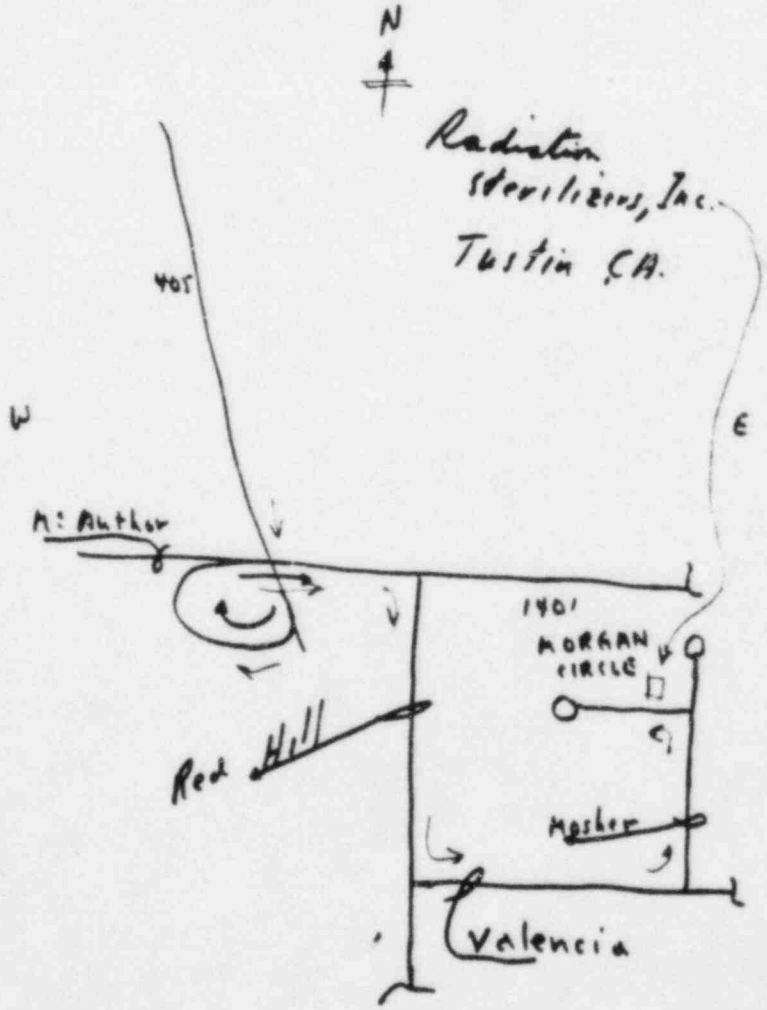
RADIATION
STERILIZERS
INCORPORATED

QUALITY ASSURANCE



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Note: This manual and the above sections are intended to conform with the requirements of 10 CFR 50 (Appendix B) regulations, U. S. Nuclear Regulatory Commission. They augment the RSI/ Tustin Procedures Manual.

Radiation Sterilizers, Inc. (RSI) was established in 1979 with the primary objective of providing gamma-sterilization services for the medical device and diagnostics industry. The first facility was constructed in Tustin, California. Subsequently, additional facilities have been constructed or are in construction at (1) Schaumberg, Illinois; (2) Columbus, Ohio; and (3) Atlanta, Georgia. The Cobe facility in Denver, Colorado, was also designed and constructed by RSI.

In each facility, products may be irradiated in either of two ways:

1. The continuous-conveyor transport system is employed to process large runs into and through the radiation cell;
2. Batch-processing is employed to irradiate items which require
   a. Special handling arrangements, such as electrical monitoring;
   b. Unique dosages or dose rates;
   c. Spatial arrangements not possible to achieve with the continuous-conveyor system.

Nuclear power plant components of various sizes and configurations are processed as batch-work typically.

In all of its activities, RSI performs as a support function to its customers. In effect, RSI operates as the customer's radiation department and carries out its assignments in strict conformance to each individual customer's instructions and specifications.

Radiation Capacity.

$Cobalt^{60}$ is the source of gamma radiation employed by RSI. The Tustin facility is licensed for 5 million curies and in terms of current source strength, it is the largest contract radiation facility in western United States.

The Tustin plant is approximately 32,000 square feet in size. Of this space, 4,000 square feet are devoted to the heavily-shielded radiation cell and maze. The balance is comprised of administrative offices and physically separated areas for processed and non-processed product storage.

Licenses.

RSI's position of leadership in the highly specialized field of gamma-processing has been achieved through the company's commitment to excellence and high standards of quality control. Medical products and safety-related nuclear components require and receive this level of performance.

RSI/Tustin is regulated by the Nuclear Regulatory Commission, the state of California's Radiological Health Section, the Federal and state Food and Drug agencies and operates within their regulations and GMPs.

Licenses, permits and registrations held by RSI/Tustin are:

State of California Radioactive Materials License	#3390-30
State of California Device Manufacturing License	#30444
California State Board of Pharmacy License	#E 007155
FDA Labeler Code	#50181
FDA Device Master File	MAF-32
FDA Drug Master File	DMF-4027

1.0 Purpose:

This Quality Assurance document establishes the basic operating policies and procedures which shall be employed by the RSI/Tustin organization to meet the requirements and provisions of:

a. The Food and Drug Administration's Good Manufacturing Practices;

b. The NRC's stipulations for processing Class 1E safety-related nuclear components.

1.1 Scope:

The Quality Assurance Program described in this document is the standard of control for RSI/Tustin. These controls shall be implemented and maintained by the areas responsible for the functions of materials handling, radiation processing, dosage measurement, document control and purchasing.

1.2 Organization Structure:

All quality assurance policies and procedures shall be instituted and/or approved by the president of RSI. Their implementation shall be delegated to the general manager of RSI/Tustin who, in turn, is responsible for the day-to-day assurance of quality performance by the Tustin operation. Periodically, the president or his delegate shall audit the RSI/Tustin facility to insure compliance with these policies and procedures.

The general manager shall be responsible for:

a. Insuring the accuracy of the Certification of Irradiation--the primary documentation furnished to RSI's customers;

b. Checking, auditing and otherwise verifying that the irradiation service requested by the customer and certified has been performed in accordance with the customer's specifications;

c. Identifying potential quality-related problems and deciding/implementing solutions;

d. Approving proposed correction actions and assuring that corrective actions are implemented;

e. Conducting periodic internal audits of each department's practices to assure conformance with approved procedures.

In the absence of the general manager, these responsibilities shall be delegated to the production manager.

Each level of supervision is responsible for the quality of work performed by him/her and his subordinates. During processing of product, the production manager and each of his shift supervisors shall be responsible for controlling the accuracy and quality of work performed under their immediate supervision.

Each major step in the handling and radiation-processing shall first be documented, reviewed and signed off by the involved shift supervisor. These documents shall then be reviewed for accuracy by the production manager. Finally, all documents shall be reviewed by the general manager prior to signing the Cerification of Irradiation.

In the event of a deviation from dosing specifications or any other action which may detrimentally affect the product, a Notice of Deviation (NOD) shall be initiated by the involved shift supervisor. Its preparation and distribution shall be in accordance with RSI Operating Procedure # 30.

To assure that all employees are alert to their responsibilities for reporting of defects and noncompliance, a copy of 10 CFR Part 21 shall remain posted in a conspicuous location.

The president of RSI shall be kept informed of all matters relating to quality assurance by the general manager. All changes to the facility's operating and quality assurance manuals shall be reviewed and approved by the president. Formal Notices of Deviation (NOD) shall be copied to the president for his review and possible action.

1.0 Purpose:

This section identifies the planning, verification, personnel indoctrination, training and management review of the Quality Assurance Program.

1.1 Scope:

The Quality Assurance procedures described below shall pertain to RSI/Tustin and shall apply to all employees who are involved directly in the handling and processing of all products.

1.2 Planning:

RSI acts as the radiation department of each customer and performs in conformance with each individual customer's instructions and specifications. Therefore, before processing any customer's products, the customer should be contacted to establish the plan(s) for RSI's handling and processing of his materials.

During this discussion, the customer's representative(s) should be made aware of RSI's procedures, the gamma irradiation process and possible material effects. Further, the representative should be made aware that the final responsibility for dose setting and sterility is the manufacturer's.

In the case of nuclear components, the representative should be provided with information regarding (a) dosage rate and location options; (b) dosimetry characteristics; (c) rotational provisions; and any other pertinent information needed to provide complete specifications.

During or following this discussion, the customer's representative should provide the following processing specifications:

a. dose requirements and permissible tolerances;
b. dosage rate instructions, if appropriate;
c. appropriate instructions regarding dosimeter placement and product rotation whenever these requirements depart from normal RSI operating procedures.

In the case of medical product manufacturers, dose distribution mapping should be proposed and discussed at any early stage.

1.3 Verification:

Wherever possible, the customer shall provide written verification of his requirements in a purchase order, protocol or similar document. These instructions shall then be entered into the RSI computer and made a part of the ensuing Customer Run Work Order(s). As a minimum, the Run Work Order shall be consulted at three specific times:

a. By the shift supervisor prior to radiation processing the product;

b. By the production manager during or after processing;
c. By the general manager at the time of certifying the dosage delivered.

1.4 Personnel Indoctrination and Training:

In addition to normal training in radiation safety practices, all managers and supervisors shall receive on-the-job training in process control, dosimetry control and other appropriate areas relating to the radiation processing of products.

Processing of class 1E safety-related nuclear components shall only be performed by the production manager or a shift supervisor whom he specifically designates. Additional on-the-job training shall be provided to this/these designee(s) to assure knowledge of proper techniques and the provisions of 10 CFR, Part 21.

1.5 Management Review:

Periodic review of employees' technical proficiency, performance and quality awareness shall be conducted by the production manager and the general manager. This review should be summarized and forwarded to the president for his review and possible comments.

1.0 Purpose:

This section describes the procedures which control the designed delivery of radiant energy to the customer's product(s).

1.1 Scope:

The following procedures cover isotope location and activity together with dose measurement systems that are employed to assure that dosage/rate delivery is in accord with customer requirements.

1.2 Isotope Placement and Location:

The energy level of the two source racks (as measured by curie content) should be maintained in as balanced a condition as possible.

Whenever new isotope is loaded, the vendor's certification of curie content shall be reviewed by the Radiation Safety Officer (RSO), the general manager and the production manager to insure that the placement decisions are understood by each. Placement of the new isotope shall be designed in a manner which provides appropriate distribution of radiant flux.

Records of isotope placement shall be maintained in a permanent file designated and labelled as "Radioactive Materials License." These records shall be up-dated periodically to account for additional isotope loading, re-distribution of isotope and/or isotope decay.

1.3 Dose-rate Measurement For Batch-processed Products and Components:

Whenever a customer's product is to be batch-processed in a manner which requires either:

a. Exceptionally high or low dosages (that is, dosages beyond the measurement capability of dosimeters standardly employed by RSI);
b. A very specific dose delivery to a nuclear component with a defined area of interest;

the batch area selected should be mapped by dosimetry to define the air equivalent dose rate if this information has not already been determined.

This information shall be discussed with the customer's representative prior to processing in thoseinstances when the actual dose rate is at variance with customer specifications.

A recording of the dose rate delivered to Class 1E nuclear components shall be made and maintained with the customer's run data in RSI files.

1.4 Dose Distribution Measurement for Conveyor-processed Products:

Whenever a customer's product is to be routinely processed on the continuous-conveyor system, the benefits of performing a dose distribution and product density study should be discussed with the customer. If the customer agrees, the data resulting from the dose-mapping study

shall be used by RSI to establish dosimeter placement and to guide dwell-time estimations.

Dose distribution measurements are performed in conformance with RSI Operating Procedure #53. The original document shall be sent to the customer. RSI shall maintain copies in (a) the customer run file; and (b) the production office dose map filebook.

New dose mapping should be considered at the following times;

a. When the source is reconfigured in a manner which affects dose distribution; or
b. When thereis any significant change in product or packaging that gives reason to believe the minimum dose zone location has been changed.

1.0 Purpose:

This section concerns the measures taken to assure that RSI suppliers have adequate quality assurance programs in effect.

1.1 Scope:

The controls which are specified below are those applicable to vendors of (a) isotope and (b) dosimetry systems. These are the primary items used by RSI to provide accurate deliver of gamma irradiation.

1.2 Isotope Procurement Control:

The cobalt^{60} sources employed by RSI shall be approved by the U. S. Nuclear Regulatory Commission for use in Category IV irradiators. Purchase orders should require a Certificate of Measurement, together with references to the specific quality control procedures employed by the vendor to assure accuracy of measurement.

1.3 Dosimeter Procurement Control:

The radiachromic dosimeters employed by RSI/Tustin shall be procured from Far West Technology, Inc. of Goleta, California or a comparable vendor. Purchase orders shall require that the following information is furnished at the time of delivery:

a. Lot number designation;
b. Certification of the sensitivity index pertinent to the purchased dosimeters.

Periodically, RSI/Tustin personnel shall conduct visits to audit its dosimeter vendor and their quality assurance procedures.

RADIATION STERILIZERS INCORPORATED

BATCH RUN DOSIMETER DATA SHEET

CUSTOMER: _____ RSI RUN NUMBER: _____

CHART ISSUE: _____ DATE: _____

Location	S.I.	I.O.D.	O. D	$\frac{\Delta O.D.}{S.I.}$	Mean	MRads	Read by
1							
2							
1							
2							
1							
2							
1							
2							
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1							
2							

Approved by: _____

Date: _____

Location	S.I.	I.O.D.	O.D.	$\frac{\Delta \text{ O.D.}}{\text{S.I.}}$	Mean	MRads	Read by
1							
2							
1							
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Approved by: _____

Date: _____

RADIATION STERILIZERS INCORPORATED

MULTIPLE BATCH DOSE DETERMINATION WORK SHEET

CUSTOMER: _____

DATE: _____

CHART ISSUE: _____

RSI RUN NUMBER: _____

DOSAGE MEASURED AS AIR EQUIVALENT ☐

INTEGRATED ☐

CUSTOMER SPECIFICATIONS:					
Product identification					
Required dosage (MRads) Minimum					
Maximum (if stated)					
Required rate (MRads/hr) Minimum					
Maximum (if stated)					
Required # rotations					

PRE-RUN DETERMINATIONS:					
Estimated dose rate					
Exposure time required					

PROCESSING DATA:					
Identify batch position					
Time placed					
Date					
Time of dose rate check					
Date					
Time of rotation #1					
Date					
Time of rotation #2					
Date					
Time of rotation #3					
Date					
Time removed from position					
Date					

Down-time accumulation					
Before check					
Before rotation #1					
#2					
#3					
Total					

CALCULATIONS:

Total exposure time					
Measured minimum dose rate					
Measured maximum dose rate					
Total minimum dose delivered					
Total maximum dose delivered					

Is dosage based on a "rate times time" calculation? Yes ☐ No ☐

COMMENTS:

Approved by: _____

Date: _____

1.0 Purpose:

This section describes the documented instructions, procedures and drawings which are employed by RSI to assure delivery of specified radiation services.

1.1 Scope:

The instructions, procedures and drawings specified below are applicable to the dose delivery and measurements conducted for medical and safety-related nuclear components.

1.2 Instructions:

Each irradiation run performed by RSI (other than informal material feasibility runs designated by the prefix RSI) shall be preceded by an RSI Work Order. This document may include a variety of instructions furnished by the customer but shall include:

a. Product identification;
b. Required dosage and dose rate (if appropriate);
c. Rotational requirements and dosimeter location (when unique).

An RSI Run Data Sheet (for conveyor-processed products) or an RSI Batch Run Data Sheet (for batch-processed products) shall be prepared for each RSI run. Upon completion of the run, dosimetry readings (whose calibration is traceable to NBS) shall be made to establish that the required dosage has been delivered to the designated product and/or area of interest.

For batch-processed products, the Batch Dose Determination Work Sheet shall be used to record cell placement, rotations and removal times and dosages whenever a "rate times time" calculation is employed to establish the delivered dosage.

1.3 Procedures:

RSI shall maintain a confidential Procedures Manual which describes all procedures relating to the operation of the facility. This manual should be reviewed and up-dated whenever necessary to account for significant changes or improvements.

RSI/Tustin shall also maintain a Quality Assurance Manual which deals specifically with quality controls employed to assure conformance to customer specifications. This manual should also be reviewed and updated when significant changes or improvements in quality assurance techniques warrant.

1.4 Drawings:

Whenever specified by the customer, RSI shall provide drawings, illustrations or photographs which depict the dose distribution, dosimeter placement or batching location of the product relative to the source. Copies of these drawings will be retained with the RSI run file.

1.0 Purpose:

This section describes the documents associated with each customer run their purposes and methods of control.

1.1 Scope:

The measures specified below shall apply to all runs, except for informal feasibility/experimental runs which are designated by the prefix (RSIxxxx). These measures apply to the issuance and control of the following documents:

a. Certification of Irradiation;
b. Dosage Distribution Map;
c. Dosage Distribution and Density Data Worksheet;
d. Multiple Batch Dose Determination Worksheet;
e. Batch Run Dosimeter Data Sheet and Run Data Sheet.

The additional documents which record inspections of product count and condition are described in Section X (INSPECTION).

1.2 Certification of Irradiation:

The Certification of Irradiation shall be furnished to all customers for all runs, except for either feasibility/experimental run or runs where certificates are specifically declined by the customer. The Certification shall include customer name, run date, the assigned run number and the product description as furnished by the customer.

The dosage information shall be taken from the Run Data Worksheet and may be expressed as specified by the customer as either:

a. The minimum requested dosage;
b. The minimum and maximum dosages measured within the run;
c. The listing of all dosimeter readings.

Nuclear components shall have their dosage expressed as either "air-equivalent" or "integrated", depending upon the customer's stated requirement.

The original copy of the Certification shall be provided to the customer. A carbon or photocopy shall be attached to the customer run file and retained by RSI/Tustin.

RADIATION STERILIZERS INCORPORATED

CERTIFICATION OF IRRADIATION

CUSTOMER: XYZ COMPANY

IRRADIATION RUN DATE: OCTOBER 15, 1983

IRRADIATION RUN NUMBER: XYZ3001-T

MATERIALS PROCESSED:

NO. CTNS	DESCRIPTION	LOT NO.
245	TUBING SETS TW 113	84691
62	CONNECTORS CN 6812	84692
1	SAMPLE FOR NAMSA	

Radiation Sterilizers, Inc. certifies that this material received not less than 2.5 MRads, within the precision limits of the dosimetry system employed.

Certified by_____

Date_____

Radiation Sterilizers Incorporated, 1401 Morgan Circle, Tustin, California 92680 / Telephone (714) 730-0611

Radiation Sterilizers, Inc.
WORK ORDER

09/22/83 INV NUMBER 7772

Run Number: XYZ3001-T

Customer: XYZ COMPANY

Dose Required: 2.5-3.5 MRADS/RPT ALL DOSES/ML CERT TO J.LEE,Q.C./ BI's LOW DOSE PT 1st TOTE

Processing Instructions:

SAMPLES TO NAMSA
PALLETIZE SAME AS RECEIVED
LOAD 4/TOTE
BLT P.O. # 31234

CARTONS	DESCRIPTION	LOT NO.
245	TUBING SETS TW 113	84691
62	CONNECTORS CN 6812	84692
1	SAMPLE FOR NAMSA	

Shipping Instructions: AM DELIV/NO FRI/SMPS NAMSA

Ship via: STAR EXP/WC MS.GOMEZ 730-2112

1.3 Dosage Distribution Map:

The Dosage Distribution Map is initiated at the customer's request to characterize the distribution of dosages delivered to the specified product within a tote. This document shall include customer name, run date, the assigned run number, the NBS dosimeter calibration reference number and the product identification furnished by the customer.

Each dosage reported shall represent the mean value of two dosimeters at each dose point. Direction of tote travel and use of cobalt ^{60} shall be specified.

The original copy of the dose map shall be provided to the customer. A carbon or photocopy shall be attached to the customer's run file and retained by RSI/Tustin. A third copy shall be entered and retained in the dose map reference book located in the production control room.

1.4 Dosage Distribution and Density Data Worksheet:

This worksheet shall be used in conjunction with the Dosage Distribution Map as a means of calculating and recording the dosimetry readings. It also includes:

a. The physical location of the measured high and low dose points;
b. The max/min dose ratio;
c. The carton bulk density;
d. The loaded tote bulk density;
e. Fill efficiency.

The original copy of this worksheet shall be attached to the customer's run file. A carbon copy shall be furnished to the customer at his request.

1.5 Multiple Batch Dose Determination Worksheet:

This form shall be employed whenever batch-processing is performed. It provides detailed processing instructions, i.e.:

a. Whether dosage will be measured as air equivalent or integrated;
b. Required dosage and tolerance permitted;
c. Required dose rate (if specified by customer);
d. Rotational requirements (if specified).

Space is provided for calculating and recording dosage on a "rate times time" basis if appropriate.

The original copy of this worksheet shall be attached to the customer's run file. A carbon or photocopy shall be provided to the customer upon request.

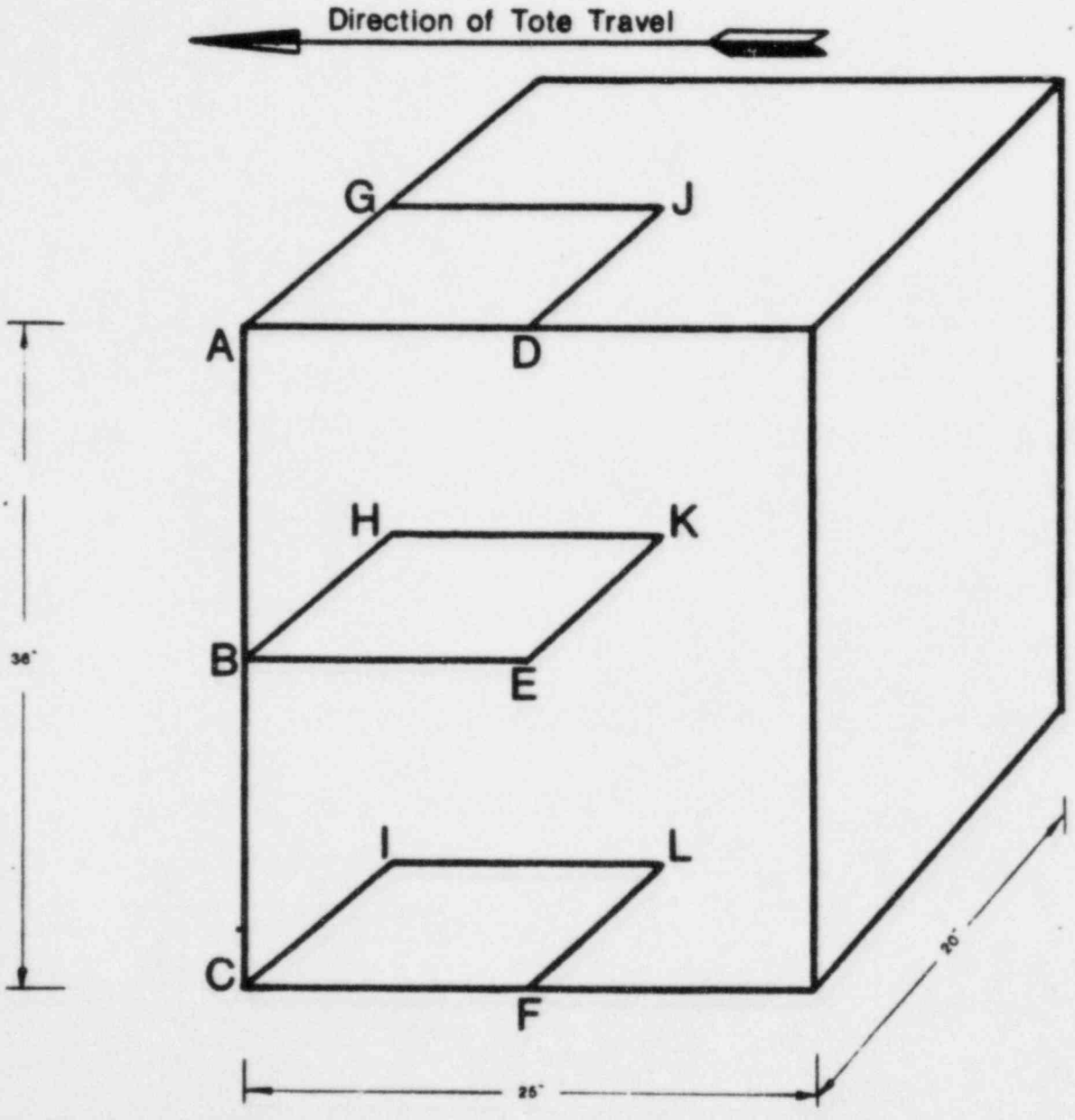
1.6 Batch Run Dosimeter Data Sheet:

This form shall be employed with batch-processed products whenever dosage is established directly from dosimetry, rather than calculated on a "rate times time" basis. It shall be controlled and distributed in the same manner as the Run Data Sheet.

RADIATION STERILIZERS INCORPORATED

DOSAGE DISTRIBUTION MAP

Customer :	Run number :
Product Identification :	Date of Run :
Source : Cobalt ^{60}	Chart issue :



DOSAGE	
A	
B	
C	
D	
E	
F	
G	
H	
I	
J	
K	
L	

Radiation Sterilizers Inc. certifies that the dosages stated above are representative readings of each position, within the precision of the dosimeters utilized.

Certified by : _____

Title : _____

Date : _____

Radiation Sterilizers Incorporated, 1401 Morgan Circle, Tustin, California 92680 / Telephone (714) 730-0611

RADIATION STERILIZERS INCORPORATED

DOSE DISTRIBUTION AND DENSITY DATA WORKSHEET

CUSTOMER _____ RUN NUMBER _____

PRODUCT NAME _____ CARTON HEIGHT (inches) _____

RUN DATE _____ CARTON WIDTH (inches) _____

DOSAGE REQUESTED _____ CARTON DEPTH (inches) _____

SHELVES EMPLOYED _____ CARTON WEIGHT (pounds) _____

DOSIMETRY SERIES _____ CARTONS/TOTE _____

DOSIMETRY DATA:

Location	S.I.	I.O.D.	O.D.	$\frac{\Delta \text{ O.D.}}{\text{S.I.}}$	Mean	MRads	Read by
A 1							
2							
B 1							
2							
C 1							
2							
D 1							
2							
E 1							
2							
F 1							
2							
G 1							
2							
H 1							
2							
I 1							
2							
J 1							
2							
K 1							
2							
L 1							
2							

Approved by _____

Date _____

RADIATION STERILIZERS INCORPORATED

MULTIPLE BATCH DOSE DETERMINATION WORK SHEET

CUSTOMER: _____ RSI RUN NUMBER: _____

DATE: _____ DOSAGE MEASURED AS AIR EQUIVALENT ☐

CHART ISSUE: _____ INTEGRATED ☐

CUSTOMER SPECIFICATIONS:					
Product identification					
Required dosage (MRads) Minimum					
Maximum (if stated)					
Required rate (MRads/hr) Minimum					
Maximum (if stated)					
Required # rotations					

PRE-RUN DETERMINATIONS:					
Estimated dose rate					
Exposure time required					

PROCESSING DATA:					
Identify batch position					
Time placed					
Date					
Time of dose rate check					
Date					
Time of rotation #1					
Date					
Time of rotation #2					
Date					
Time of rotation #3					
Date					
Time removed from position					
Date					

RADIATION STERILIZERS INCORPORATED

BATCH RUN DOSIMETER DATA SHEET

CUSTOMER: _____ RSI RUN NUMBER: _____

CHART ISSUE: _____ DATE: _____

Location	S.I.	I.O.D.	O. D	$\frac{\Delta O.D.}{S.I.}$	Mean	MRads	Read by
1							
2							
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Approved by: _____

Date: _____

1.7 Run Data Sheet:

This document shall be employed with the conveyor-processed products. All blanks providing identification, required dosage and loading information shall be completed prior to processing.

For both Data Sheets, the sensitivity index (S.I.) shall be derived from the dosimeter box cover as specified by the vendor. Initial optical density (I.O.D.) and post-irradiation optical density (O.D.) shall be read from optical density meters which are calibrated at the same time as the current batch of dosimeters. All calculations shall be initialled by the individual performing the calculations and shall be approved in writing and dated by the production manager or his designee.

The original copies of these two Data Sheets (whichever is appropriate for the type of run) shall be attached to the customer's run file. A carbon or photo copy shall be provided to the customer upon request.

1.8 Inspection Documents:

In addition to the above, documentation shall be originated with each run which demonstrates inspection and verification of count and condition at four distinct times:

a. When the product is received (number of customer's shipping containers);
b. Prior to radiation-processing the product (number of totes employed);
c. Immediately following the radiation-processing of the product (number of individual packages/boxes);
d. At the time of shipment (number of customer's shipping containers).

These documents shall be completed by the person making the inspection and approved by his direct supervisor or the traffic manager. When completed, the appropriate document(s) shall be attached to the customer's run file for review prior to issuance of the Certification of Irradiation.

1.9 Document Retention:

All copies of the above documents shall be assembled and filed according to Run Number in the RSI customer files. They shall be retained for at least five years and shall be offered to the customer prior to discarding after that time.

RADIATION STERILIZERS INCORPORATED

RUN DATA WORKSHEET

CUSTOMER: _____ DOSE REQUIRED:

RUN NUMBER: _____ Minimum: ____ MRads

DATE RUN: _____ Maximum: ____ MRads (if specified)

CHART ISSUE: _____

LOADING INFORMATION:

Time started: _____ Carrier #: _____ Total number totes: _____

Run was loaded by [ ]

All necessary dosimeters were properly placed by [ ]

All specified biological indicators were properly placed by [ ]

DOSIMETRY DATA:

Location	S.I.	I.O.D.	O.D.	$\frac{\Delta \text{ O.D.}}{\text{S.I.}}$	MRads	Read by

Approved by _____

Date _____

RADIATION STERILIZERS INCORPORATED

INCOMING MATERIAL CONTROL SHEET

CUSTOMER _____ RSI RUN NUMBER _____

TRUCK UNLOADING INFORMATION:

Date product was unloaded _____ Time received _____

Quantity unloaded _____ pallets, cartons, drums, overshippers (circle one)

Unloaded by [ ]

Customer control tag was affixed by [ ]

ACCOUNTABILITY INFORMATION:

Does your count agree with count given on customer's shipping document? Yes ___ No ___

If not, notify traffic manager or production manager immediately and prior to processing.

Did you notice any damaged products or containers? Yes ___ No ___

If yes, notify traffic manager or production manager immediately and prior to processing. Also, make note of damage on carrier's copy of customer shipping document.

Were any special processing instructions (dosage, shelf loading, return carrier) given by company carrier? Yes ___ No ___

If yes, specify _____

_____

Attach this form to RSI's copy of customer's shipping document and bring to RSI office for processing.

APPROVED BY TRAFFIC MANAGER _____

DATE _____

RADIATION STERILIZERS INCORPORATED

MATERIAL HANDLING CONTROL SHEET

RUN NUMBER _____

INCOMING COUNT _____

UNLOADING INFORMATION (to be completed by line worker)

Date run was unloaded from totes: _____ Unloaded by [ ] [ ] [ ]

Count of product unloaded: _____ cartons Counted by [ ]

Dosimeters were retieved and delivered to control room by [ ] [ ]

Pallets were wrapped according to special instructions (if any) by [ ]

Did you see any damaged product? ___ Yes ___ No

If yes, specify the number of cartons and the type of damage: _____

_____

Was Production Manager or General Manager notified? ___ Yes ___ No

Return to shift supervisor for signature.

APPROVED BY _____
Shift Supervisor

DATE _____

SHIPPING INFORMATION (to be completed by RSI person loading truck):

Date run was shipped: _____ Truck was loaded by [ ]

Count of product shipped: _____ boxes/pallets. Counted by [ ]

Check condition of pallets and cartons while loading.

Did you see any damaged products? _____ Yes _____ No

If yes, specify type _____

Was cert given to driver? _____ Yes ____ No

CARRIER INFORMATION (to be completed by driver):

Load was picked up by _____

Driver's count: _____

Driver's evaluation of load condition _____ O.K. _____ Damaged

If damaged, specify _____

RETURN TO TRAFFIC MANAGER.

APPROVED BY _____
Traffic Manager

DATE _____

1.0 Purpose:

This section describes the documentation of quality assurance which is required by RSI from its vendors of materials used in radiation-processing of products.

1.1 Scope:

The controls specified below are those which are applicable to purchases of isotope and dosimeters. These are the primary purchased items used by RSI to provide accurate delivery of gamma radiation.

1.2 Isotope Procurement:

The cobalt^{60} irradiator sources utilized by RSI shall be procured directly or indirectly from a qualified isotope supplier which either is, or is comparable to, Atomic Energy of Canada, Ltd. (AECL). The supplier shall furnish at the time of delivery a Certificate of Measurement together with AECL (or comparable) quality control specification references. Each Certificate shall be signed by a representative of the supplier's quality control department.

1.3 Dosimeter Procurement:

The radiachromic dosimeters employed by RSI shall be purchased from Far West Technology, Inc. of Goleta, California. The Far West Technology lot number, which provides traceability to an acknowledged standard, will be provided. Further, Far West Technology shall certify the accuracy of the specified Sensitivity Index (S.I.) or (R.S.)

Calibration of the Far West Technology dosimeters and dosimeter reader shall be accomplished by the calibrated irradiation services of the National Bureau of Standards (NBS). This procedure is described in RSI Operating Procedure #54.

A formal description of the Far West Technology quality assurance program shall be maintained in RSI files. Periodically, a visit shall be made to the Far West Technology facility to observe and audit the quality assurance program.

1.4 Calibration Services By National Bureau of Standards (NBS):

Whenever a new lot of dosimeters is purchased from Far West Technology, a calibration run of samples from this lot shall be performed by NBS. The calibration shall involve several groups of 10 dosimeters (see RSI Operating Procedure #54 for details.) Each group is to be irradiated and read by the NBS physicist.

The NBS readings shall be reported and irradiated dosimeters returned to RSI as quickly as possible after irradiation. The dosimeters shall be read by RSI and a curve fitting equation derived which closely aligns the NBS and RSI readings.

The NBS correspondence and subsequent RSI calculations shall be regarded as primary documents and controlled appropriately.

1.5 Record Retention:

Documentation from AECL, Far West Technology and NBS shall be retained in RSI files for a period of time which is not less than fifteen years.

Section VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

1.0 Purpose:

This section describes the measures established to identify and control the essential items used in gamma-processing.

1.1 Scope:

The controls listed below apply to source identification and dosimeter lots. These are the primary items used by RSI to process customers' products.

1.2 Isotope Identification:

Each isotope capsule shall be identified by serial number and curie content at the time of delivery by AECL or other approved vendor. The location of each isotope capsule within the RSI isotope racks shall be recorded in the Radioactive Materials License file at the time of loading. If the isotope capsule(s) are relocated at a later time, their new positions shall be recorded in a similar fashion. The form employed for these recordings shall be the RSI Source Control Sheet.

1.3 Dosimeter Lot Identification:

Lot numbers shall be assigned and identified by Far West Technology, Inc. with each shipment. Following calibration of the lot, the NBS calibration run shall be identified by the XRG-xxx number assigned by NBS. An RSI Chart Issue number shall be assigned to identify the calibrated dosimeter lot and optical density reader/bandwave. For example, Chart Issue Number 1-A-309 shall indicate (a) reader #3021; (b) 510 nm band/A; (c) calibration date of 9th month of 1983.

1.0 Purpose:

This section identifies the measures employed in processing special irradiation runs of product.

1.1 Scope:

The controls described below pertain to experimental and batch processed runs which a customer requires to be performed for:

a. Materials evaluation;
b. Dose determination/validation studies;
c. Batch processing of nuclear components;
d. Dose mapping of medical products.

1.2 Materials Evaluation:

Materials testing by the manufacturer may involve either: (a) a feasibility run, or (b) a qualification run.

A feasibility run is used to evaluate the radiation effects on a given material/product under normal run conditions. The item shall be identified with an RSI-xxxx run number and placed in an empty or partially-empty tote to be processed through the number of passes specified by the customer. No certificate will be issued although dosimeter readings may be provided verbally.

A qualification run is used to evaluate the radiation effects on a given material/product at a specified dose level. The item shall be identified with a specific customer run number and two dosimeters placed in appropriate locations. Typically, the item shall be placed in a batch location to obtain maximum control on the dose delivered. No certificate will be issued although dosimeter readings may be provided verbally.

1.3 Dose Validation:

A dose validation run may be requested by the customer to establish sub-lethal and d-values at specified dose level(s). The item(s) shall be identified with a specific customer run number and two dosimeters placed in appropriate locations. Typically, the item shall be placed in a batch location to obtain maximum dosage control. A Certification of Irradiation shall be issued to the customer.

Whenever very low dosages are requested for this type of study, RSI shall place the product in the batch area which provides the most uniform dosage. Further, consideration should be given to reading dosimeters at the 600 nm waveband.

1.4 Batch Processing of Nuclear Components:

Batch processing of nuclear components shall require specific instructions from the customer's quality assurance/control manager, project engineer or other responsible individual. Processing of the material shall be in accord with RSI Operating Procedure #42 and be undertaken only under the direct supervision of the production manager or his designee.

A Certification of Irradiation shall always be provided. Additional information, data and/or drawings may be requested and shall be provided, if specified.

1.5 Dose Mapping of Medical Products (Conveyor-processed):

Dose mapping may be requested by a customer as a part of his validation study. Dose mapping establishes the high and low dose points of a loaded tote thus producing useful information for placement of biological indicators as well as dosimeters. An RSI Dose Distribution study shall also include calculations of package and tote bulk density, max/min ratio and tote fill efficiency.

The standard dose map study shall employ 12 pairs of dosimeters which are placed to define the leading quadrant of a filled tote. Processing and dose measurements shall be performed in accordance with RSI Operating Procedure #53. A Certified Dosage Distribution Map, together with other appropriate data, shall be provided to the customer.

1.6 Document Retention:

For each of the above special processes, copies of the data and calculation work sheets shall be placed within the customer files. An additional copy of the dose map shall be provided to the production manager for retention in a special filebook. This record shall be referred to when placing dosimeters during production runs.

1.0 Purpose:

This section describes the inspection program for all activities affecting quality.

1.1 Scope:

The measures specified below are those employed by RSI/Tustin personnel to insure:

a. that count and condition of the product is maintained during the radiation process;
b. that accuracy of dosimeter readings is maintained;
c. that batch processing of nuclear safety-related components and experimental medical products is performed properly and in accord with customer-specified tolerances.

1.2 Pre-irradiation Product Handling:

Shipments of non-sterile products to RSI/Tustin must conform with 21CFR 801.150. All non-sterile products shall be handled and stored on the non-sterile side of the warehouse. Non-processed materials shall not be permitted on the sterile side until their processing is completed.

To assure product accountability, a count of product containers and an inspection of container condition shall be made by RSI personnel as the product is received. Findings shall be documented and signed off on RSI form entitled "Incoming Material Control Sheet." This form shall be reviewed and approved by the RSI traffic manager. Any discrepancies shall be noted and resolved with the customer prior to processing.

1.3 Product Loading:

At the time of tote-loading, cartons to be processed on the continuous conveyor shall be inspected for integrity. The quantity of totes involved with each customer's run shall be counted. This quantity and the number of initial carrier on which the first item of the run is placed shall be noted and signed off by the RSI person loading the run on the RSI form entitled "Run Data Worksheet". These entries shall be reviewed and approved by the production manager.

1.4 Batch Loading:

Prior to batch-processing a nuclear component or experimental medical product run, all details affecting dose delivery shall be specified on RSI form entitled "Multiple Batch Dose Determination Work Sheet." These instructions shall be reviewed and approved by the production manager prior to placing the product(s) in the radiation cell.

1.5 Dosage Calculations:

Dosimeters are employed to inspect/determine that the required dosage has been delivered. Only dosimeters which are calibrated and traceable to National Bureau of Standards shall be employed for dose measurement. Following irradiation of the customer's product, these dosimeters shall be read and radiation dose calculated by the shift supervisor. All calculations and readings shall be noted and signed off on the RSI form "Run Data Worksheet." For batch processed products, the RSI form "Batch Run Dosimeter Data Sheet" shall be employed. These data shall be reviewed, signed and dated by the production manager or his designate.

1.6 Product Unloading:

A third inspection of total container count and conditions shall be made and recorded as product is removed from the irradiation containers or from batch locations within the radiation cell. The RSI form employed shall be the "Material Handling Control Sheet." All notations shall be reviewed and signed off by the shift supervisor. Any discrepancy shall be immediately brought to the attention of the production manager or general manager for appropriate action.

1.7 Notice of Deviation:

If any of the above inspections reveal a processing deviation, a Notice of Deviation shall be completed and distributed. A processing deviation is defined as any occurrence at RSI/Tustin which could adversely affect the product's sterility, performance or appearance.

Instructions for preparing this notice and notifying the customer are described in Procedure #30 of the RSI/Tustin Procedures Manual.

1.8 Product Shipment:

Prior to product shipment, all documentation shall be assembled and where requested, a Certification of Irradiation shall be prepared. The documents shall be reviewed and the Certificate signed by the general manager (or his designate in his absence).

At the time of shipment, a final inspection and count or product shall be made by both RSI personnel and the customer's carrier to verify that all containers are as originally received. Their findings shall be noted and initialled on RSI form entitled "Material Handling Control Sheet." The completed form shall be reviewed and signed by the traffic manager.

Following shipment, all documentation for the customer's run shall be assembled and filed according to customer identification prefix and run number. These records shall be maintained for a minimum of five years.

RADIATION STERILIZERS INCORPORATED

NOTICE OF DEVIATION

COMPANY: _____ RSI RUN NUMBER: _____

ATTENTION: _____ RSI NOD NUMBER: _____

PRODUCT NAME: _____ CUSTOMER PURCHASE ORDER: _____

PRODUCT NUMBER: _____ DATE RECEIVED: _____

LOT/SERIAL NUMBER: _____ DATE IRRADIATED: _____

APPLICABLE CUSTOMER REQUIREMENTS:

DATE OF DEVIATION: _____ SUPERVISOR IN CHARGE: _____

DESCRIPTION OF DEVIATION:

CUSTOMER NOTIFIED BY: _____ DATE: _____ TIME: _____

PRODUCT DISPOSITION: Quarantine ☐ Return to customer ☐ Scrap ☐

COMMENTS/RECOMMENDATIONS:

DISTRIBUTION:
- Original to customer file
- Copies to:
  - Customer engineering
  - Customer quality control
  - RSI production manager
  - RSI general manager
  - RSI president

REPORT COMPLETED BY: _____
signature

DATE: _____

1.0 Purpose and Scope:

RSI/Tustin performs no testing of the effects of its irradiation process. Testing of radiation effects on materials and sterilization shall be performed by the customer or his designated laboratory.

The customer shall be made aware of this limitation by RSI personnel and encouraged to have testing performed by an independent resource in accordance with FDA's Good Laboratory Practices (GLP's).

1.0 Purpose:

This section describes the calibration procedures which are employed to assure accuracy of dose measurement.

1.1 Scope:

RSI/Tustin's measurement equipment is limited to dosimeter readers and cycle timer checks. RSI/Tustin performs no testing of either sterility or material effects.

1.2 Dosimeter Readers:

The dosimeter reader is, in effect, calibrated each time a lot of dosimeters are calibratedin conjunction with NBS. To provide assurance that the dosimeter's light source is performing consistantly, an optical response check shall be conducted periodically and results recorded.

The optical response check shall consist of inserting four neutral density filters, one at a time, into the appropriate receptacle in the reader. These four readings shall be recorded on the appropriate RSI form and compared with the prior reading. Readings shall be similar and with 5%. If a variation greater than 5% exists, the reader shall be immediately taken out of service and returned to its manufacturer, Far West Technology, for service and/or repair.

The optical response check shall be made on all readers in service on a routine monthly schedule. Checks should include performance at both the 510 and 600 nm wavelength (510 nm = mandatory; 600 nm = optional). Records of these monthly checks should be produced and approved by the production manager and retained for periodic reference.

1.3 Cycle Timer:

The cycle timer controls the dwell time in-between carrier movement cycles and thus has a direct effect on the dosage delivered to products processed on the continuous conveyor. Its accuracy shall be checked monthly by comparing time elasped to a separate digital timer. In effect, the cycle timer is checked continuously because time and source strength are integrated through dosimetric readings.

RADIATION STERILIZERS INCORPORATED

FWT RADIACHROMIC READER OPTICAL RESPONSE CHECK

FWT RADIACHROMIC READER:

Model Number _____

Serial Number _____

FWT NEUTRAL DENSITY FILTERS (Set #_____) at 510 nm bandwave:

Filter Identification	Prior O.D. Reading	Date of Prior Check	Current O.D. Reading	% Change
Red				
Gold				
Green				
Blue				

FWT NEUTRAL DENSITY FILTERS (Same set) at 600 nm bandwave:

Identification	Prior O.D. Reading	Date of Prior Check	Current O.D. Reading	% Change
Red				
Gold				
Green				
Blue				

Read by _____

Approved by _____

Date _____

Radiation Sterilizers Incorporated, 1401 Morgan Circle, Tustin, California 92680 / Telephone (714) 730-0611

Section XIII. HANDLING, STORAGE AND SHIPPING

1.0 Purpose:

This section defines the measures employed to insure (a) that all customer goods are handled, moved and stored in a manner which maintains lot integrity and (b) that processed and non-processed products remain physically segregated.

1.1 Scope:

These procedures shall apply to all materials to be processed, whether processed on the continuous conveyor or by the batch system.

1.2 Receiving and Staging:

Handling of newly received materials shall be performed in accord with Procedure #5 of the RSI/Tustin Procedure Manual. Product count and condition shall be verified upon receipt; discrepancies shall be resolved with the customer before further processing begins. Each customer's in-shipment shall be assigned a run number and logged into the traffic manager's log. This run number consists of (a) a three-letter code which is unique to each customer and (b) a four-digit number which indicates the year and the number of runs processed during the year (e.g. PHL3040).

An RSI run identification tag shall be prepared and affixed to the incoming lot. Incoming products shall always be considered non-sterile and staged on the non-processed side of the warehouse floor.

1.3 Storage:

Processed products shall always be stored on the processed goods section of the warehouse floor. Identification during storage shall be in accord with Procedure #20 of the RSI/Tustin Procedure Manual. The exception to this will be in storage of batch-processed materials.

Batch-processed materials, such as nuclear components, shall be stored in the Control Room until dosimetry measurements have been made and the requested dosage assured. If product/container size permits, the material will then be removed to the RSI office for storage until customer pick-up is made. If the product is too large to be stored in the office, it shall be placed in a designated control area.

1.4 Shipping:

Shipping of processed products (except for batched materials) shall be made from the processed goods shipping side of the warehouse, except under special circumstances which require the direct supervision of the production manager. All measures shall be in accord with Procedure #22 of the RSI/Tustin Procedure Manual.

When batch-processed materials are ready for shipment, the customer shall be contacted so a special pick-up can be arranged.

1.0 Purpose:

This section defines the identification systems used to identify the processing status of any run.

1.1 Scope:

These procedures shall apply to all materials being processed, whether on the continuous conveyor or by the batch system.

1.2 Identification Tag:

Once a customer's product is received and a run number assigned, an RSI Run Identification Tag bearing that number shall be affixed to the product in a visible location. If the product requires more than one pallet, a tag shall be affixed to the first and last pallet of the row.

When the product run is loaded into totes, the Run Identification Tags shall be affixed to the first and last totes designating the beginning and end of the run. When the run is processed and off-loaded from totes on to pallets, the Run Identification Tags shall be affixed to the front and back pallet of the row as long as the product is in storage.

1.3 Processing Travelers:

The material control documents provide the information required by a traveler form. The Incoming Material Control Sheet shall be used to designate the date, time and quantity of product received for a customer run. This form shall be filled out and initialed by the receiving personnel. This form shall be completed before further processing takes place.

The Run Data Worksheet shall designate (a) time a run is started; (b) the carrier number containing the first tote: and (c) the number of totes loaded with the customer's product. It shall be filled out and initialled prior to calculating the dosimetry readings.

The Material Handling Control Sheet shall be employed to designate count and condition of product as (a) unloaded from the totes; (b) loaded on to the customer's truck by RSI personnel; and (c) received by the customer's carrier on his vehicle. This form shall be completed at each stage prior to further processing.

1.4 Logs:

A production log shall be maintained in the production control room which designates the date and time each new run is begun.

Placement, rotation and retrieval of batch-processed products shall be indicated by date and time in a special log maintained in the production control room.

Section XV. NONCONFORMING MATERIALS, PARTS OR COMPONENTS

1.0 Purpose:

This section defines the measures employed to control product which has been run and does not conform to customer specifications.

1.1 Scope:

These procedures shall apply to all materials being processed, whether on the continuous conveyor or batch system.

1.2 Nonconforming Materials:

If a product run yields a dosage in excess of customer specifications or if damage exists due to improper handling, it shall be considered as being nonconforming. These are circumstances which could adversely affect the product's sterility, performance or appearance.

1.3 Notice of Deviation:

Whenever a physical count/inspection or dosimetry reading indicates a nonconforming product, a Notice of Deviation shall be prepared in accordance with Procedure #30 of the RSI/Tustin Procedure Manual. The person discovering the nonconformance shall initiate the Notice of Deviation and shall immediately inform either the production manager or the general manager who shall contact the customer as soon as possible.

1.4 Product Segregation:

If nonconformance involves one or a limited number of cartons from a run (as may occur with carton damage), the damaged sections shall be circled with red ink in a manner which will be readily recognized by the customer. These carton(s) will be stored with remaining product and arranged so that the designated carton(s) will be apparent to the customer.

If a run has received a dosage in excess of specifications, it shall be repalletized and stored in the processed goods area. A marker sign stating "STOP. This product is on HOLD" shall be placed on the front pallet of the row and/or any other position which clearly indicates its quarantined status.

1.5 Customer Notification of Quarantine:

The customer shall be notified of the product's marking or quarantine at the time he is notified of the deviation. The customer shall be given the opportunity to remove samples for testing whether the deviation is acceptable or not.

STOP!

PRODUCT ON HOLD

Section XVI. CORRECTIVE ACTION

1.0 Purpose:

This section defines the responsibility for (a) defining the cause of nonconforming product and (b) initiating and monitoring corrective action.

1.1 Scope:

These procedures shall apply to all materials processed, whether on the continuous conveyor or batch system.

1.2 Deviation Log:

The general manager shall be responsible for insuring proper distribution of the Notice of Deviation to both customer representatives and internal RSI personnel. He or the production manager shall be responsible for evaluating the situation and determining the cause of the nonconformance. The general manager and the production manager shall be responsible for evaluating the cause and establishing corrective action.

This information and these decisions shall be formally written up and filed together with the Notice of Deviation in the Deviation Log. Wherever corrective action is indicated, this and the date of its implementation shall also be specified and initialled.

The Deviation Log shall be reviewed periodically with the RSI president or designate during his visit to the facility.

1.0 Purpose:

This section defines the documentation required for each production run.

1.1 Scope:

These documents shall apply to all materials processed, whether on the continuous conveyor or batch system.

1.2 Documents:

For each run, an individual file shall be collected, filed and stored for ready access by RSI personnel, the customer's representative and, if appropriate, investigative personnel from NRC or FDA.

This file shall consist of the following documents:

a. The customer purchase order and/or instruction sheet;
b. Incoming Material Control Sheet;
c. RSI computer-generated Work Order;
d. Run Data Worksheet (for conveyor-processed products);
e. Multiple Batch Dose Determination Work Sheet and Batch Run Dosimeter Data Sheet (for batch-processed products);
f. Photocopy or carbon of Certification of Irradiation;
g. RSI copy of invoice/shipper.

For each dose distribution mapping, the additional material will be included in the customer's run file:

a. Dose Distribution and Density Data Worksheet; and
b. Photocopy of Dosage Distribution Map.

Whenever nonconformance is involved, the file shall also include a photocopy of the Notice of Deviation.

1.3 Agreement Forms:

RSI/Tustin shall attempt to obtain written agreements with each of its medical products customers which specify the obligations of both parties and references to Sections 201.150 and 801.150 of the FDA regulations (CFR Title 21). These agreements, when obtained, shall be maintained in a separate file and up-dated periodically.

1.0 Purpose:

This section defines the auditing procedures employed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness.

1.1 Scope:

These procedures shall apply to all materials processed, whether on the continuous conveyor or batch system.

1.2 Responsibility:

Periodically, the RSI president of his designate shall conduct an audit of procedures employed by RSI/Tustin to verify compliance with all aspects of the quality assurance program specified in this manual.

1.3 Contents of Audit:

The auditing individual shall draw a random sample of customer run files (at least a tote of 5 runs from 5 separate companies) and review the documents in each file for compliance with the quality assurance program. He shall specifically look for:

a. Completeness of documentation (using Section XVII for reference);
b. Accuracy of calculations;
c. Insurance that all steps have been performed and signed off.

The auditing individual shall also review the Deviation Log to insure that corrective actions have been specified and implemented. He shall also audit the summary of the last NBS calibration of dosimeters to insure that proper limits are being maintained.

Results of this audit shall be summarized and sent to the general manager with any appropriate recommendations for corrective action.

RSI INTERNAL QA AUDIT REPORT

AUDITOR: _____ DATE: _____

SYSTEM OPERATIONS

AUDIT ITEM	COMMENTS
DOSIMETER CALIBRATION	
DOSIMETER READER	
OPTICAL RESPONSE CHECK	
TIMER CHECKS	
DOSIMETER VENDOR	
NOTICE OF DEVIATIONS FILE	

SYSTEM SAFETY RELATED ITEMS

AUDIT ITEM	COMMENTS
SYSTEM SAFETY CHECK DEFICIENCIES	
METER CALIBRATIONS DEFICIENCIES	

GENERAL PLANT ITEMS

AUDIT ITEM	COMMENTS
HOUSEKEEPING	
WORK IN PROGRESS DOCUMENTATION	

EVALUATION OF RANDOM RUN FILES

RUN NO.	(CUSTOMER NAME)	COMMENTS

RSI INTERNAL QA AUDIT REPORT

AUDITOR: Bruce C. Meyer DATE: 3/23/84

SYSTEM OPERATIONS

AUDIT ITEM	COMMENTS
DOSIMETER CALIBRATION	Last NBS calibration 9/27 & 29/83 Calibration curves in use 1A309 & 2B309 dated 10/1/83. Data in order. Deficiency: dosimeter lot # missing.
DOSIMETER READER OPTICAL RESPONSE CHECK	Last check 11/30/83. Checks performed 5 times last 6 months, Data satisfactory
TIMER CHECKS	Last check 12/30/83. Checks performed 3 times last 3 months. Data satisfactory.
DOSIMETER VENDOR	Last audit 11/9/83 by W. Hall, T. Hurley and B. Fairane. Deficiency: record missing.
NOTICE OF DEVIATIONS FILE	Two items noted 1983. Corrective action taken satisfactory

SYSTEM SAFETY RELATED ITEMS

AUDIT ITEM	COMMENTS
SYSTEM SAFETY CHECK DEFICIENCIES	Last check 12/30/83. File up to date.
METER CALIBRATIONS DEFICIENCIES	Last calibration 12/4/83. File up to date.

GENERAL PLANT ITEMS

AUDIT ITEM	COMMENTS
HOUSEKEEPING	Generally satisfactory, however, more attention required to floor cleaning and hiding maintenance work in progress from visitor's view.
WORK IN PROGRESS DOCUMENTATION	Generally satisfactory, however alert personnel to need for maintenance of proper tags on staged and in-process material (two tags picked up from floor of cell while escorting visitors' tour

EVALUATION OF RANDOM RUN FILES

RUN NO. (CUSTOMER NAME)	COMMENTS
TMI-3064 (Tronomed)	Documentation satisfactory. Deficiency: no dose map on file. Corrective action being taken on next run 12/12/83.
EGS-3019 (Evergreen)	Documentation satisfactory. Deficiency: no dose map in file.
IMC-3318 (Imec)	Documentation satisfactory. Deficiency: no dose map in file.
STP-3057 (Stanpac)	Deficiency: shipping into material control sheet not completed and approved.
GLD-3007 (Gould)	Component test under 10CFR21 documentation satisfactory.
FLC-3002 (Fluid Comp)	Component test under 10CFR21 and IEEE323 documentation satisfactory