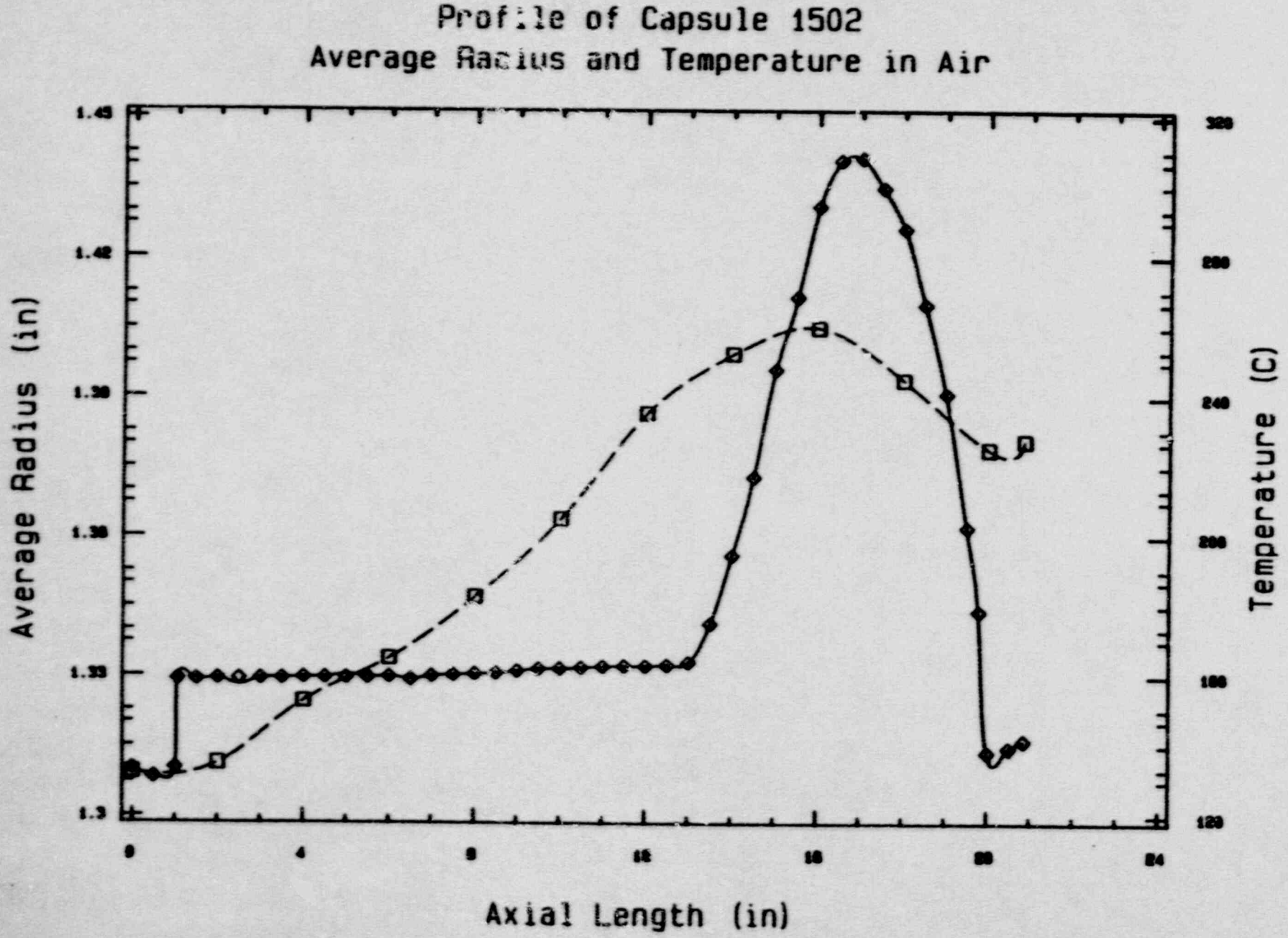
1502
(Leaker)
1502

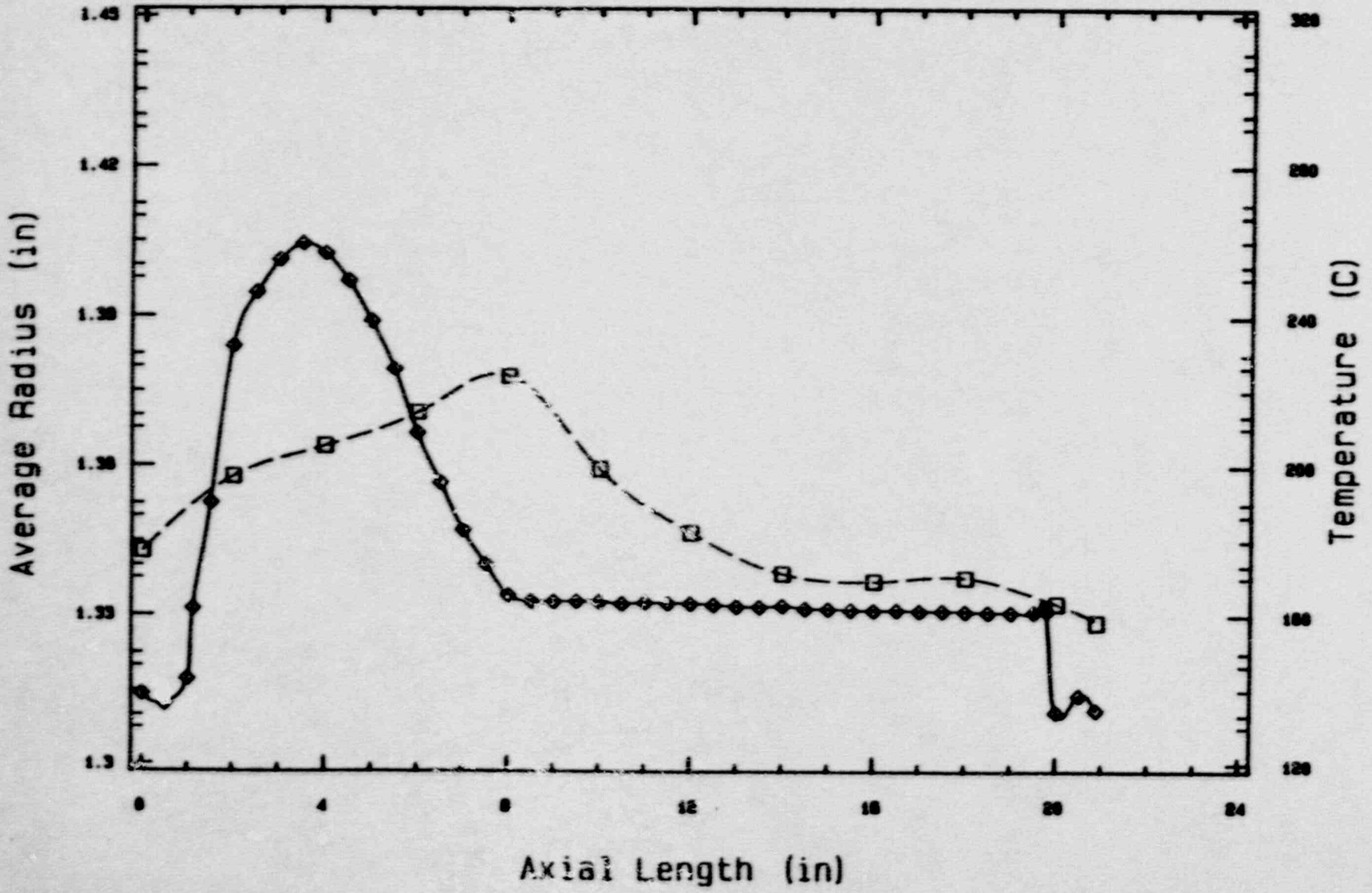
1502
(Leaker)

CAPSULE EXAMINATION SUMMARY

- Metrology
  - Initial and Sequential Measurements to Determine Profile Changes
  - Temperature Profile

Changes after Thermal Cycling Only in Azimuthal Asymmetry -- Not in Circumference


Profile of Capsule 1502
Average Radius and Temperature in Air
Average Radius (in)
Temperature (C)
Axial Length (in)


Profile of Capsule 1504
Average Radius and Temperature in Air
Average Radius (in)
Temperature (C)
Axial Length (in)
1.45
1.42
1.38
1.35
1.3
320
280
240
200
160
120
0
4
8
12
16
20
24

CAPSULE EXAMINATION SUMMARY

- Gamma–Ray Profile
  - Axial and Radial Scans

Void Space Above CsCl Approximately 6 inches.
Salt Fills the Swollen Region of the Inner Capsule.
Evidence of a Small Spike of Salt in the Annulus
at the Swollen End of Both Capsules.

CAPSULE EXAMINATION SUMMARY

- Penetration of Annulus
  - Volume of Annulus

    Approximately 60% Of Nominal 180 cc.

  - Communication Between Ends of Capsule

    For 1 atm Pressure Differential;
    Capsule 1502 – 0.05 std cc/min.
    Capsule 1504 – 4.0 std cc/min.

  - Gas Sample Analysis

    Capsule 1502 – 85% Hydrogen, Low Oxygen.
    Capsule 1504 – 5% Hydrogen (Consistent with Non-Leakers), Low Oxygen.

CAPSULE EXAMINATION SUMMARY

- Helium Leak Detection
  - External Pressurization -- Sealed Capsule
  - External Pressurization -- Internal Vacuum
  - Internal Pressurization -- External Vacuum

No evidence of a leak in either capsule.
Sensitivity 1E-7 to 1E-8 std cc/min

CAPSULE EXAMINATION SUMMARY

- Additional Leak Detection
  - Application of a "Wet Blanket" to Leach Activity from the Surface
  - Immersion in a Temperature Controlled Water Bath

No Unambiguous Evidence for a Leak Site.

CAPSULE EXAMINATION SUMMARY

- Dye Penetrant
  - Full Application of High Temperature Penetrant

Capsule 1502 -- No Evidence for Cracks or Holes.
Capsule 1504 -- Test in Progress.

RSI/Decatur Capsule Failures

Cap #	Pour #	Date Poured	Weight (kg)	Fail Mode	Pour Spout	Inner Cap	Companion Capsules		
							Decatur	W'ville	WESF
811	80-40	8/19/80	2.337	C	2	992			
849	80-41	9/05/80	2.607	C	5	784		869	
930	80-43	9/19/80	2.654	C	1	914			
913	81-14	3/25/81	2.725	C	1	1035	910		
1093	81-46	7/24/81	2.639	C	7	1245			
1196	81-51	8/18/81	2.595	C	1	1263		1195	
1502	82-21	7/07/82	2.701	L,R,C	6	1438	1542		1541
	82-23								1357
1504	82-23	7/27/82	2.311	R,C	3	1560	1501	1503	1497
							1502		1550
1553	82-33	9/03/82	2.725	C	4	1581			
1562	82-34	9/02/82	2.692	C,R	7	1585	1556	1558	
							1561	1560	
							1563		
1600	83-05	5/02/83	2.605	C	3	1631		1592	
								1598	

Weight = Salt Weight

C = Clunk; L = Leak; R = Ring Guage

Pour Spout

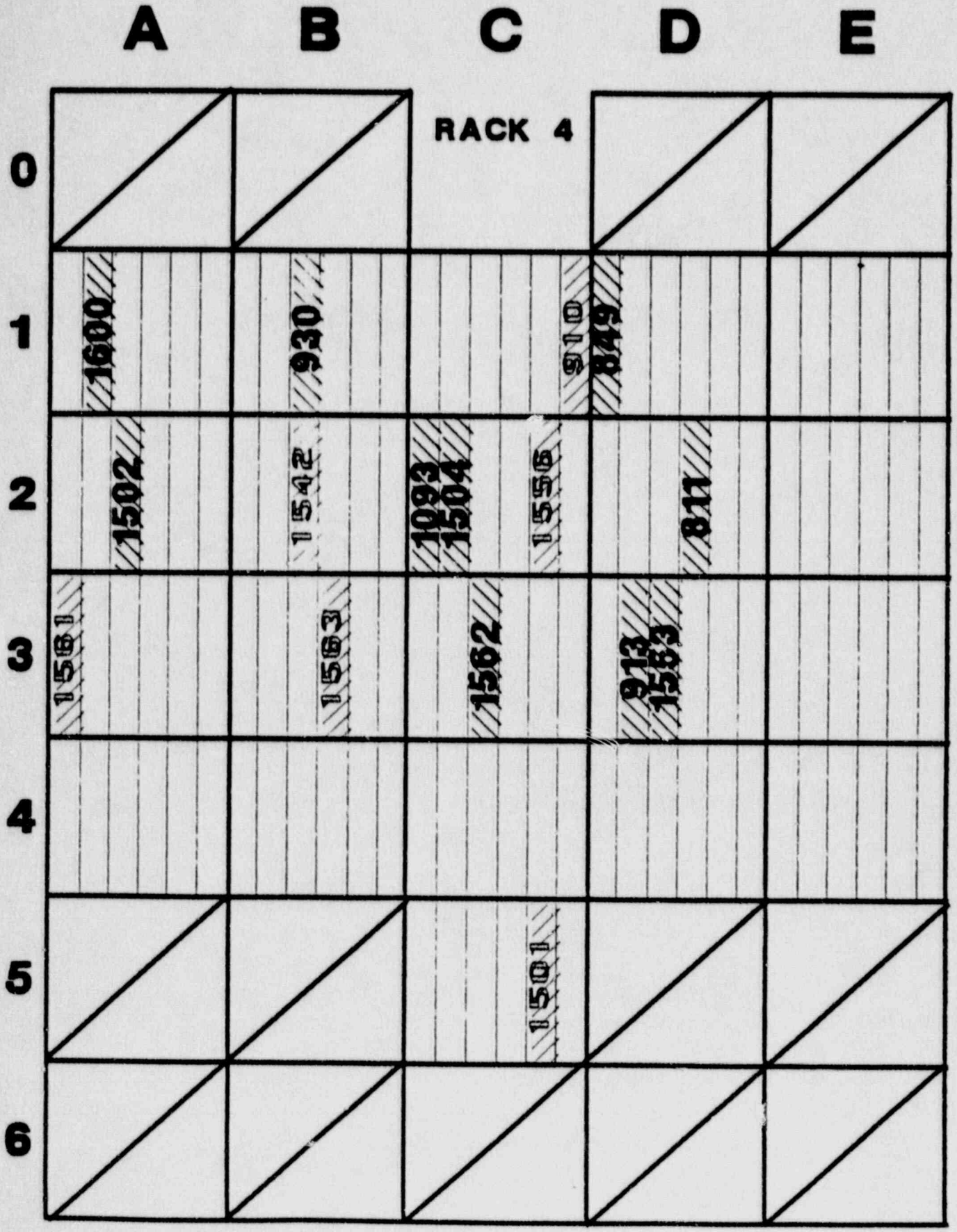
7 6

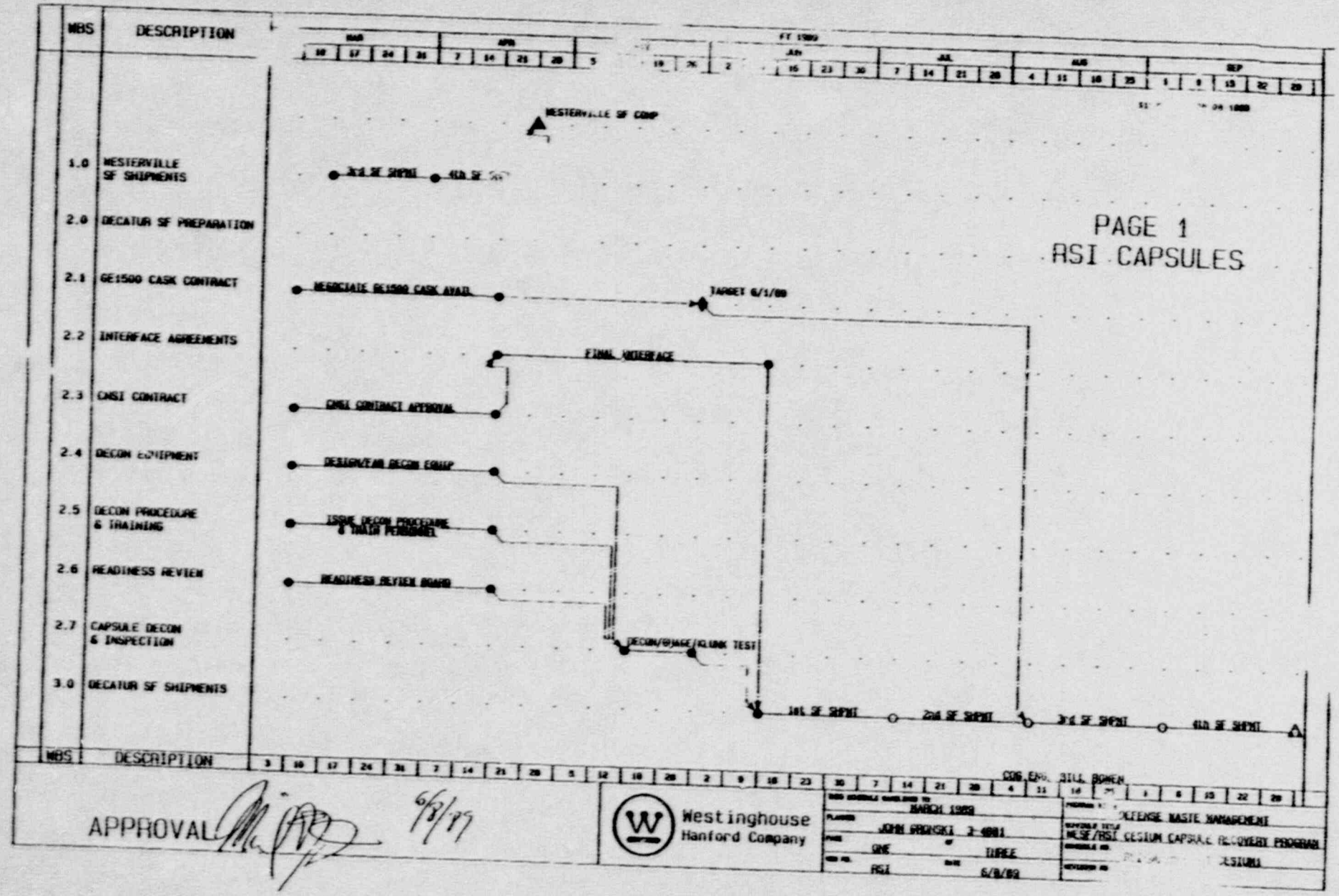
3 4 5

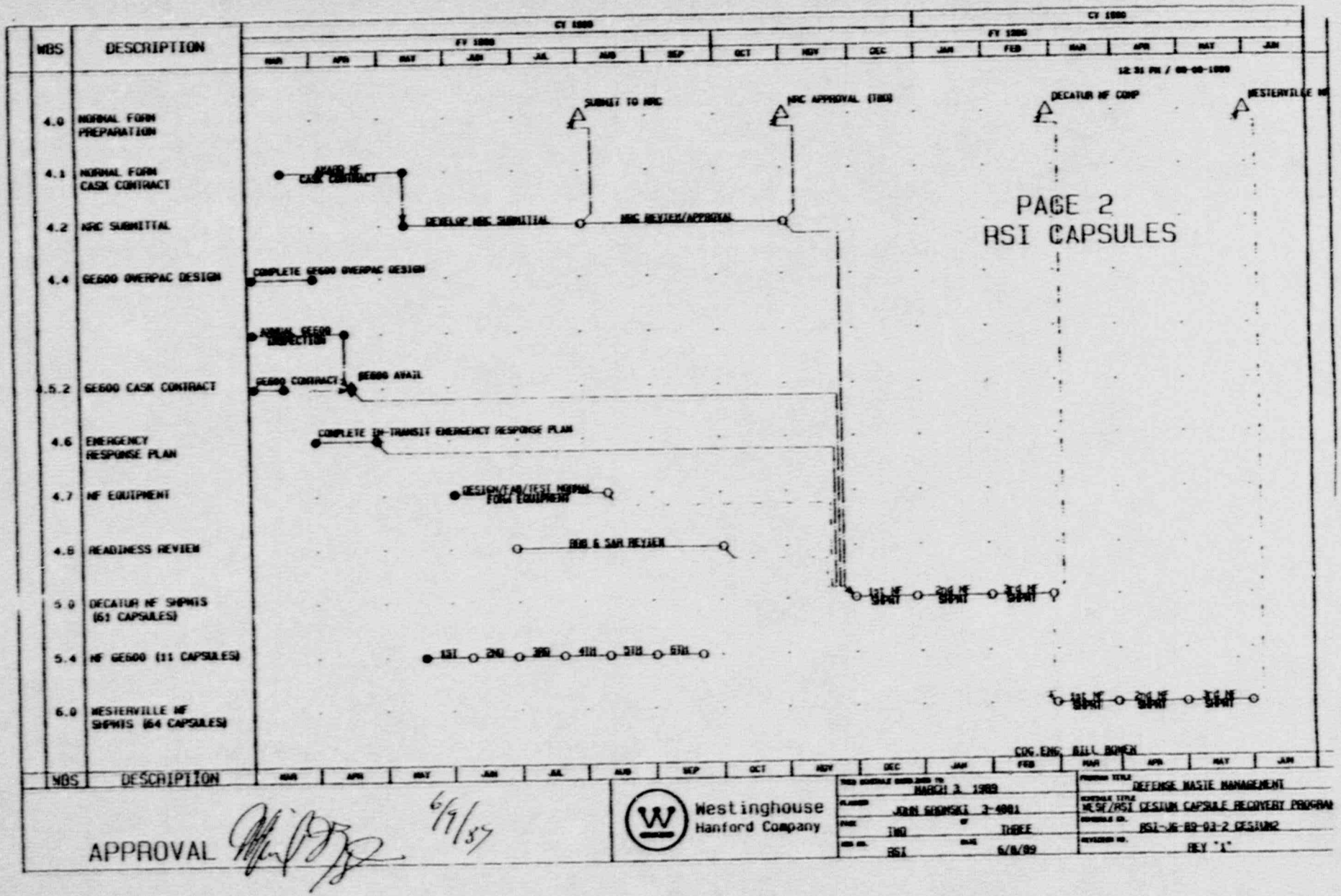
2 1

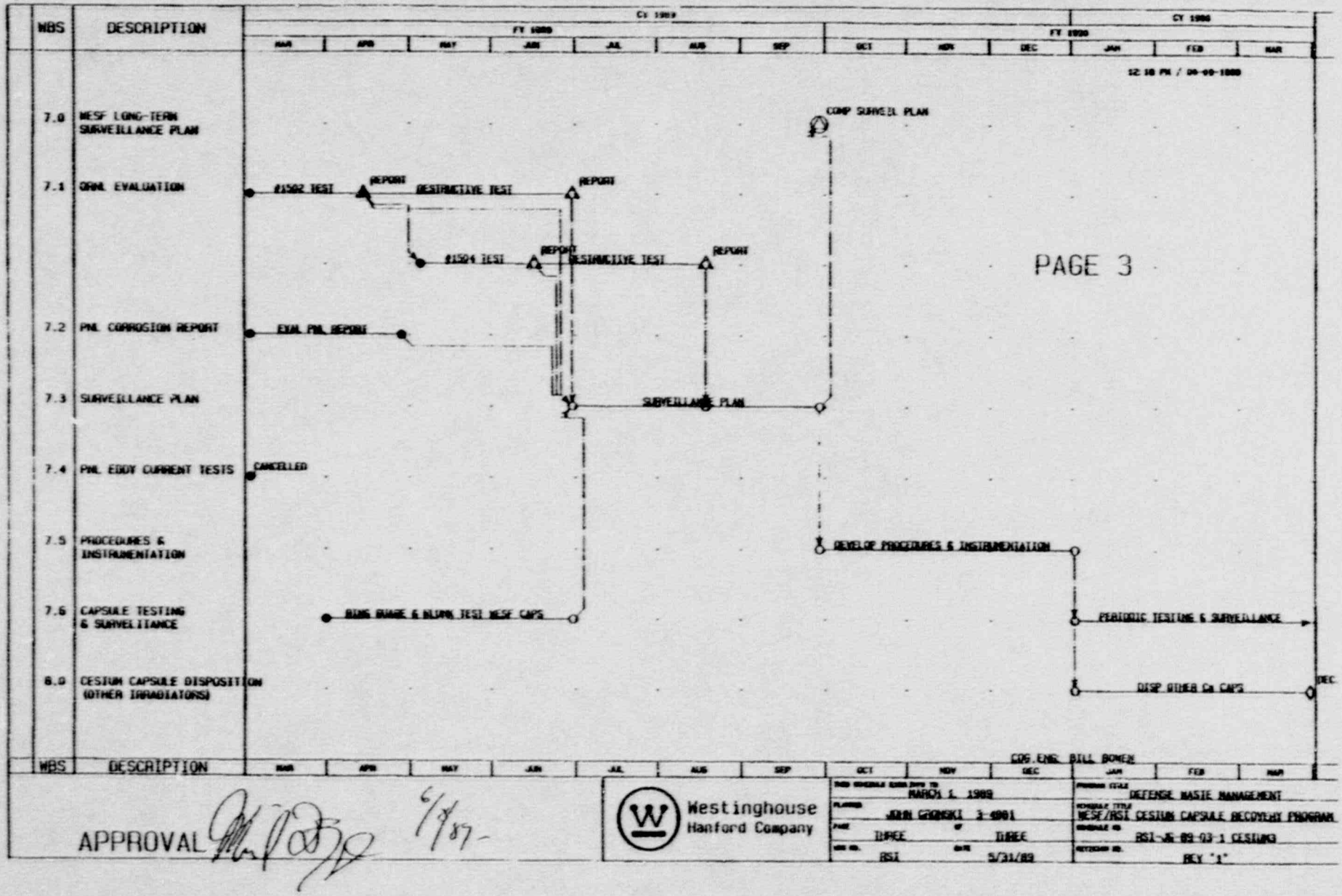
Bottom

Va? Co?


A
B
C
D
E
RACK 4
0
1
2
3
4
5
6
1600
1502
1581
930
1542
1563
1093
1504
1562
1555
910
1501
849
811
913
1563


WBS
DESCRIPTION
1.0 WESTERVILLE SF SHIPMENTS
2.0 DECATUR SF PREPARATION
2.1 GE1500 CASK CONTRACT
2.2 INTERFACE AGREEMENTS
2.3 CASI CONTRACT
2.4 DECON EQUIPMENT
2.5 DECON PROCEDURE & TRAINING
2.6 READINESS REVIEW
2.7 CAPSULE DECON & INSPECTION
3.0 DECATUR SF SHIPMENTS
WESTERVILLE SF COMP
NEGOCIATE GE1500 CASK AVAIL
TARGET 6/1/89
FINAL INTERFACE
CASI CONTRACT APPROVAL
DESIGN/FAB DECON EQUIP
DECON/BRAGG/KLINK TEST
1st SF SHPMT
2nd SF SHPMT
3rd SF SHPMT
4th SF SHPMT
PAGE 1
RSI CAPSULES
APPROVAL
6/8/89
Westinghouse
Hanford Company
MARCH 1989
JOHN PRONSKI 2-4981
ONE
THREE
RSI
6/8/89
DEFENSE WASTE MANAGEMENT
WESF/RSI CESIUM CAPSULE RECOVERY PROGRAM


WBS
DESCRIPTION
CY 1988
FY 1988
CY 1989
FY 1989
12:31 PM / 00-00-1900
4.0 NORMAL FORM PREPARATION
4.1 NORMAL FORM CASK CONTRACT
4.2 NRC SUBMITTAL
4.4 GE600 OVERPAC DESIGN
5.2 GE600 CASK CONTRACT
4.6 EMERGENCY RESPONSE PLAN
4.7 NF EQUIPMENT
4.8 READINESS REVIEW
5.0 DECATUR NF SHPMTS (61 CAPSULES)
5.4 NF GE600 (11 CAPSULES)
6.0 WESTERVILLE NF SHPMTS (64 CAPSULES)
SUBMIT TO NRC
NRC APPROVAL (TBD)
DECATUR NF COMP
WESTERVILLE NF
AWARD NF CASK CONTRACT
DEVELOP NRC SUBMITTAL
NRC REVIEW/APPROVAL
COMPLETE GE600 OVERPAC DESIGN
ANNUAL GE600 INSPECTION
GE600 CONTRACT
GE600 AVAIL
COMPLETE IN-TRANSIT EMERGENCY RESPONSE PLAN
DESIGN/FAB/TEST NEPHW FORM EQUIPMENT
RER & SAR REVIEW
1ST NF SHPMT
2ND NF SHPMT
3RD NF SHPMT
1ST
2ND
3RD
4TH
5TH
6TH
PAGE 2
RSI CAPSULES
CDG ENG. BILL BOWEN
WBS
DESCRIPTION
APPROVAL
6/9/89
Westinghouse
Hanford Company
THIS SCHEDULE SUPERSEDES TH MARCH 3, 1989
PLANNER JOHN SHONSKI 3-4081
PAGE NO. TWO OF THREE
WBS NO. RSI DATE 6/8/89
PROGRAM TITLE DEFENSE WASTE MANAGEMENT
SCHEDULE TITLE WESF/RSI CESIUM CAPSULE RECOVERY PROGRAM
SCHEDULE ID. RSI-J6-89-03-2 CESIUM2
REVISION NO. REV "1"


WBS
DESCRIPTION
CY 1989
FY 1989
FY 1990
CY 1990
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV
DEC
JAN
FEB
MAR
12:10 PM / 04-09-1989
7.0 MESF LONG-TERM SURVEILLANCE PLAN
7.1 QUAL EVALUATION
7.2 PNL CORROSION REPORT
7.3 SURVEILLANCE PLAN
7.4 PNL EDDY CURRENT TESTS
7.5 PROCEDURES & INSTRUMENTATION
7.6 CAPSULE TESTING & SURVEILLANCE
8.0 CESIUM CAPSULE DISPOSITION (OTHER IRRADIATORS)
COMP SURVEIL PLAN
#1502 TEST
REPORT
DESTRUCTIVE TEST
REPORT
#1504 TEST
REPORT
DESTRUCTIVE TEST
REPORT
PAGE 3
EVAL PNL REPORT
SURVEILLANCE PLAN
CANCELLED
DEVELOP PROCEDURES & INSTRUMENTATION
BIAS CHARGE & BLANK TEST MESF CAPS
PERIODIC TESTING & SURVEILLANCE
DISP OTHER Cs CAPS
DEC
COG ENG: BILL BONER
WBS
DESCRIPTION
APPROVAL
6/8/89
Westinghouse
Hanford Company
MARCH 1, 1989
JOHN GRONSKI 3-4981
THREE
OF
THREE
RSI
5/31/89
DEFENSE WASTE MANAGEMENT
WESF/RSI CESIUM CAPSULE RECOVERY PROGRAM
RSI-WBS-89-03-1 CESIUM
REV "1"