EXHIBIT_____(DC 5)

SURE-WAY SYSTEMS

QSR MANUAL

(Last Modified December 2004)

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Appendix

820.1 Scope of this Quality System Manual

Sure-Way Sharps (SWS) conducts a reusable sharps container reprocessing business which involves the emptying and reprocessing of filled sharps containers at [redacted] waste processing facility. While the disposal of regulated medical waste from these containers is regulated by the [redacted] in accordance with a [redacted] permit, the activity of returning sharps containers to service is regulated by the U.S. Food and Drug Administration (the FDA). The FDA classifies reusable sharps containers as Class II Medical Devices, which must be prepared for repeated service in accordance with Title 21 of the Code of Federal Regulations (21 CFR).

The FDA defines Sure-Way System's sharps container reprocessing work as a "remanufacturing" activity, because each cycle of container emptying, disinfection and reassembly prepares the previously used sharps container for service as if it were new and being used for the first time. As a manufacturing process, 21 CFR Part 820 requires that Sure-Way System's sharps container reprocessing activities be performed in accordance with current "good manufacturing practices" (GPM) more fully detailed under the Quality System Regulations (QSR) of Part 820 of Title 21 of the Code of Federal Regulations (CFR). to ensure that the containers are safe and effective for their intended use. Apendex I contains a complete copy of 21 CFR 820.

This manual has been developed to put in place a Quality System which meets every requirement of 21 CFR 820. For this reason, the section numbering in this manual correlates directly to the applicable subsections of 21 CFR 820. For example, this section correlates to 21 CFR 820.1.

820.3 Definitions

The following definitions are drawn from 21 CFR 820.3:

A. Quality – The totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

B. Quality System – The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

820.5 Quality System

This manual establishes and maintains the Quality System for Sure-Way System's sharps container reprocessing activities at its [redacted] plant.

820.20(a) Quality Policy

The safety of personnel and patients at client facilities depends upon Sure-Way System's supply of completely disinfected, completely durable and properly reassembled reusable sharps containers. Understanding this important responsibility, and recognizing that quality must be established as a business priority to successfully ensure the safety of the public, Sure-Way System's owners and managers fully stand behind the Quality System established and maintained by this Quality System Manual, and we require every employee of Sure-Way System's to do the same.

820.20(b) Quality System Staffing and Organization

Sure-Way System's Quality System has the following participants and top-down structure:

A. Management with Executive Responsibility – Defined as the three executive officers of Sure-Way Systems, Inc., specifically its President Gary Chilcott, Vice President Dudley Chilcott (COO). and General Manager NAME.

B. Management Representative – A member of management personally responsible for establishment and maintenance of the required Quality System. Sure-Way Systems designates General Manager NAME as the Quality System Management Representative. Regarding matters of quality, this person is one of the three managers with executive responsibility, who reports to the other two executive managers as necessary to ensure that quality remains a business priority.

C. Production Supervision – The production supervisor has the responsibility to ensure full compliance with the established Quality System and the authority to require full compliance by subordinate production personnel. For matters of quality, the production supervisor reports directly to the Management Representative.

D. Production Personnel – Individuals who directly perform tasks of container reprocessing, inspection and reassembly. These individuals report directly to the Production Supervisor.

E. Procurement Supervisor – This person has the responsibility for ensuring that all components utilized in the assembly of reusable sharps containers meet all the applicable requirements of this Quality Systems Manual. For matters of quality, the Procurement Supervisor reports directly to the Management Representative.

F. Internal Auditor – This person is independent of the production department and is assigned by the Management Representative to audit the performance of the Quality System. This person reports the results of his audit to the Management Representative.

G. External Auditor – A qualified auditor will be periodically engaged by the company to independently audit the performance of the Quality System. This person reports the results of his audit to the Management Representative.

820.20(c) Management Review

The Management Representative shall assess the suitability and effectiveness of the Quality System at quarterly intervals, in conjunction with his review of the quarterly internal audit and annual external audit reports. These Quality System reviews shall be documented on the Appendix III Audit Completion Record. The Management Representative is responsible for implementation of needed changes to the Quality System.

820.20(d) Quality Planning

Sure-Way System's Quality Plan is fully established by this manual.

820.20(e) Quality System Procedures

Sure-Way System's Quality System Procedures are fully established by this manual.

820.22 Quality Audits

Audits of the Quality System established by this manual shall be conducted at least quarterly by the Internal Auditor and at least once per year by the External Auditor. Appendix II contains the Audit Worksheet to be used by the Internal Auditor. Appendix III contains the Audit Completion Record.

Auditors shall deliver their reports, including required corrective actions, directly to the Management Representative. The Management Representative shall assign needed corrective actions and ensure their satisfactory completion.

820.25 Quality Training

Personnel other than those involved in production will be trained on their Quality System responsibilities through guided individual review of this Quality Systems Manual. The Management Representative shall conduct this training and document its completion on the Appendix IV Quality Manual Training Worksheet.

All production personnel will be responsible for in-process verification of the quality of their work. Production personnel will receive quality training as a component part of their production training, which is established in the Facility Operating Manual. As a minimum, this production training must cover awareness of device defects which may occur from the improper performance of their specific jobs. Device defects of concern include:

- Residual sharps or foreign material in sharps containers after emptying and disinfection,
- Incomplete disinfection of the emptied sharps containers.
- Inadequate structural integrity of the reprocessed components, and
- Inadequate integrity of the reassembled sharps containers.

820.3(j) Design Master Record (DMR) and Document Control

In accordance with Section 820.3(j) the Design Master Record (DMR) is the compilation of all designs, specifications, production procedures, quality assurance programs, bar code and labeling specifications, installation, and servicing methods. The master files are located at corporate headquarters and or regional office as needed. With respect to SWS, as a remanufacturer, this DMR includes the following:

- Design and material specifications for the reusable sharps containers and appurtenances.
- Design and specifications for the tipper and washer as well as other integral components of the processing system.
- All memos and detailed design drawings regarding formal modifications of either the containers, lids, or processing equipment.
- All operational procedures with respect to receiving and handling both new reusable containers as well as those delivered for processing and reuse.
- All procedures with respect to the operation and maintenance of the processing equipment.
- All specifications regarding the environmental procedures to be maintained at each processing facility.
- All procedures associated with the acceptance criteria and quality assurance.
- All labeling procedures.
- All protocols with respect to the installation of the brackets and containers within the healthcare facilities.

Under the requirements of Section 820.30 and 820.40 SWS is required to prepare, control changes to, and maintain the DMR. Any changes and modifications to the procedures, plans, specifications, or criteria need be documented.

The flow of information for modifications should be as follows:

Plant personnel
↓
Plant Operations Manager
↓
Plant General Manager
↓ ↓
COO Compliance Officer
↓
CEO Customer/Professional Review Team

All suggestions should be in written form and signed. A special review team may be formed by the CEO or COO in the event such proposed change needs further discussion. In the event a decision is made to modify the DMR, such change shall be documented with design drawings, specifications, modified procedures, or modified documentation procedures. The DMR documentation shall be subsequently modified with appropriate signatures, and should contain an effective date. It is the General Mangers responsibility to insure all plant employees receive and understand any such changes that effect them (Section 820.40(a), and shall arrange for additional training as necessary, working with the Compliance Officer.

820.30 Design Controls

21 CFR 820.30 establishes requirements for design controls to ensure the quality of medical devices. In accordance with Section 820.3(j) the Design Master Record (DMR)

Under the requirements of Section 820.30 and 820.40 SWS is required to prepare, control changes to, and maintain the DMR. To that end, any changes and modifications to the procedures, plans, specifications, or criteria need be documented. As indicated throughout this QSR, this procedure is meant to be fluid and flexible and all company employees should be made keenly aware of the intent of this effort. In this regard all customers and employees are encouraged to suggest changes which may result in a higher quality product. Such modifications will process through 820.3(j) DMR system.

820.40 Document Controls

Sure-Way System's Quality System utilizes two manuals important for product quality which require Document Controls. These controlled manuals are:

- This Quality System Manual, and
- The Facility Operating Manual

The master copy of these manuals are retained by the Management Representative. The Management Representative is responsible for updating all three facility copies of these manuals, which are located in the Regional Office and Corporate.

Changes to both documents are performed by and approved by the Management Representative, who will maintain historical records of all changes. Attachment V contains a Manual Change Record Form, on which will be documented the nature and reason for the change as well as the date of the change. The collection of the change records constitutes the Section 820.186 Quality System Record.

820.50 Purchasing Controls

The requirements of this section are related to those of Section 820.30 on Design Controls, and must be addressed simultaneously.

New sharps containers purchased by Sure-Way System for its reusable sharps container program must have successfully completed an FDA 510(k) Pre-Market Notification for that product. An order may not be placed with a sharps container manufacturer unless it has previously provided evidence of successful completion of pre-market notification, such as a letter from the FDA to the container supplier.

Additionally, new sharps containers purchased by Sure-Way Systems for its reusable sharps container program will comply with the Quality System in place and in accordance with 21 CFR 820, including a design control system which complies with 21 CFR 820.30. An order may not be placed with a sharps container manufacturer unless it has previously certified that it has a Quality System in place in accordance with 21 CFR 820, including a design control system which complies with 21 CFR 820.30.

Purchasing documents shall state that the manufacturer must have written authorization by Sure-Way Systems for any changes or alterations to its product or manufacturing process so that Sure-Way Systems may determine whether the changes may affect the quality of the finished sharps container.

820.60 Component Identification

Component identification is required from the point that each individual container or lid is selected from new stock for use. Each container or lid will receive a unique bar-code designations. The bar-code designation will include a code for the individual container, customer usage, date, processing and inspection history.

The facility operating manual requires that the bar-code be read with each container cycle, to track usage.

820.70(a) Production and Process Controls

Production processes for disinfection, inspection and reassembly of previously used and emptied sharps containers are established in the Operating Procedure contained in the Facility Operations Manual. These processes have been established to ensure that sharps containers processed for reuse meet the product specifications established in Section 820.181.

The automated container wash unit maintains proper washing cycle, water temperatures, injects detergent and other agents as necessary to ensure thorough cleaning and adequate disinfection of the sharps containers and lids.

The Operating Procedure requires that each container and lid be visually inspected for complete absence of residual material after they exit the container wash unit. Additionally, the Operating Procedure requires performance of a validation test prior to initial use of the system and a quarterly challenge test thereafter, to ensure suitable disinfection of the reusable sharps containers.

The Operating Procedure also requires that the structural integrity of each container and lid be examined for suitability prior to reassembly, and that the complete assembly be examined for integrity thereafter. Individual components must be visually inspected to ensure absence of cracks and retention of flexibility comparable to that of a new sharps container. Assembled components must be visually inspected to ensure that the lid is completely secured to the base by the locking pins.

820.70(b) Production and Process Changes

Changes to the Operating Procedure may not be performed without prior approval by the State REGULATORY BODY and may only be implemented after successful completion of challenge testing as specified in the Operating Procedure. The Management Representative will perform and approve all changes to the Operating Procedure prior to submittal to the STATE REGULATORY BODY.

820.70(c) Environmental Controls

Environmental controls are achieved through performance of all production tasks in a fully enclosed, heated building.

820.70(d) Personnel Hygiene

The Facility Operating Manual contains all necessary requirements relative to the health, cleanliness, personal practices and clothing of operating personnel.

820.70(e) Contamination Control

Contamination of finished product is prevented by control of the work flow as established by the Facility Operating Manual. Filled sharps containers are introduced to the process at the beginning of the production line, which is located in floor space designated as the RMW Staging Area. Emptied and disinfected components exit the wash process at the other end of the production line, in a clean area designated as the Container Reassembly Area.

820.70(f) Building

The STATE REGULATORY AGENCY has confirmed that our building is of suitable design and contains sufficient space to perform all necessary operations.

820.70(g) Equipment

The Tipper Unit was designed specifically for and manufactured to specifications for the reusable sharps containers and Sure-Way System's processing procedures. It has been installed in accordance with all of the institutional and manufacturer's specifications.

The container wash unit is a commercially available dishwasher, which provides the process conditions specified by Sure-Way Systems Inc and manufacturer. It has also been installed in accordance with all of the manufacturer's specifications.

Required maintenance and inspection tasks for this equipment are established in the Facility Operating Manual.

820.72 Inspection, Measuring and Test Equipment

This process uses no inspection, measuring and test equipment but does utilize microbiological indicators as discussed in Section 820.75, Process Validation.

820.75 Process Validation

The Facility Operating Manual requires performance of a validation test prior to initial use of the system and a quarterly challenge test thereafter, to ensure suitable disinfection of the reusable sharps containers. This test is performed using microbiological indicators as documented in the Facility Operating Manual and approved by the NAME OF STATE REGULATOR.

820.80(b) New Component Acceptance

Sure-Way Systems continues to develop and upgrade selection and function of reuse sharps containers to provide new containers and lids which better meet the product specifications of Section 820.181 and which are initially manufactured in accordance with a documented Quality Program. Consequently, Sure-Way Systems performs full inspection of new components upon receipt, to verify proper item count and size. No specific documentation is required upon receiving new sharps containers and lids.

However, each new container and lid will be individually inspected for suitability for service when selected from stock for introduction for use. Only containers and lids which have the necessary physical integrity will be entered into service, upon which bar-code identification will be affixed to each item. Installation of the bar-code sticker and entry of the item into the container database constitutes documentation that the new component is suitable for its intended use.

If defects in the new components are discovered upon this initial inspection, the Appendix VI Defect Notification Worksheet will be completed for action by appropriate personnel.

These criteria are as follows:

- Verification from the manufacturer that the plastic used in the construction of the container meets the SWS specifications.
- Verification by the manufacturer of any drop tests or other process testing that were performed and the results of such tests.
- Verification by the manufacturer of the dates on which the containers were manufactured.
- Visual inspection to determine that all containers were not cracked or otherwise damaged. To the extent such damage is evident the person doing this inspection should put the damaged or otherwise non compliant container of appurtenance aside and record this on the acceptance form.
- All new and accepted containers shall be stored and inventoried.

A new container acceptance form shall be completed and signed by the employee accepting these containers a form of which is attached as Appendix VI. This completed form shall be filed at the facility where the containers are received and a copy will be sent to corporate headquarters.

820.80(c) In-Process Acceptance

As established in the Standard Operating Procedure, each container and lid will be visually inspected for complete absence of sharps or visible residue upon completion of the container wash step. The appearance of foreign material requires additional processing as stated in the procedure. No documentation of in-process acceptance is necessary.

820.80(d,e) Finished Device Acceptance

Following completion of assembly of each container, the Standard Operating Procedure requires the assembler to verify the adequacy of the physical integrity of the finished assembly in accordance with the Section 820.181 product specifications. The assembler will sign and date the batch worksheet indicating his authorization for the entire batch of containers to be returned to service.

Component parts found to be unsuitable for additional use will be removed from the batch and replaced with new items in accordance with Section 820.80(b) above. Items removed from service will be held in a reject bin for subsequent removal from the database and destruction in accordance with Section 820.90(a) below.

820.86 Acceptance Status

The status of each individual container and lid which has been introduced into service will be tracked using a bar-code system and database. A component will be indicated to have one of only two possible states:

- Accepted for use and in service, or
- Rejected and destroyed

The database will track the number of cycles each accepted item has experienced to date or the number of cycles each rejected item has experienced up to the time of rejection.

820.90(a) Control of Non-Conforming Product

Non-conforming product can be identified at the points of:

- Initial inspection before introduction to use,
- Visual inspection after discharge from the container wash unit, or
- Visual inspection during final assembly.
- Visual inspection upon delivery and installation in hospital.

Components found to contain sharps upon exiting the container wash unit will be manually emptied of sharps in accordance with the Standard Operating Procedure and returned to the beginning of the work process. No documentation of this in-process rejection is necessary.

Components found to contain residual foreign material will be cleaned with a long-handled brush in accordance with the Standard Operating Procedure and returned to the beginning of the work process. No documentation of this in-process rejection is necessary. However, if this component cannot be cleaned of visible residual foreign material upon repeated cleaning efforts, it shall be placed in the reject bin.

Components which are found during final assembly to lack the necessary physical integrity to meet the Section 820.181 product specification are also placed in the reject bin.

The Appendix VI Defect Notification Worksheet shall normally be completed only for new components which fail initial inspection. Defects attributable to normal use, that is, normal wear-and-tear leading to rejection from use, do not require documentation except for the recording of the item's rejection and destruction in the bar-code database. However, Production Personnel are to initiate an Appendix VI Defect Notification Worksheet if a defect is identified in used components which cannot be attributed to normal use.

820.90(b) Non-Conformity Review and Disposition

Non-conformity review and disposition will normally be required only for components, which fail initial inspection prior to acceptance for use, indicating a supplier defect. The Appendix VI Defect Notification Worksheet triggers investigation of the non-conformity and determination of necessary corrective action in accordance with Section 820.100.

Communication of Defect Notifications and corrective actions with suppliers will be conducted by the Procurement Supervisor . The Appendix VI Defect Notification Worksheet will be used to document the non-conformity review and completion of all necessary corrective actions.

The Management Representative will be provided a copy of the Appendix VI Defect Notification Worksheet upon completion of all corrective actions.

820.100 Corrective and Preventive Action

Non-conformity reviews and customer complaint reviews will be conducted in order to determine the corrective and preventive actions needed to improve the work process and consistently deliver sharps containers which meet Section 820.181 Product Specifications.

Such reviews will be led by the Production Supervisor and Procurement Supervisor, who will include additional employees and the Management Representative at their discretion.

In cases regarding non-conformity of new components, the review will yield a specific statement of the way in which the delivered components fail to meet Section 820.181 Product Specifications.

In cases regarding customer complaints or cases in which previously used components are rejected from continued use for reasons other than normal wear-and-tear, the review shall consider the following possible causes of the defect:

- Problems with the automated Tipping Unit
- Problems with the Container Wash Unit
- Difficulties during visual inspection
- Difficulties during final assembly
- Unexpected issues during storage or transit
- Problems with containers in patient/institution rooms

The review shall determine the root cause or causes of the non-conformity, considering component supply, work processes and even the requirements of this Quality System. corrective and preventive actions shall be identified which will address each root cause, and completion of these actions shall be documented on the Appendix VI Defect Notification Worksheet or Appendix VII Customer Complaint Worksheet as appropriate.

The Management Representative is responsible for implementing all necessary changes to operating and quality procedures.

The Production Supervisor is responsible for training production personnel regarding all work procedure changes.

The Procurement Supervisor is responsible for communication of defect notifications and confirmation of necessary corrective actions with manufacturer.

The Appendix VI Defect Notification Worksheet or Appendix VII Customer Complaint Worksheet will be used to fully document the identification and completion of all corrective and preventive actions.

820.120 Device Labeling

Each container and lid will be uniquely bar-coded, with labels affixed in a designated position on the component.

"Usage labels," that is, labels containing instructions for use, are not required for sharps containers due to the obvious nature of their use. (21 CFR 801.116) Regulated labeling required by DOT, OSHA and other regulating bodies clearly identifies fill levels, UN biohazard symbols, manufacturer information, general warnings, related packaging numbers and wording is prominently placed on the front of each container. Consequently, the label control requirements of 820.120 are not applicable in this work process.

820.130 Device Packaging

Finished replacement sharps containers are stored, delivered and returned in covered rolling steel carts, to protect the integrity of the reprocessed containers. The carts are designed specifically for these sharp containers. The containers hang from their mounting lip while in the cart, this prevents containers from touching one another and eliminates rubbing and other potential damage during transit. The rolling carts also have drip treys, cross-contaminant dividers and biocide coverings to eliminate spillage and cross-contamination. The biocide covering acts as a secondary containment for filled returned containers. Additionally carts have a locking device to restrict access to the containers while in transit or storage.

820.140 Handling

Reuse Sharps containers and/or delivery carts are assigned to specific clients, based on usage and customer needs. Each cart's handling documentation process of regulated medical waste will reduce possible damage, deterioration, contamination or other adverse effects upon sharps containers during handling.

820.150 Storage

Completed sharps containers will be stored in delivery carts assigned to specific hospitals and so labeled, preventing mix-ups. Filled delivery carts will be stored in the clean supplies staging area until delivered to the client hospital, which will prevent damage, deterioration, contamination or other adverse effects upon sharps containers during storage.

Completed carts to be moved to the clean supplies staging area must first have an authorization signature from the assembler on the batch worksheet. Only the assembler who signs the worksheet may move the completed cart to the clean supplies staging area. No approval is needed to withdraw filled carts from the staging area for delivery to client hospitals, due to the scheduled rotation of such carts.

820.160 Distribution

Carts filled with reassembled sharps containers will be distributed to client hospitals as scheduled. Carts may be drawn from the clean supplies staging area without documentation, following verification that the cart contains disinfected and reassembled sharps containers as evidenced by the assembler's signature on the batch worksheet.

Each distribution technician will visually inspect the cart, contents and packaging to insure the cart is secured, containers are in good condition, appropriately documented, and the cart's secondary barrier and accessories are in place, before loading and securing cart into the distribution truck. All carts will be secured into the truck in such a way that will prevent them from rolling, tipping or unnecessarily rubbing other carts.

820.170 Installation

At the customer's discretion, sharps containers are placed on floors or countertops. Other sharps containers are mounted in pre-existing wall enclosures, utilizing a key-lock to secure contents. No specific instructions are needed for such installation due to the obvious nature of the task, beyond the need to mount wall enclosures securely and to completely close and lock the container after each container is changed out.

820.180 Record Retention

Batch worksheets shall be retained for at least two years.

Database records for each container shall be retained for at least two years after a component is removed from use and destroyed.

All completed worksheets required by this manual shall be retained at least seven years. These worksheets are:

Appendix II – Audit Worksheet
Appendix III – Audit Completion Record
Appendix IV – Quality Manual Training Worksheet
Appendix V – Manual Change Record Form
Appendix VI – Defect Notification Worksheet
Appendix VII – Customer Complaint Worksheet

820.181 Device Master Records

Due to the simplicity of the reusable sharps containers, Device Master Records as required by 21 CFR 820.181 are entirely provided in this section.

a. Standard Product Specifications

The following Standard Product Specifications are established to ensure that our clients always receive sharps containers which are safe and effective for their intended use. These specifications apply to all component parts, whether new or reused, at the points of container inspection and assembly:

- Each sharps container component, if previously used, is free of visible residual material and is properly disinfected,
- Each component part of the sharps container possesses the necessary physical integrity for use, and
- Each fully assembled sharps container is of the necessary physical integrity to ensure intactness at the customer facility and during transportation.

b. Additional Requirements for Procurement of New Components

1. New sharps containers purchased by Sure-Way Systems for its reusable sharps container program must be purchased after successfully completed an FDA 510(k) Pre-Market Notification for that product.

2. Additionally, new sharps containers purchased by Sure-Way Systems for its reusable sharps container program must be purchased with a completed Quality System in place in accordance with 21 CFR 820, including a design control system which complies with 21 CFR 820.30.

c. Components Sizes

Specified container and lid sizes are:

1 gallon
2 gallon
4 gallon
10 gallon
17 gallon

The above requirements, supplemented by other sections of the Quality Systems Manual, constitute the entirety of the Device Master Record for reusable sharps containers employed by Sure-Way Systems.

820.184 Device History Records

Device history is maintained through the bar-code database. This database will record by component part the dates in which:

- The component entered service
- The component was assembled into a finished sharps container and approved for initial or subsequent use, and
- The component was rejected and destroyed.
- The component was lost or disposed of by customer will result in a non entry, after 6 months of inactivity it will be considered lost and disposed of.

The signed batch record provides substantiation for each entry of initial or subsequent use into the bar-code database.

820.186 Quality System Records

The Quality System Record is defined and maintained in accordance with Section 820.40 above.

820.198 Complaint Files

Oral customer complaints shall be entered into Appendix VII Customer Complaint Worksheet by the person receiving the complaint. A Complaint Worksheet shall also be initiated upon receipt of written complaints, with the complaint letter attached.

Complaints will be immediately reviewed in accordance with Section 820.100 above. Necessary corrective and preventive actions shall be documented.

Every complaint will be followed up by a written or oral reply to the customer, which will be attached to or documented in the Appendix VII Customer Complaint Worksheet.

820.200 Servicing

Reusable sharps containers require no on-site maintenance or inspection servicing.

820.250 Statistical Techniques

Statistical techniques are not employed in process monitoring.

APPENDIX II – AUDIT WORKSHEET

Reference QSR 820.22

Quarterly Internal Audit Yes / No

Annual External Audit Yes / No

Name(s) of Auditor (Print):

Employer:

_____ _____

_____ _____

Audit Completion Date: _____

Audits of the Quality System shall be conducted at least quarterly by the Internal Auditor and at least once per year by the External Auditor. The audit will review the QSR Manual to establish operational and documentation compliance with existing guidelines, regulations and industrial standards. The audit will also update the Quality System (QSR) to meet new requirements.

Auditors shall deliver their reports, including required corrective actions, directly to the Management Representative. The Management Representative shall assign needed corrective actions and ensure their satisfactory completion.

Audit References Reviewed:

21 CFR 820	Y/N _____
State Agency	Y/N _____
Previous Audit	Y/N _____
Quality Manual Training Worksheet	Y/N _____
Manual Change Record Form	Y/N _____
Defect Notification Worksheet	Y/N _____
Customer Complaint Worksheet	Y/N _____
Other _____	Y/N _____

#1 List Regulatory changes required: Source: _____

QSR Section: # _____ Tile _____

Change(s); _____

_____

_____

_____ See Attachment Yes / No

Corrective Actions Needed: Responsibility:

_____ _____

_____ See Attachment Yes / No

#1 List **Internal** changes warranted: Source:_____

Change(s); _____

_____

_____

_____ See Attachment Yes / No

Corrective Actions Needed: Responsibility:

_____ _____

_____ _____

_____ See Attachment Yes / No

Signature/Date: _____ ___/___/___ Production Supervisor

_____ ___/___/___ Management Representative

APPENDIX III – AUDIT COMPLETION RECORD

Reference QSR 820.22

Quarterly Internal Audit Yes / No

Annual External Audit Yes / No

Name(s) of Auditor (Print):

Employer:

_____ _____

_____ _____

Audit Completion Date: _____

Current Standard

Section No.	Title	Change
_____	_____	_____
		_____
		_____

Upgraded Standard

Section No.	Title	Change
_____	_____	_____
		_____
		_____ See Attachment Yes / No

Other Corrective Actions Needed: **Responsibility:**

_____

_____

_____ See Attachment Yes / No

Audit Action:

QSR Manual does not require changes at this time: No Change _____

QSR Manual updated with written attachment to manual: Yes / No _____

QSR Manual requires immediate reprinting and redistribution: Yes / No _____

Signature/Date: _____ __/__/__ Production Supervisor

_____ __/__/__ Management Representative

Appendix IV

QUALITY MANUAL TRAINING WORKSHEET

SURE-WAY SYSTEMS INC.

REGION _____

Training Objective:

1. Employee demonstrates the ability to discuss and understands each section of the Quality Systems Manual.
2. Employee demonstrates the ability to reference and research sections of the Quality Systems Manual.
3. Employee demonstrated proper set up, testing, inspection and quality control procedures for standard remanufacturing procedures as outlined in the QSR.
4. Employee successfully identified defects in product line.
5. Employee has successfully filled out a sample of the Defect Notification and Customer Compliance Worksheet.
6.

The following employees have completed the Quality Manual Training Program and by signing this document attest that they have met the 'Training Objectives' list above.

Employee	Date	Supervisor Initials

Appendix V – Manual Change Record Form

820.40 Document Control and 820.186 Quality System Record

Manual Change Record Form, documents the nature and reason for the change as well as the date of the change. The collection of the change records constitutes the Quality System Record.

Sure-Way System's Quality System utilizes two manuals. These controlled manuals are: This Quality System Manual (QSR), and Facility Operating Manual. Changes to both documents are performed by and approved by the Management Representative, who will maintain historical records of all changes.

Date _____/_____/_____

Change to: (circle) QSR Facility Operating Manual

Page # _____

Section # _____

Title _____

Brief Statement:

Justification for Change:

_____

_____

_____

_____

Nature of Change:

_____

_____

Official Change:

Ref Number _____ Title _____

See Attached Yes / No _____

Change: _____

_____

_____

_____

_____

Signature/Date: _____ ___/___/___ Production Supervisor

_____ ___/___/___ Management Representative

APPENDIX VI (a) **SHIPPING & ACCETANCE REPORT**

RECEIVING REPORT

SWS - PO # _____

Vendor Order # _____

Shipping Track # _____

Transporter: _____ Date received: _____
(Attach receiving papers)

Vendor _____ Contact Name _____

Shipped From: _____ Contact No. _____

Receiving Employee (SWS): _____ Date: _____
_____ (Print): _____

____ **No Damage**
____ **Damage Report Shipping**
COMPLETE If any part of order is damaged upon arrival. Do not sign off on load until after an initial inspection. Immediately report damage and complete this section. Possibly reject damaged items or entire load as necessary.
____ Take picture of damage.
____ Driver provided damage claim form, claim contact info and SIGNED off on damage.
____ Damaged (circle) Pallet Shipping Container Box Item
Describe Damage; _____

_____

_____

Driver Signature _____ Date: _____
Provide copy to driver.
SUBMIT TO CENTRAL OFFICE. Filed in QSR 'Defect Notification Record'

Acceptance Criteria for New Containers and Appurtenances

SWS has establish acceptance criteria (Section 820.80) for newly manufactured containers/product received from the manufacturer for introduction into the supply network.

Complete as needed:

_____ Acceptance Check List

_____ Defect Notification Check List

APPENDIX VI (b)

NEW PRODUCT
DEFECT NOTIFICATION
ACCETANCE REPORT

SWS PO Number _____ **Date:** _____

New Product
These containers are in new condition and meet criteria as follows: (Adapt for equipment as needed)

Check only if it meets criteria.
ACCEPTED

- ☐ Verification from the manufacturer that the plastic used in the construction of the container meets the SWS specifications. Central Office
- ☐ Verification by the manufacturer of any drop tests or other process testing that were performed and the results of such tests. Central Office
- ☐ Properly labeled.
- ☐ All accessories and attachments are in good working condition.
- ☐ Verification by the manufacturer of the dates on which the containers were manufactured.
  - o Date _____ (Stamped on Bottom)
- ☐ Visual inspection to determine that all containers/units were not cracked or otherwise damaged.
  - o Accepted Units #_____

  Description
  - o Number of Damaged Units Set aside #_____
  - o Defect Notification Complete Yes / No
- ☐ Bar Codes added to units and logged in.
- ☐ All new and accepted containers are stored and inventory completed.
- ☐ Defect Notification Worksheet submitted.

I certify that all items have been thoroughly inspected, any not compliant units have been identified and set aside, all units that meet all criteria are certified and ready for service:

SWS Authorized Signature _____

DEFECT NOTIFICATION WORKSHEET
APPENDIX VI (c) **REPORT**

Processing: Yes / No Date: _____
New Product Yes / No

Notification Unit(s) does not meet Acceptable Criteria:
Unit(s) description and/or bar code:

Item	Bar Code/Ident#	Descript of Damage
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

____ Additional items listed on back or attached.

Cause of Damage:

_____

_____

_____

Corrective Action:

_____

_____

_____

Action Taken:

____ Units destroyed. ____ Took Corrective Action (above)
____ Units set aside for repair. ____ Re Design/Engineering Needed

Signature/Date: _____ __/__/__ SWS Technician

_____ __/__/__ Plant Manager

_____ __/__/__ General Manager

_____ __/__/__ COO

Acceptance criteria for reuse containers
SWS has established the following acceptance criteria for New and reuse/processed containers which have completed processing and following acceptance, will be reintroduced into the sharps system.

Acceptance Criteria: (Like New Condition)

- Containers shall be clean and free from all visible material.
- Containers shall be checked to insure the integrity of each container remains in tack. Which means free of cracks or other penetrations, locking mechanisms are in place, and are visibly presentable.
- Container Bar Code is attached and readable.
- Containers shall be properly assembled, inspected and packaged according to customer need.
- Containers shall be loaded into hospital/transport cart(s) with inspection label attached to include container, count, inspector name and date affixed.
- In the event a container does not meet the aforementioned acceptance criteria it shall be either reintroduce into the system for reprocessing or put aside for destruction.

These acceptance criteria shall be documented in the form of a manifest for plant manager and driver records.

Documentation and reporting is required for all new and reuse containers. Applicable copies are available from the supervisor and or QSR Appendix:

(a) Shipping & Receiving Report
(b) New Product Defect Notification Report
(c) Defect Notification Report (Re-Use Containers)

This acceptance log will be filed at the processing facility and summarized monthly this summary will be forwarded to the COO and Compliance Officer.

APPENDIX VII – CUSTOMER COMPLAINT WORKSHEET

Name Reporting Customer: _____ Date: _____
(Attach letter/email if any)
Facility _____
Address _____
Phone _____

Name Reporting Employee: _____ Date: _____
(Print):

Report of Defect Identified:

Bar-Code Number (If any): _____

Location of Defective Part: _____

Defect Description: _____

_____

Supervisory Review – Exact Non-Compliance with Product Specification:

_____

Cause of Non-Conformity:

_____

_____

_____

Corrective Actions Needed: Responsibility:

_____ _____

_____ _____

_____ _____

Signature/Date: _____ ___/___/___ Production Supervisor

_____ ___/___/___ Procurement Supervisor

Customer Reply Completed: _____ ___/___/___
(Attach letter/email if any) Title

Corrective Actions Completed:

Signature/Date: _____ ___/___/___ Production Supervisor

_____ ___/___/___ Management Representative

SURE-WAY SYSTEMS

Facility Operations Manual

(Last Modified November, 2004)

TABLE OF CONTENTS

EXHIBITS

EMPLOYEE INTRODUCTION:

The 'SURE-WAY SYSTEMS' Facility Operations Manual is based on the QSR program that provides strict regulatory and operational guidelines that must be fallowed. This manual is intended for Sure-Way Systems employees who have been assigned duties in processing, customer service and/or managing the Reusable Sharps Container System.

Your input is critical to the effectiveness of the program. Your suggestions are not only requested but demanded, your input can and will be a part of this program. This program is laid out to facilitate your input as well as others.

This ***manual is organized by subject matter*** and references section numbers of the regulating, 21 CFR 820, and specifically outlined in the Sure-Way Systems QSR manual. The ***QSR is organized by section*** number and may be used as an easy reference for this manual. You must become familiar with these regulatory guidelines to effectively perform your duties.

Appendix, Forms, Attachments are all supportive information to facilitate you in better understanding the program and EASY ACCESS to reports and forms required for your job. It also clearly outlines what the reporting process is and who you are to submit the report to.

SECTION 1
OVERVIEW OF QSR AND APPLICATION FOR SWS

Sure-Way Sharps (SWS) is in the business of installing and servicing a proprietary reusable sharps program in healthcare facilities. There are a number of regulatory compliance issues with respect to this business from a variety of local, state and federal agencies depending on location. The primary agency which regulates our business is the Food and Drug Administration (FDA). Under the FDA guidelines, SWS is classified as a "remanufacturer". SWS has its containers manufactured under the strict FDA guidelines (ref #). In addition the process SWS uses for the processing of sharps containers and the subsequent redistribution of those containers to healthcare institutions is subject to the Good Manufacturing Practices (GMP) more fully detailed under the Quality System Regulations (QSR) of Part 820 of Title 21 of the Code of Federal Regulations (CFR). This regulation covers the quality management and organization, device design, buildings, equipment, purchase and handling, production and process controls, packaging, labeling, device evaluation, distribution, installation, complaint handling, servicing and records of our business.

The regulations are quite clear in stating that SWS must follow an approved Quality Systems Manual (QSR), specifically designed for the reusable (remanufacturing) sharps container program. The program must be flexible. The primary objective of SWS and the QSR is to assure our products that we distribute to our healthcare clients meet the guidelines of their intended purpose.

The specific purpose of this manual is to provide all employees SWS's policies and procedures for the operation of our business, including our QSR plan as it effects the operation. This QSR plan should clearly identify quality standards and be fluid, in that managers and staff see ways to improve our operations to insure a quality product to our customers. Clear procedures that facilitate and encouraged any constructive input as to how such operational changes could be improved, both from a product quality and safety perspective.

This Facility Operations Manual has been designed to follow the QSR guidelines as outlined Part 820 of Title 21 of the CFR. In addition, all of the standard procedures for operations, reporting, training, and tracking complaints are included as well.

This manual should be read by all employees prior to being assigned. It is imperative that all employees understand our business and feel apart of maintaining the quality of our products.
The QSR guidelines specifically states:

> "the system is an integrated effort and total system approach to satisfy safety and performance needs of the manufacture, product and the end-user"

This manual is organized to cover the applicable QSR requirements for our operation, which are the general areas of concern in the regulations.

QSR Requirements sections are as follows:

- Quality Systems
- Process validation
- Personnel and training
- Building and environment
- Equipment and calibration
- Device Master Record
- Document and change control
- Labeling and Tracking
- Acceptance Criteria
- Product evaluation
- Storage distribution and installation
- Complaints
- QSR audit
- Facility inspections

SECTION 2
QAULITY SYSTEMS

The QSR that is put in place for the SWS proprietary sharps business has been tailored for our process extracting those portions of the QSR/GMP FDA guidelines and regulations as we believe they apply to our process and business.

The principle functions of this QSR are as follows:

- Overall management policies and directives
- Quality assurances with respect to the design and manufacture of our processing equipment.
- Quality assurances with respect to raw products and the manufacture of our proprietary sharps containers and appurtenances.
- Policies and procedures with respect to hiring personnel and training of them adequately to perform their respective jobs in a fashion to assure compliance with the QSR.
- Operational procedures and documentation for the operation of our processing equipment.
- Quality assurance policies and procedures to insure the cleaned containers comply with our standards.
- Reporting and documentation procedures to enable us to identify non compliant containers and to then determine the cause and make the necessary corrections.

The SWS corporate policy/mission with respect to our operations is as follows:

" It is the policy of SWS to strive to provide the highest quality product and quality assurance program for our products which will in turn provide the highest quality service to our customers. To that end SWS will continue to improve our training of personnel and continue to strive for improvements in our processing and delivery of our products to insure customer satisfaction and customer retention. All employees are encouraged to be a part of maintaining this standard of excellence by being ever vigilant to our overall mission and making any contribution they may deem appropriate to improve the quality of our product and our QSR system."

SWS has designated at the corporate level the position of Compliance Officer (Management Representative) whose job it is, among other things, to:

- Implement and monitor the overall QSR implementation company wide
- Provide assistance to local General Managers in documentation systems
- Oversee the development and implementation of personnel training
- Implement and monitor methodology to handle complaints from operations.
- Provide assistance to local General Managers by conducting QSR system audits.

The Compliance Officer reports directly to the COO and is an available resource to all company employees for purposes of implementing the QSR.

Modifications of Equipment/Product:
The tipper and washer have been design and manufacturing as processing equipment for SWS proprietary product line, any modification of their design or the containers or appurtenances are documented and submitted and signed off by the CEO, and the COO.

A complete file history of the manufacturing of the reusable containers is maintained at the corporate offices. Such file include all pertinent information regarding the design details, and raw materials used in the manufacturing process. As each batch of containers is ordered, the following information shall be maintained for each order:

- Date of purchase order
- Number and size of containers by lot
- Quantity of appurtenances such as lids etc.
- Specification of plastic to be used
- Location of manufacturing takes place
- Dates actual manufacturing took place
- Test results for tests conducted at the manufacturer
- Date containers or appurtenances were delivered
- Signoff and acceptance signature for person accepting order.
- Details of any inconsistencies of material received versus the specifications. Details of any containers rejected.

This product history (see new sharps container acceptance checklist form in Exhibit 1) shall be sent to the COO who shall in turn signoff on this new product form.

Records will be maintained for any modification made, to the design or specifications, in the corporate offices detailing:

- Purpose of change of design
- Who is responsible of such redesign
- Potential impacts of the operations on such modification
- A sign-off by the person responsible for the redesign or modification as well as the COO shall be included in the file.

SECTION 3
PROCESS VALIDATION

The requirement for process validation (Section 820.75) is to provide for a system that will consistently produce products which are fit for the intended use. With respect to the SWS system, this applies primarily to the process of tipping and washing the containers in our processing facility. In that regard SWS has developed a process log completed while processing takes place. The processing log is contained in Exhibit 2 herein.

The facility Plant Manager shall insure that this processing log is kept at all times when containers are being tipped and washed. To provide documentation as it relates to the operation of the proprietary tipping and washing equipment to determine if the process is operated within the designated operational parameters. This processing log will be used in the event that the quality assurance programs or complaint process, identifies an incident of non compliant product (container) as a result of the operation of the processing plant. This log will enable the COO and others to determine if any design changes to the process should be made to insure compliant product (container).

As each group of containers are processed and stacked, they are inspected and either accepted or rejected as meeting process criteria. These container logs shall be maintained for each rack of containers and shall contain the following information through a bar code system :

- Process Equipment and New sharps Container Acceptance Checklist, Bar Code log.
- Date and Time Container and Cart are Processed.
- Size and Number of Containers.
- Acceptance or rejection of container summary.
- Inspector conducting and acceptance the product.

Process personnel document the acceptance or rejection of each container and such documentation is maintained with the bar code process log. This verifies the operation of the processing equipment and validation of such throughout the run. The plant manager and process personnel attest to such documentation by affixing a signature when completed. Hard and Electronic copies of all logs shall be kept at the facility and copies of monthly operations and container logs shall be forwarded to the COO at corporate headquarters monthly. Copies of such logs shall be kept for a period of at least 3 years at both locations.

SECTION 4

PERSONNEL AND TRAINING

Section 820.25 of the regulations requires that SWS shall have personnel trained in quality awareness. To that end SWS has established hiring and training guidelines to assure that qualified personnel are hired and has establish training programs for all employees which encompass OSHA Blood Borne Pathogen regulations, safety, haz-mat criteria, process operations as well as training protocols with respect to Quality System Regulations (QSR)implementation. Contained in Exhibit 4 are copies of the various training guidelines for:"

- OSHA Blood Borne Pathogens
- Safety equipment
- SOP for tipper
- SOP for washer
- Training guidelines for the QSR

Job descriptions for all positions are contained in the SWS employee manuals and as posted at individual facilities. Each employee shall receive training prior to being incorporated into the operational staff. Additional training or refresher courses are required at regular intervals. The training intervals for each type training are outlined below: (Annual Training will be Documented)

OSHA Blood Borne Pathogen	Once per year
Haz Mat	As needed
Safety	Once per year
SOP for washer	Once per year
SOP for tipper	Once per year
SOP for processing	Once per year
QSR oversight	Once per year
Quality Control and Safety Training	Weekly

All employees shall be familiar with the handling of complaints (Section 820.198) and the procedures for handling, documenting, and forwarding such complaints to the responsible parties.

The Compliance Officer shall periodically perform internal audits, Section 820.20 and QSR Appendix VI & VII form, to assess any deficiency in the employee training protocols requiring modification. Such audits shall be coordinated with the COO to insure that such audits shall be consistent company wide. Results of audits shall be sent to the COO and copies shall be kept at corporate headquarters. To the extent there are deficiencies in training which are made apparent during the audit, a corrective action memo should be prepared (Section 820.22) and forwarded to the COO and the action to correct such deficiency should be outlined and implemented.

SECTION 5

BUILDINGS AND ENVIRONMENT

Under Section 820.70 the SWS processing facilities shall have sufficient space to allow for proper cleaning, inspection, maintenance, and other operations to meet the SWS quality criteria. All employees shall be trained in orderly operations and environmental control (Section 820.25).

The reusable sharps system's primary specifications are cleanliness, disinfection, and mechanical operation of reuse containers. The environment surrounding the processing facility shall be maintained in a clean and orderly manner, with rigorous cleanup at the end of each shift. The Operations Manager will inspect the cleanliness and environmental standards if found insufficent, corrective action shall be instituted by the General Manager.

Additional requirements with appropriate visible signage include:

- Proper attire and dressing facilities
- Controlled access into processing area
- Eating, drinking, and smoking are prohibited in processing areas.
- Maintained safe working equipment and environment.
- Weekly Safety, Quality Control Meetings

All employees shall be instructed as to the proper clothing and cleanliness standards for the facility, and enforced by the shift supervisor.

Periodic inspections shall be conducted by the General Manager, COO, and or Compliance Officer to audit the implementation of these requirements.

SECTION 6
EQUIPMENT AND CALIBRATION

Section 820.70 requires that SWS develop, conduct, control, and monitor the production process to ensure that the processed reuse containers conform to our quality standards.

To that end, all processing facilities will be subject to the following requirements:

- The tipper and washer will undergo daily and periodic checks to insure all systems are working as required.
- A maintenance schedule for the tipper and washer will be available and it will be the responsibility of the Plant Manager to perform such maintenance on individual components in accordance with the schedule or as required. All maintenance shall be documented and filed appropriately.
- Water chemicals and process water shall be checked at regular intervals by an outside consultant to insure compliance. This should be documented and should be kept on hand at the facility properly filed.
- Once per quarter, QC Confirmation tests are performed utilizing *Bacillis subtillis.* These tests are conducted by an independent outside microbiologist.

These activities will be documented and filed on site with respect to validation of the process. A monthly summary will be prepared by the Operations Manager and forwarded to the General Manager.

The Compliance Officer shall provide oversight the General Manager with respect to compliance with these requirements, and shall conduct periodic audits to insure compliance.

SECTION 7
DEVICE MASTER RECORD (DMR) AND DOCUMENT AND CHANGE CONTROL

In accordance with Section 820.3(j) the Design Master Record (DMR) is in essence the compilation of all designs, specifications, production procedures, quality assurance programs, labeling specifications, installation, and servicing methods. With respect to SWS, as a remanufacturer, this DMR includes the following:

- Design and material specifications for the reusable sharps containers and appurtenances. These files are located at corporate headquarters.
- Design and specifications for the tipper and washer as well as other integral components of the processing system. These files are located are located at corporate headquarters.
- All memos and detailed design drawings regarding formal modifications of either the containers, lids, or processing equipment. These files are also located at corporate headquarters.
- All operational procedures with respect to receiving and handling both new reusable containers as well as those delivered for processing and reuse. These procedures will be filed at both corporate headquarters and at each processing facility.
- All procedures with respect to the operation and maintenance of the processing equipment. This will be available at both the corporate headquarters as well at each processing facility.
- All specifications regarding the environmental procedures to be maintained at each processing facility. This will be available at both corporate headquarters as well at each processing facility.
- All procedures associated with the acceptance criteria and quality assurance. This will be made available at both corporate headquarters and at each processing facility.
- All labeling procedures. This will be made available at both corporate headquarters as well at each processing facility.
- All protocols with respect to the installation of the brackets and containers within the healthcare facilities. These will be made available at both the corporate headquarters as well as at each processing facility.