Exhibit JAK-22

Exhibit JAK-22

SURE-WAY SYSTEMS

QSR MANUAL

(Last Modified September 2003)

Notes:

1) Writing in postal policies from SWS

2) Complete training materials / practices

3) Training history file / employee -

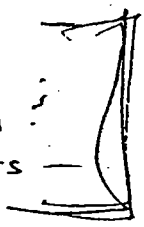
4) Design titles - schedules — Reviews - new materials - plans / specs —

5) Audit forms -

6) Job descriptions in plant -

7) Employee comments - ? Policies -

8) Signage - @ plant ?



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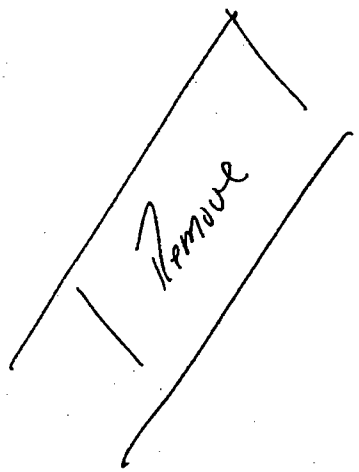
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SECTION 1
OVERVIEW OF QSR AND APPLICATION FOR SWS

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 design a system to comply with the QSR, but that system should be specifically designed for our purposes, and above all should 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 be considered fluid in that as managers as well as staff see ways to improve our operations to insure a quality product to our customers, they are encouraged to provide any constructive input as to how such operational changes could be improved, both from a product quality perspective but from a safety perspective as well.

This QSR 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. It is SWS's policy that all employees should feel they are a part of this QSR process and will be encouraged to help improve it. 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. The following 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
- 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 the SWS business which we believe are required to be governed by 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 procedures laid out herein are intended to be fluid and should be modified as needed to insure that the highest quality product results. To that end all employees are encouraged to make comments on how our procedures can be improved.

The SWS corporate policy 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 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 the methodologies to handle complaints arising from the operations.
- Provide assistance to local General Managers by conducting QSR system audits.

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

The CEO and the COO will oversee the implementation of the QSR and shall make policy and operational decisions which result from the implementation of the QSR as needed. Top management of SWS is and will continue to be dedicated to its quality policies embodied in the QSR.

The design and manufacturing of both the processing equipment (tipper and washer) as well as the containers has undergone much scrutiny to date and detailed drawings, specifications, and fabrication drawings shall be maintained at the corporate offices at all times. Any modification of the design of the processing equipment and or the containers or appurtenances shall be documented in such file and signed off by the CEO, and the COO. This includes any changes in raw materials used in the fabrication of the containers.

There shall be a detailed signoff checklist on all tippers and washers which are manufactured for SWS prior to acceptance. In addition, while this equipment is being manufactured, periodic visits shall be conducted to assure such equipment is being manufactured to our specifications.

A complete file history of the manufacturing of the reusable containers shall be maintained at the corporate offices. Such file shall 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. This shall be filed appropriately and easily accessed for future reference.

To the extent the design or specifications or design of either the containers or the processing equipment is modified, a complete record of such modification shall be maintained 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 which is written documentation of there a number of key elements of the process which are completed while processing takes place. The processing log in contained in Exhibit 2 herein.

The facility General Manager and the Operations Manager shall insure that this processing log is kept at all times when containers are being tipped and washed, so as to provide documentation as it relates to the operation of the proprietary tipping and washing equipment. This documentation is essential for the Operations Manager to determine if the process is operated at all times within the designated operational parameters, and if not, why not. This processing log will be used in the event that through the quality assurance programs or through the complaint process, a determination can be made as to whether the reason for the non compliant product (container) is as a result of the operation of the processing plant. In addition, this log will enable the COO and others to determine if any design changes to the process would be in order, to insure that a compliant product (container) results.

As each group of containers are processed and stacked, they will be inspected and either accepted or rejected as meeting process cleanliness criteria. These container logs shall be maintained for each rack of containers and shall contain the following information (see exhibit 3 for container logs) :

- Date and time rack is completed
- Number and size of containers.
- Acceptance or rejection of containers summary
- Sign off by individual conducting the acceptance inspection.

It is imperative that process personnel document the acceptance or rejection of each batch of containers and such documentation is maintained with the process log to verify the operation of the processing equipment and validation of such throughout the run. The shift supervisor and local

Operations Manager as well as the individual process personnel attest to such documentation by affixing a signature when completed. 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 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 QSR

Job descriptions for all positions are contained in the SWS employee manuals and as posted at individual facilities. It is SWS policy that all persons hired for employment shall meet and or exceed the general criteria outlined for each position. In addition, 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:

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

Such training shall be documented in the employee's file and copies shall be sent to the COO so copies can be maintained at corporate headquarters.

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) to assess any deficiency in the employee training protocols requiring modification. Such audits shall be coordinated with the COO to insure that the intervals and content of such audits shall be consistent company wide. The results of such audits shall be forwarded to the COO and copies of the documentation for such audits shall be kept at the facility as well as 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, maintenance, and other operations to in order to provide the necessary environment to enable the processing and handling of the reusable sharps container in such a manner as to meet the SWS quality criteria. All employees shall be trained in orderly operations and environmental control (Section 820.25).

Since the specifications of the SWS reusable sharps system are primarily cleanliness and disinfection, 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 regulations are less strict in this regard as compared to having to maintain sterile conditions, which we do not. A person shall be designated per shift to insure this is the case. In the event that through inspections by the local Operations Manager, these cleanliness standards are not being met, corrective action shall be instituted by the General Manager.

Additional requirements with appropriate visible signage should include:

- Proper attire and dressing facilities
- Controlled access into processing area
- Eating, drinking, and smoking shall be prohibited in the processing area.
- Maintenance of devices required to maintain safe working environment.

All employees shall be instructed as to the proper clothing and cleanliness standards for the facility, and the shift supervisor as well as the local operations manger shall enforce these standards.

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 reusable sharps 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 periodic checks to insure all systems are working as required. These inspections shall be documented by the Operations Manager and all maintenance and adjustments will be noted.
- A maintenance schedule for the tipper and washer will be available and it will be the responsibility of the Operations 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.
- A Gram positive/Gram negative testing will be conducted at least once per month on random samples of containers to verify the efficacy of the processing facilities. This procedure has been designed by an independent outside microbiologist who also conducts these monthly tests.
- 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 in a file with respect to validation of the process and such report shall available on file at the local processing facility. A monthly summary will be prepared by the Operations Manager and forwarded to the COO and Compliance Officer.

The COO and the Compliance Officer shall provide oversight to 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.

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, *which is to provide a product to our users which both meet SWS specifications of superior quality but our customer's requirements as well.* In this regard all employees are encouraged to suggest changes which may result in a higher quality product.

The flow of information for modifications should be as follows:

Plant personnel
↓
Plant Operations Manager
↓
Plant General Manager
↓ ↓
COO Compliance Officer
↓
CEO ←

All suggestions should be in written form and signed, with spaces provided to person receiving the information approving the flow of such information up the decision ladder. All changes to the QSR shall be approved in writing by the COO, Compliance officer, and the CEO. A special committee made 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. This information shall be disseminated to all affected employees in a manner that they understand and can implement. 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 such changes (Section 820.40(a), and shall arrange for additional training as necessary, working with the Compliance Officer.

SECTION 8
ACCETANCE CRITERIA

Acceptance Criteria for New Containers and Appurtenances

SWS has establish acceptance criteria (Section 820.80) for newly manufactured containers received from the manufacturer for introduction into the supply network. 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 Exhibit 1. This completed form shall be filed at the facility where the containers are received and a copy will be sent to corporate headquarters.

Acceptance criteria for processed containers

SWS has established the following acceptance criteria for processed containers which have received processing and following acceptance will be reintroduced into the sharps system:

- 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.
- Containers shall be stacked into loading racks with acceptance stickers attached there to wherein the name of the employee accepting and the date will be 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 the manifest form (see Exhibit 7) wherein the following information will be noted:

- Date
- Inspector or inspectors
- Number of containers accepted and rejected by size
- Notes with respect to reasons those containers failed to be accepted
- Signature of the inspector

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

SECTION 9
LABELING

SWS has established a labeling protocol (Section 820.120) to verify the integrity of the container for use as intended by the healthcare facility.

Each container prior to being introduced into the healthcare loop shall be labeled confirming its inspection by a plant employee and that the container meets all of the SWS criteria with respect to introduction into the healthcare facility. This label will be affixed to the container and shall contain the following information:

- Company name (SWS)
- Address and phone number
- Name of person accepting the container
- Generator name.

Date -

SECTION 10
PRODUCT EVALUATION

In accordance with Section 820.80 SWS has developed the acceptance criteria detailed in SECTION 8. To the extent containers fail to meet the criteria, such failure and possible causes are reported in the detail process log. To the extent the containers are damaged and no longer meet the specifications, they are put in a holding area and held for later destruction and the cause of such damage shall be determined. A report shall be prepared on a monthly basis (see Exhibit 5 for form) by the Operations Manager delineating:

- Number and size of containers damaged or otherwise determined to be unfit for reuse
- Delineating the damage (i.e. damaged lid locks)
- A determination of the cause of such damage
- Corrective actions, if any, suggested to minimize further damage (i.e. increased training, change of plastic recipe, modifications of the processing equipment. Etc.)

This report (Section 820.100) should outline and analyze any necessary modifications in the DMR which may be required to reduce this damage, if wastage becomes unacceptable. This report shall be provided to the COO and the Compliance Officer for the ultimate determination as to whether the DMR should be modified. Also contained in this report will be the disposition of those containers which are damaged and or unfit for use.

SECTION 11
STORAGE, DISTRIBUTION AND STORAGE

SWS has established procedures of the storage (Section 820.150), distribution (Section 820.160), and installation (Section 820.170) of the reusable containers and appurtenances.

All containers which have been accepted for use shall be stored in racks awaiting distribution to the healthcare facilities. This are shall be kept clean and loaded racks shall be staged for queuing onto the route trucks for distribution.

All distribution trucks shall be maintained in a clean and orderly fashion commensurate with the delivery of reusable sharps containers. The racks of containers shall be secured for transport so as to prevent damage enroute.

At the delivery point, in the case of dock-side service the containers shall be delivered to a healthcare representative who shall inspect the containers and either accept or reject the containers. This shall be logged on the delivery log (see Exhibit 6) with a sign off by the healthcare representative. To the extent containers are rejected, they shall be segregated and the delivery log shall note such and the containers sent back to the processing facility. Such rejected containers shall be treated in the same fashion as those rejected from the processing facility with the reasons for rejection noted and handled in the same fashion as outlined in Section 10.

In the case of full service installations, the employee placing the containers in service will reject any containers not meeting SWS acceptance criteria and such will be noted on the delivery log. Containers rejected will be treated in the same fashion as outlined in Section 10.

The SWS bracket installation procedures are contained in Exhibit 8.

SECTION 12
COMPLAINTS

SWS is required to provide for a complaint file (Section 820.198). Complaints shall be documented on the complaint form provided in Exhibit 9. As necessary, these complaint forms shall be analyzed by the Operations Manager as well as the Compliance Officer. The purpose of this analysis is to determine what modifications may be necessary to the DMR to eliminate these complaints. All complaints shall be reviewed by the Operations Manager, the General Manager, COO, and the Compliance Officer. On the complaint form, any corrective action shall be indicated and this completed complaint form shall be redistributed to the General Manager, operational personnel, and plant personnel as necessary. It is vital that those complaints contain the following information and that all plant personnel be keenly aware of the SWS quality standard and be made mindful of this entire process:

- Properly documented from an origination point (such as the healthcare facility)
- Analyzed by supervisory personnel (Operations Manager) to determine the probably source of the problem.
- Recommendation made with respect to corrective action
- Analyze any potential modifications necessary to the DMR which may alleviate the problem if necessary.

SECTION 12
QUALITY SYSTEM AUDITS

In order to insure that the QSR is being implemented and maintained in accordance with Section 820, SWS will at periodic intervals conduct audits of the QSR system at its facilities. This audit will be conducted by the Compliance Officer or an outside auditor (Section 820.22). These audits will be for internal purposes and will be used primarily to determine how the QSR system is working and if additional changes need to be made.

Featured in Exhibit 10 is the form of the QSR system audit form which will be used in the system audit. It is important that all employees understand the importance of this system audit and should be indoctrinated not only in the QSR system but the use and value of the QSR audit.

It will be up to Compliance Officer to determine how often such audits are performed. Notice of such audits may or may not involve prior notice to the General Manager or his personnel. Such audits are not meant to be, nor should they be disruptive to the operations and the Compliance Officer (or others performing such audits) should perform the audits with this in mind.

Results of these audits shall be available on file at each facility as well as in corporate headquarters. Once completed, the audits results will be distributed to the General Manger, COO, and the CEO for evaluation of any changes that may be needed to the DMR. The General Manger will be responsible for distributing the results of the audit to the local staff employees.

SECTION 13
FACILITY INSPECTIONS

FDA determines compliance with the QSR requirements by facility inspections. The general procedure is as follows:

- Upon arrival, the FDA inspector will present his/her credentials and issues a Notice of Inspections form from the FDA.
- Initial contact will be with the General Manager who will be responsible for hosting the inspection and accompany the inspector throughout the term of the inspection. In the event the General Manger is unavailable, a predesignated alternative will be selected by the General Manger.
- The inspector will have access to all applicable material and will be provided copies of documents that he/she requests.
- A predesignated inspection procedure will be made detailing how the inspection will be conducted, and will be used as a guide in showing the inspector around.
- Upon completion of the inspection, the inspector will conducts a close out meeting wherein any deficiencies will be noted on FDA form 483. At this close out meeting, the General Manager will be in attendance in that corrective actions will need to be agreed to with someone with the authority to carry such changes out.

At any time when notice is received that an FDA visit is scheduled the GM (or designee) shall notify the COO & Compliance Officer immediately of the scheduled visit. The GM shall delegate all staff as the procedures for a site tour.

EXHIBIT 1

PROCESS EQUIPMENT ACCEPTANCE CHECKLIST
NEW SHARPS CONTAINER ACCEPTANCE CHECKLIST

EXHIBIT 2

SHARPS PROCESSING LOG

DATE_____ START TIME_____
A.M. P.M.

PLANT MANAGER_____

PLANT WORKERS_____

_____

PLANT START UP CHECKLIST

[ ] Circuit Breakers
[ ] Lights On
[ ] Visual Inspection of Washers/Tipper to check and see if Washers/Tipper
were cleaned properly after last working shift.
*Were Washers/Tipper Cleaned Properly after last working shift? [ ]YES [ ] NO
[ ] Pilot Light on water heater
[ ] Temperature Knob turned to HIGH on Water heater
[ ] Instant Heater Temperature Gauge Set on 180 degrees Farenheight
[ ] Drain valves closed
[ ] Check washer chemical levels
[ ] Power on washers
[ ] Fill Washers
[ ] Tank Heat On
[ ] Test RUN Washers to check for proper operation
*Do washers seem to operating properly? [ ]YES [ ]NO
*If washer does not seem to be operating properly, stop machine and
check for possible causes.
[ ] Temperature Gauges functioning Properly
*Temperature Readings
Scrapper-_____ Power Wash-_____ Final Rinse-_____

Pots & Pan Washer-_____
[ ] Washer chemical pumps
[ ] Conveyor functions properly

[ ] Tipper Power On
[ ] Tipper conveyor functioning properly
[ ] Lid remover assembly functioning properly
[ ] Automated Tipper assembly functioning properly

* Total # of rejected containers for this shift _____
* Problems were related to _____
_____
_____
_____

* Corrective Action Taken _____
_____
_____

(over)

DATE _____ SHUT DOWN
TIME _____ A.M. P.M.

PLANT MANAGER _____

PLANT WORKERS _____
_____

PLANT SHUT DOWN CHECKLIST

[ ] Turn OFF Tank heat on washer
[ ] Power OFF Washers/ Tipper
[ ] Open Washer drain valves
[ ] Clean Tipper
[ ] Clean Washers
[ ] Remove scrapper trays from washer and empty
[ ] Remove water jet assemblys and clear of any debris
[ ] Clear Pump Intake screens of debris
[ ] Clear Water Tank and Drain area of debris
[ ] Reinstall scrapper trays
[ ] Reinstall water jet assemblies

[ ] Leave washer doors open for inspection
[ ] Sweep floor thoroughly
[ ] Mop Floor using solution of bleach/water
[ ] Rinse out mop & bucket and place back in storage area
[ ] Put hand truck and all other equipment in storage area
[ ] Turn off lights
[ ] Turn off circuit breakers

_____

_____

Signature Date

EXHIBIT 3

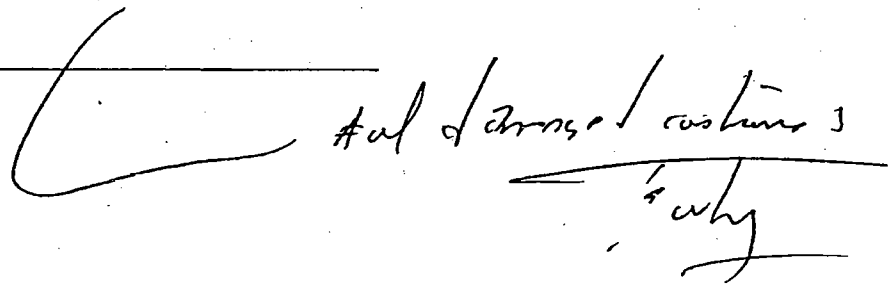
DAILY CONTAINER LOG

10 & 17 Gal. Check List

Date: _____

Containers Cleaned & Disinfected	_____
UN certification stickers on 2 sides	_____
Sharps Only stickers on all 4 sides	_____
Lids Cleaned & Disinfected	_____
Sharps Only sticker on every lid in stack	_____
Stickers are clean and legible	_____

Inspected by: _____



10 & 17 Gal. Check List

Date: _____

Containers Cleaned & Disinfected	_____
UN certification stickers on 2 sides	_____
Sharps Only stickers on all 4 sides	_____
Lids Cleaned & Disinfected	_____
Sharps Only sticker on every lid	_____
Stickers are clean and legible	_____

Inspected by: _____

10 & 17 Gal. Check List

Date: _____

Containers Cleaned & Disinfected	_____
UN certification stickers on 2 sides	_____
Sharps Only stickers on all 4 sides	_____
Lids Cleaned & Disinfected	_____
Sharps Only sticker on every lid	_____
Stickers are clean and legible	_____

Inspected by: _____

EXHIBIT 4

PERSONNEL TRAINING GUIDELINES

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

SURE-WAY SYSTEMS, INC.
SURE-WAY TRANSPORTATION, INC.
dba: SURE-WAY SHARPS DISPOSAL SERVICE
amended
OCTOBER, 1998

BIOHAZARD

In accordance with OSHA Bloodborne Pathogens standard the following exposure control plan has been developed and implemented:

PURPOSE

To establish responsibilities and procedures for the protection of personnel from bloodborne pathogens, i.e. HIV and HBV.

OBJECTIVES

A. To protect personnel from the health hazards associated with bloodborne pathogens.

B. To provide appropriate treatment and counseling should an employee be exposed to bloodborne pathogens.

C. To reduce the risk of being infected by bloodborne pathogens.

D. To comply with OSHA regulation.

DEFINITIONS

Blood means human blood, its components and products created from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause diseases in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV).

Bodily Substance Isolation, is equivalent to Universal Precautions, is an infection control system where all body substances are considered to be potentially infectious.

Cerebrospinal pertains to the brain and spinal cord.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated laundry is laundry which has been soiled with blood or other potentially infectious materials or which may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical, thermal or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles, and rendering the surface or item safe for handling, use, or disposal.

Engineering Controls means controls (i.e. sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogenic hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Gloves refers to "latex type" gloves designed to provide limited protection for existing abrasions and cuts, on the hands, during emergency operations and station/equipment cleaning, by providing a barrier against bodily fluids and disinfectants.

Handwashing Facility means an adequate supply of waterless soap or potable running water, single use towels or hot air drying machines.

HBV means Hepatitis B Virus.

HIV means Human Immunodeficiency Virus Type-1

Leakproof Bags are bags that are sufficiently sturdy to prevent tearing or breaking and can be sealed securely to prevent leakage. Such bags are red in color and/or display the universal biohazard symbol.

Occupational Exposure means reasonably anticipated exposure to skin, eye, mucous membrane, or parenterally infectious materials that may result from the performance of job related duties.

Other Potentially Infectious Materials refers to the following human body fluids: semen,

vaginal secretions, cerebrospinal fluid, pleural fluid, peritoneal fluid, pericardial fluid,

synovial fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly

contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; and

* Any unaffixed tissue or organ (other than intact skin) from a human (living or dead); and

* HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV containing culture medium or other solutions.

Parenteral refers to piercing mucous membrane or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

Pathogens refers to any disease-producing microorganism or material.

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (i.e. uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are **not** considered to be personal protective equipment (PPE).

Regulated Waste refers to liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure. Examples include, but are not limited to, hospital and clinic patients, trauma victims, clients of drug and alcohol facilities, and human remains.

Sterilize refers to the use of a physical, thermal or chemical procedure to destroy all
microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious with HIV, HBV, and other bloodborne pathogens.

Work Practice Controls are controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique, removal of contaminated clothing prior to leaving work site or as soon as feasible).

1. Exposure Determination

OSHA requires employers to perform an exposure determination to identify which employees may incur occupational exposure to blood or other potentially infectious materials. This exposure determination is made without regard to the use of personal protective equipment, (i.e. employees are considered exposed even if wearing personal protective equipment.) . This exposure determination is required to list all job classifications in which employees may be expected to incur such occupational exposure, regardless of frequency. Sure-Way Systems, Inc. considers the following job classifications in this category:

A. Plant personnel:
   a. Plant Manager
   b. Plant Operator(s) / Technicians
   c. Plant Laborer(s)
B. Transportation personnel:
   a. Transportation Manager
   b. Collection Technician(s) (drivers)
C. Sharps personnel:
   a. Sharps Manager
   b. Sharps Operator(s) / Technician(s)

2. Implementation Schedule and Methodology

OSHA also requires that this plan include a schedule and method of implementation for the various requirements of this standard. The following complies with this requirement:

Compliance Methods
Universal precautions will be observed by Sure-Way Systems, Inc. personnel, Sure-Way Sharps Disposal Service personnel, Sure-Way Transportation, Inc. personnel (hereafter referred to as "Sure-Way employees" or "personnel") to prevent contact with blood or other potentially infectious substances. All blood or other potentially infectious material will be considered infectious regardless of the perceived status of the source.

Work practice and engineering controls will be utilized to minimize and/or eliminate exposure to all personnel. Where occupational exposure remains after the institution of these controls, personal protective equipment will be utilized.

A. Handwashing and shower facilities will be made available. All employees shall wash their hands and other exposed or potentially exposed skin with soap and water or antiseptic solutions, or flush with water as soon as possible following contact with blood or other potentially infectious materials.

B. Contaminated needles and other contaminated sharps shall be placed immediately in appropriate containers for disposal.

C. Eating, drinking, smoking, applying cosmetics (to include lip balms), and contact lens handling are prohibited in areas where there is a reasonable likelihood of exposure.

D. Foods and drinks shall not be kept in trucks or in the plant where the potential of exposure is present. (this does not refer to office space, lunch or break rooms)

E. All procedures involving blood or other potentially infectious materials shall be performed in such a way as to minimize

splashing, spraying, splattering, and the generation of droplets of these substances.

F. Laundry facilities or services will be available at all work stations. All garments which are penetrated by blood shall be removed, and deposited in an appropriate container, prior to leaving work stations or as soon as feasible. All employees shall have one change of clothing at work station.

The above controls will be reviewed and updated at least annually or whenever necessary by the Managers, General Manager and involved and interested personnel in a collaborated effort between the above parties.

After removal of gloves or other personal protective equipment, employees shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water or antiseptic agents in conjunction with clean cloth/paper towels. When antiseptic hand cleansers or towelettes or waterless soaps are used, hands shall be washed with soap and running water as soon as feasible.

If exposure is incurred to skin or mucous membranes, these areas shall be washed or flushed as appropriate.

Needles

Contaminated needles and other sharps will not be bent, recapped, removed, sheared or intentionally broken. OSHA allows an exception to this if the procedure requires that the contaminated needle be recapped or removed, no other alternative is feasible and the action is required by the medical procedure. If such an action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique.

Contaminated Equipment

Equipment which has become contaminated with blood or other potentially infectious material shall be examined prior to servicing or shipping and shall be decontaminated as necessary (unless it can be demonstrated that decontamination is not feasible).

A. An appropriate biohazard warning label shall be attached to any contaminated equipment, identifying the contaminated portions.

B. Information regarding the remaining contamination shall be conveyed to all potentially impacted personnel, as well as the person(s) handling, shipping and servicing the equipment.

Warning Labels:

A. Warning labels must be affixed to containers of regulated waste containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials.

B.Labels must include the following:

BIOHAZARD

C. These labels must be fluorescent orange or orange-red or predominately so, with lettering or symbols in contrasting color. Labels must either be an integral part of the container or must be affixed as close as feasible to the container by string, wire, adhesive or other method that prevents their loss or unintentional removal. Red bags or containers may be substituted for labels.

D. Labels required for contaminated equipment must also indicate which portions of the equipment remain contaminated. Regulated waste that has been decontaminated does not need to be labeled or color-coded.

Personal Protective Equipment

Personal Protective Equipment is the employees' "last line of defense" against bloodborne pathogens. All personal protective equipment used by Sure-Way personnel shall be provided without cost to the employee. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use for the duration of time which the protective equipment will be utilized.

The following protective equipment will be made available to Sure-Way personnel:

A. Impervious gowns
B. Latex/rubber gloves
C. Particle mask
D. Eye protection
E. Rubber boots

All personal protective equipment will be removed prior to leaving the work area. All disposable personal protective gear will be placed in a red trash bag designating biomedical waste and prepared for appropriate disposal.

Gloves will be utilized during the handling of waste and or waste containers. Disposable gloves are not to be washed or decontaminated for re-use and are to be replaced as soon as feasible when their ability to act as an effective barrier is compromised, (e.g., punctured or torn).

Masks and eye shields or combination devices are required to be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can reasonably be anticipated. Disposable masks and eye shields are for single use only and shall not be washed or decontaminated for re-use and are to be replaced as soon as feasible when their ability to act as a barrier is compromised, (e.g., saturated, torn or punctured).

The OSHA standard also requires appropriate protective clothing be used, such as lab coats, gowns, aprons, clinic jacket, or similar outer garments be worn whenever potential exposure to the body is anticipated.

Contaminated work surfaces, bins, trays, container tippers, carts, pails or receptacles will be decontaminated with bleach solution and/or EPA registered germicide as soon as feasible after completion of procedures with any spill of blood or other potentially infectious materials.

Immunization

All Sure-Way personnel will be offered Hepatitis B vaccine at no cost to the employee. The vaccination series will be offered within 10 working days of initial assignment, unless the employee previously had the vaccine or wishes to submit to antibody testing which shows the employee to have sufficient immunity. Employees who decline the Hepatitis B vaccine will sign a declination statement (appendix A). Employees who initially decline the vaccine will retain the option to change their mind and have the vaccine provided at no cost.

Exposure/Contamination Procedures

The following guidelines will be followed:

A. An employee should not remain at work when ill. An employee who remains in a working capacity while ill:

a) may contaminate co-workers with whom they come in contact.

b) is more susceptible (due to their lowered immune system) to contracting communicable diseases.

B. Employees with minor wounds (open cuts, sores, breaks in the skin, etc.) should not report to their work area until they have properly dressed and bandaged the wounds.

C. Employees with extensive skin lesions or severe dermatitis on hands, arms, head, face, or neck shall not handle equipment or

waste unless the effected areas are adequately covered or protected.

Post-Exposure Evaluation and Follow-Up

When an employee incurs an exposure incident during the performance of their job, it will be immediately reported to their immediate supervisor and they must be seen at a medical facility. The exposure will be carefully and accurately documented on the Infectious Exposure Form (Appendix B).

Any exposure contamination or contraction of an infectious disease that occurs off the job shall be reported to their supervisor. This information will remain a confidential part of the employees' medical records.

All employees who incur an exposure incident will be offered post-exposure evaluation and follow-up in accordance with the OSHA standard.

This follow-up will include the following:

*Documentation of the route of exposure and the circumstances related to the incident (Infectious Exposure Form).

*Completion of the State Workers Comp. Report Form by affected personnel.

*If possible, the identification of the source and its status.

*Results of testing of the source will be made available to the exposed employee.

*The employee will be offered the option of having their blood collected for testing of his or her HIV/HBV serological status. The blood sample will be preserved for up to 90 days to allow the employee to decide if the blood should be tested for HIV serological status. However, if the employee decides prior to that time that testing will or will not be conducted, then the appropriate action can be taken and the blood sample discarded.

*The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service and recommendations from the consulting physician.

*The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will also be given information on what potential illnesses to be alert for and to report any related experiences to appropriate personnel.

The following person(s) will assure that the policy outlined here is implemented and will maintain records pursuant to this policy:

A. General Manager / Personnel Director
B. Plant Manager
C. Sharps Manager
D. Transportation Manager
E. Personnel File Clerk

A written opinion shall be obtained from the health care professional who evaluated the employee. Written opinions will be obtained in the following instances:

A. whether Hepatitis B vaccination is indicated for the employee;

B. whether the employee has received the Hepatitis B vaccination;

C. whenever the employee is sent to a health care professional following an exposure incident;

D. confirmation that the employee has been told about any medical conditions resulting from the exposure incident which require further evaluation or treatment.

Health care professionals shall be instructed to limit their opinions to:

A. whether the Hepatitis B vaccine is indicated and if the employee has received the vaccine or for evaluation following an incident;

B. whether the employee has been informed of the results of the evaluation; and

C. whether the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials.

Medical Record Keeping

Managers are responsible for implementation and maintenance of pertinent medical records of their employees. These records will include the following:

A. name of employee

B. social security number of employee

C. copies of the employee's Hepatitis B vaccination status
   a) date of any vaccinations
   b) medical records relative to the employee's ability to receive vaccination

D. copies of the results of the examinations, medical testing and follow-up procedures which took place as a result of an exposure

E. copies of information provided to the consulting healthcare professional as a result of any exposure to bloodborne pathogens

As with all information in these areas, it is the responsibility of the manager/supervisor to maintain the confidentiality of these records. There will be no disclosure of this information without the employee's written consent (except as required by law). The company shall maintain employee medical records in accordance with law.

Training

Training for all personnel will be conducted prior to initial assignment of tasks where occupational exposure may occur. Training will include the following:

A. The OSHA standard for bloodborne pathogens
B. Epidemiology and symptomology of bloodborne diseases
C. Modes of transmission of bloodborne pathogens
D. Explanation of this Exposure Control Plan, (i.e. points of the plan, lines of responsibility, how the plan will be implemented, etc.)
E. Procedures which might cause exposure to blood or other potentially infectious materials

F. Control methods which will be used to control exposure to blood or other potentially infectious materials:
   a) Engineering controls
   b) Work practice controls
   c) Personal protective equipment
G. Personal protective equipment available for emergency personnel
   a) Location(s)
   b) Application
   c) Removal
   d) Disposal
H. Post exposure evaluation and follow-up
I. Signs and labels utilized in system
J. Hepatitis B vaccination program
   a) No cost program
   b) Method of administration
   c) Benefits of vaccination

All training records required by the OSHA standard will be maintained by the manager and stored in the Sure-Way Systems central office (or archives) for a period of three years from the date on which training occurred.

Dates

All provisions required by the standard will be implemented by the manager of each region/division or his/her representative. They will be responsible for scheduling training for their personnel.

All employees will receive annual refresher training.

Training materials will be made available for personnel by the company.

APPENDIX A

Employee's Name: _____ **Date:** _____

Address:

_____

Home Phone: _____ **S.S./Employee ID #**_____

Hepatitis B Vaccine Declination

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to m4e.
(FR Doc. 91-28886 Filed 12-2-91; 8:45 am)

Declining Employee's Signature:

_____

Witness:_____

Date: _____

Date to review decision again: _____

APPENDIX B

Sure-Way
INFECTIOUS EXPOSURE FORM

Exposed employee's name:_____
Title:_____

Social security #:_____ Employee #:_____ Home phone:_____

Source:_____
_____

Location of exposure:_____
_____

Suspected or confirmed disease:_____
_____

Type of exposure:_____

Date of exposure:_____ Time of exposure:_____a.m. / p.m..

What were you exposed to?:

_____

What parts of your body became exposed? Be specific:_____

_____

Did you have any open cuts, sores, or rashes that became exposed? Be specific:_____

_____

How did the exposure occur? Be specific:_____

_____

_____
_____
_____
_____
_____
_____

Did you seek medical attention? Yes No

Where?_____Date:_____
_____

Supervisor notified Yes No
Date:_____ Time:_____ am / pm

Supervisor's
signature:_____Date:
_____

Your
signature:_____
_____Date:_____

Sure-Way
Bloodborne Pathogen Exposure Control Plan

Training recognition / confirmation

Date(s) of training: _____

Employee's
name:_____
Title:_____

Address:_____
City:_____ State:_____ Zip: _____

Social security #:_____ Home phone:_____

I received training specific to the Sure-Way Bloodborne Exposure Control Plan on the date above. I agree to utilize the precautions as indicated.

Instructor's signature:_____Date: _____

Employee's signature:_____ _____Date:_____

Standard Operating Instructions
Sure-Way Systems Model 1999 Manual Tipper

Start-up

1. Inspect the tipper, look for loose or poorly operating components.
2. Inspect the tipper area to see that it is clean and clear of any waste or debris.
3. Dry Run, place an empty flight bar into the feed tray and push it back into the flipper arm and proceed to flip the flight bar. Watching for proper operations without stress and smooth transfer onto conveyor.
4. Start conveyor if applicable and watch for easy transfer into washer feed tray.
5. When all systems check out start processing.

Operation

1. Make sure all operators have on proper PPE.
2. Place the flight bar on the loading platform with the locking mechanism up and on the right.
3. Place containers in each of the openings in the flight bar, locking pins are to the left.
4. Lock the containers into the flight bar.
5. Remove the locking pins and the final closure pins. Place the pins in a disinfectant solution bucket for later reuse.
6. Open each container final closure lid and inspect to see that the container is not overfilled.
    a. If it is remove it and follow company procedures.
    b. If properly filled it can be safely dumped, close lid.
7. Double check to see that all the containers are securely locked in and push the loaded flight bar onto the tipper launching platform.

8. **Stand clear of tipper crank in case it slips, firmly grasp the crank and rotate it until the flight bar drops free of flipper.**
9. **Set a fresh flight bar up for loading and repeat the process.**

Sure-Way Sharps Containers
Sharps Processing
Safety Provisions and Operations Instructions

1. Plant Start-Up

1.1 Pre-Start Inspection

Prior to commencing shift operations, visually inspect all equipment to determine that it is functional and that there are no defects or damage.

1.2 Tipper Power-On

Activate tipper power by turning key to power on. Be sure the emergency stop buttons are pulled to the up position.

1.3 Washer-On

Activate the washer by placing the "Power" and "Motor" switches in the "on" position.

1.4 Test Cycle Tipper

Run the tipper through one cycle to make sure it is operating correctly.

1.5 Test Automatic Washer

Run an empty flight bar through the washer and note the speed of the belt to make sure it has 15 seconds of rinse and 3 minutes in the wash cycle. Note the activation of the wash cycle chemical pump during the wash cycle and make sure you have an adequate supply of washer chemicals for your shift check the PH in the wash water. FDA rules allow for either 3minutes of dwell time in the wash cycle or 15 seconds at 180° Sure-Way will do one or the other.

1.6 Check The Wash and Rinse Water Temperatures

The inflow to the rinse should be at least 180° F and the wash water should be 120° F. The rinse will only be one 180° if Sure-Way chooses to use less than 3 minutes in the wash cycle.

1.7 Position Cart

Position the full and empty carts at the designated locations prior to start up.

1.8 Miscellaneous

- Check the inventory of spare pins and the pin puller

- Check to see that the floor and machines are clear of any waste residue

2. Protective Equipment

2.1 Goggles (Optional)

Inspect and clean goggles to assure that they fit properly to the face and that visibility is good.

2.2 Clothing

Wear company provided coveralls and water resistant apron from your locker or the locker room supply cabinet. Inspect to ensure cleanliness and integrity of the material.

2.3 Gloves

Use clean pairs of gloves from the locker room supply cabinet. Make sure that there is a new separate pair of clean gloves on the clean side of the washer. Dirty side gloves should never be placed with clean side gloves. Change gloves as they become worn or if they leak.

3. Training

3.1 Sharps Training Supplemental to Existing Worker Training Program

All sharps processing operators will require completion of the basic SWS training program as well as the Sure-Way sharps training described in this section with in the first month..

The additional 8 hours training will consist of:

- Proper use of personal protective gear (PPE).
- Safe operation and hazard recognition of the electrical and mechanical equipment.
- Proper handling for misplaced sharps and procedures to be used should a needle stick occur.
- Understanding of the construction and function of the various machines and tools used in the operation of the sharps operation.

- Troubleshooting common problems that can occur in the coarse of plant operation.
- Quarterly safety meetings to discuss safety issues that are noted by the plant safety coordinator.

4. General

A number of functions of the sharps processing plant will require close periodic monitoring and reorientation in order to demonstrate and document consistent compliance with the sharps processing requirements to ensure consistent satisfaction of disinfection and public health criteria. The following operation components will be monitored as follows:

- Wash temperature 120° F minimum.
- Rinse temperature 180° F minimum.
- Constant monitoring of the temperatures in the 2 cycles by the operator and logged daily.
- Wash water changed every 8 hours of operation or more often as the operator deems necessary.
- Monitoring of the chemical tanks to ensure adequate supply and proper pump operation.

5. Operations Sequence

1. Dress in the appropriate personal protective equipment.
2. Read the previous shift report.
3. Do the pre-check on the equipment.
4. Start the washer to get the temperature up.
5. Receive loaded transport carts at the loading dock.
6. Move the cart to the staging area for processing.
7. Remove the safety pins on the sharps containers.
8. Place the sharps containers in the flightbar of the tipper.
9. Activate the tipper.
10. Check to see that the flightbar and the containers are tipped properly and moving down the belt to the washer.
11. The operator will redo steps 7-9 until the cart is empty.
12. The empty transport cart will be taken to the transport cart washout area and will be chemically washed and inspected for cleanliness.
13. The inspected and cleaned transport cart will then be ready to be reloaded.

6. Reassemble and Inspection Operator

1. Dress in the appropriate personal protective gear.
2. Read the previous shifts shift report.
3. Wipe down the exit table with disinfectant and inspect area for adequate supplies.
4. Constantly monitor water cleanliness, temperature, and chemical flow.
5. Remove the washed containers as they come out of the washer and allow them to dry.
6. Inspect them for cleanliness; if they are dirty, recycle them through the washer. Inspect for structural integrity; if they are structurally damaged, place them in the recycle bin.
7. The clean container will have the washed lid placed on it and the security pin installed.
8. The reassembled container will be placed in the cleaned transport cart.
9. When the transport cart is full it is ready for its trip back to the health care facility.
10. The transport cart is taken to the clean room for storage until it goes back to the health care facility.

Washer Operation & Container Reassembly

Start-up Procedure

1. Personal Protective Equipment, make sure you have on water resistant footwear, rubber gloves and safety glasses.
2. Check water leveling the wash tank and check that there is adequate detergent and sanitizing agents in the containers feeding the automated chemical dispenser.
3. Change out the wash waster after 8 hours of operation or when considered dirty by the operator, which ever comes first.
4. Check the pre-heater for the rinse line to see that it is to the 180 degree temperature prior to starting and that it will maintain that temperature
5. Check conveyor to see that it is clean and not stressed.
6. Check the spray nozzles, push the pump on button and see that they are clear and that the spray is working properly.
    - If not check the water level in the tank
    - Make sure the level of the water covers the impeller .
    - See that the screen over the intake is clean
    - Make sure the pump is on by looking at the fan spinning on the top of the pump
7. Clean area around the washer is clean and clear of trip hazards pay particular attention to the transit area between the tipper and washer
8. Inspect to see that the screens are clean before refilling the wash tank and use proper procedures in removing the contents of the screens and screen buckets.
9. Refill with water through the automated chemical dispenser after wash tank is clean and test chemical concentrations levels in the water to see that they are satisfactory.
10. PreHeat Water, start heaters 1 hours before you expect to operate.

11. Start operation when the wash is above 120 on the wash side and the rinse is at 180 or base temperature for sanitization.

Wash Procedure

12. Dirty emptied sharps containers in the transport trays along with the lids all up-side-down, enter the washer where it is picked up by the conveyor system.
13. At the washer out feed table, after the container has been sanitized, the detailer takes the washed containers and inspects them for debris and cleanliness. If necessary they are hand washed with a chlorine based sanitizer only after a through inspection is made for sharps are trapped in the container that could cause injury.
    - If trapped sharps are found specialized tools are used to remove the sharp. The sharp removed and sent out for proper disposal.
14. Once the container passed the detailers inspection it is reassembled and placed in a transport cart for redistribution back to the health care facilities.
15. Periodically random sharps containers are pulled form the transport carts after detailing and sent to a lab for sanitization testing utilizing gram positive and gram negative testing for specific known pathogens.
16. Chemical levels, feed systems and quality controls will be checked by our chemical treatment service provider on a scheduled basis. Not intended to take the place of the sanitization test.
17. Operator will closely monitor water temperature.

EXHIBIT 5
DAMAGED CONTAINER REPORT

Exhibit Nine
Damage / Condition
Report Form

How to use
the Kmart receipt @
dock as a result
of # of cartons –
signed off by
someone that they
were good to
go – ~~where~~
Accepted!

EXHIBIT 6
CONTAINER DELIVERY LOGS

(page break)

EXHIBIT 8
BRACKET INSTALLATION PROCEDURES

[are there written
procedures –
need –]

Sure-Way Systems, Inc.
Container Installation Order

FACILITY_____ DATE ORDERED_____

ORDERED BY_____

DEPARTMENT_____

DEPARTMENT CONTACT / DIRECTOR_____

INSTALLATION DATE_____

SURE-WAY INSTALLATION TECHNICIAN_____

_____ # of new container locations _____ container size

_____ # of new container locations _____ container size

_____ # of new container locations _____ container size

_____ # of new container locations _____ container size

_____ # of new container locations _____ container size

_____ **TOTAL # OF LOCATIONS INSTALLED**

_____ **PRICE PER LOCATION**

_____ **TOTAL ADDITIONAL MONTHLY COST TO THE FACILITY**

Authorized By:

_____
Printed Name Title

_____
Signature Date

Authorized Sure-Way Representative:

_____
Printed Name Title

_____

Signature Date

_____FAXED TO MONTANA _____DATE

EXHIBIT 9
COMPLAINT FORM

Date:_____ Time:_____

Hospital:_____

Department:_____

Caller:_____
First Last

Phone #:_____

Complaint
/Concern:_____
_____
_____
_____

Action
Taken:_____
_____
_____
_____

EXHIBIT 10

QSR AUDIT FORM

EXHIBIT 7
GENERATOR MANIFEST

Sure-Way Systems, Inc. 813-716-1770 **MANIFEST #**
13200 58th Street North Regulated Medical Waste 6.2
Clearwater, Fl. 33760
***In Case of Accident 24 hour emergency response # 1-800-226-0911**

CUSTOMER / GENERATOR INFORMATION:

*** DELIVERY DESCRIPTION OF CLEAN CONTAINERS ***

_____Cart - 2 gallon
_____Cart - 4 gallon
_____1 gallon sharps containers---------- Total # of containers_____
_____2 gallon sharps containers---------- Total # of containers_____
_____4 gallon sharps containers---------- Total # of containers_____
_____10 gallon grey sharps containers---------- Total # of containers_____
_____10 gallon red sharps containers---------- Total # of containers_____
_____17 gallon grey sharps containers---------- Total # of containers_____
_____17 gallon red sharps containers---------- Total # of containers_____

*** PICK UP DESCRIPTION *** **Gallons**

_____Cart - 2 gallon
_____Cart - 4 gallon
_____1 gallon sharps containers---------- Total # of containers_____ _____
_____2 gallon sharps containers---------- Total # of containers_____ _____
_____4 gallon sharps containers---------- Total # of containers_____ _____
_____10 gallon grey sharps containers---------- Total # of containers_____ _____
_____10 gallon red sharps containers---------- Total # of containers_____ _____
_____17 gallon grey sharps containers---------- Total # of containers_____ _____
_____17 gallon red sharps containers---------- Total # of containers_____ _____

Notes:

TOTAL GALLONS PICKED UP _____

"This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation."

_____ _____ ___/___/_____
Generator Signature Print Name Date

TRANSPORTER INFORMATION:
Sure-Way Systems, Inc. Transporter Registration # **7355**
13200 58th Street North
Clearwater, Fl. 33760 (813) 716-1770 Fax (727) 532-0122
I certify receipt of the above:

_____ _____ ___/___/_____
Driver Signature Print Name Date

DESTINATION TREATMENT FACILITY:
Medico Environmental Services, Inc. Permit # 1030210-003AV
13200 58th Street North
Clearwater, Florida 33760 (727) 532-0099 Fax (727) 532-0122
I certify receipt of the above:

_____ _____ ___/___/_____
Receiving Signature Print Name Date

CERTIFICATE OF DESTRUCTION PROVIDED ON INVOICE

WHITE - **Sure-Way** YELLOW - **Sure-Way** PINK - **CUSTOMER**

Employee manual – ✓

Job Descriptions – ✓

Training –

Timing –

Workers –