Exhibit JAK-1T

BEFORE THE WASHINGTON STATE
UTILITIES AND TRANSPORTATION COMMISSION

In Re Application of No. GA-079331 of SURE-WAY SYSTEMS, INC. For A Certificate of Public Convenience and Necessity to Operate Motor Vehicles in Furnishing Solid Waste Collection Service	DOCKET NO. TG-042089 **PREFILED TESTIMONY OF JENNIFER A. KREBS**

Jennifer A. Krebs, subject to penalties of perjury of the laws of the State of Washington, declares as follows:

1. I am one of the attorneys working on this matter on behalf of Protestant Stericycle of Washington, Inc. ("Stericycle").

2. As part of Stericycle's efforts to investigate the regulatory fitness of Sure-Way Systems, Inc., our office sent out requests for public records to a number of state and federal agencies. I supervised receipt and collection of the information we received from these agencies. I also conducted Internet searches for public records regarding Sure-Way Systems, Inc. I am also familiar with Sure-Way's responses to Stericycle's data requests in this matter.

GARVEY SCHUBERT BARER
A PARTNERSHIP OF PROFESSIONAL CORPORATIONS
eighteenth floor
1191 second avenue
seattle, washington 98101-2939
206 464-3939

3. On January 26, 2005, our office requested public records from the Food and Drug Administration ("FDA") regarding Sure-Way Systems, Inc. The following items were received by our office from FDA in response to this request:

a. An FDA Establishment Inspection Report issued to Sure-Way Systems, Inc. for an inspection on January 10, 13 & 14, 2000. This Report was redacted by the FDA. A true and correct copy of this report, as redacted by the FDA, is attached hereto as Exhibit JAK-2.

b. A 510(k) clearance letter, issued to Sure-Way Systems, Inc. by the FDA, dated December 16, 1999. A true and correct copy of this letter is attached hereto as Exhibit JAK-3.

c. An FDA Warning Letter issued to Sure-Way Systems, Inc. on February 22, 2000. A true and correct copy of this letter is attached hereto as Exhibit JAK-4.

d. Sure-Way Systems, Inc.'s "Response to FDA 483 Inspection Memorandum," dated February 28, 2000. A true and correct copy of this response, as redacted by the FDA, is attached hereto as Exhibit JAK-5.

4. On March 10, 2005, our office requested public records from the State of Montana Department of Environmental Quality ("DEQ") regarding Sure-Way Systems, Inc. The following items were received by our office:

a. A violation letter dated August 10, 1999 issued by DEQ to Sure-Way Systems of Montana. A true and correct copy of this letter is attached hereto as Exhibit JAK-6.

b. A memorandum to DEQ, dated December 4, 2000, from Gary Chilcott describing the Sure-Way Systems sharps disposal system as "FDA approved." A true and correct copy of this memorandum is attached hereto as Exhibit JAK-7.

5. On March 10, 2005, our office requested public records from the State of North Dakota Department of Health ("DoH") regarding Sure-Way Systems, Inc. The following items were received from DOH by our office:

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a. A letter to Sure-Way Systems, Inc. from DoH, dated April 5, 2002, related to improper waste disposal and enclosing an interoffice memorandum. True and correct copies of this letter and the enclosed memorandum are attached hereto as Exhibit JAK-8.

b. A DoH interdepartmental memorandum dated January 11, 2001, describing recent enforcement actions taken against Sure-Way Systems, Inc. A true and correct copy of this memo is attached hereto as Exhibit JAK-9.

6. On April 12, 2005, our office requested public records from the Occupational Safety and Health Administration ("OSHA") in Washington, D.C. regarding Sure-Way Systems, Inc. The following items were received from DOH by our office:

a. An OSHA Citation and Notification of Penalty issued to Sure-Way dated January 8, 2001. A true and correct copy of this Citation and Notification of Penalty is attached hereto as Exhibit JAK-10.

b. A letter from Dudley Chilcott of Sure-Way Systems, Inc. to Bruce Beelman of OSHA in response to the Citation and Notification of Penalty, dated January 22, 2001. A true and correct copy of this letter is attached hereto as Exhibit JAK-11.

7. In July 2005, I visited the FDA website and conducted searches for public documents related to Sure-Way Systems, Inc. and the processing of reusable sharps containers. True and correct copies of documents that are available on-line from the FDA website are attached hereto, as follows.

a. Four printouts of information from the FDA's establishment registration database are attached hereto as Exhibit JAK-12. This information can be found by visiting the FDA's establishment registration database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/Registration.cfm and entering "Sure-Way Systems" into the "Establishment Name" field.

b. A printout of information from the FDA's medical device listing database is attached hereto as Exhibit JAK-13. This information can be found by visiting the FDA's

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medical device listing database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm and entering "Sure-Way Systems" into the "Owner/Operator Name" field.

c. One printout of information from the FDA's 510(k) Premarket Notification database is attached hereto as Exhibit JAK-14. This file can be found by visiting the FDA's 510(k) database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm and entering "Sure-Way Systems" into the "Applicant Name" field.

d. Two FDA warning letters issued to Safety Disposal System, Inc., a processor of reusable sharps containers, are attached hereto as Exhibit JAK-15. These letters can be found by visiting the FDA's Warning Letters Archive at http://www.accessdata.fda.gov/scripts/wlcfm/company_archive.cfm?FL=S.

8. Exhibit JAK-16 is Sure-Way's initial Premarket Notification submission to the FDA dated August 1999 (without attachments) provided to our office in response to our data requests under cover of letter from Sure-Way's counsel, dated June 1, 2005. A copy of that letter is included in the exhibit.

9. Exhibit JAK-17 is a copy of the Sure-Way Sharps Disposal Service Contract provided to our office by Sure-Way in response to our data requests in this proceeding.

10. Exhibit JAK-18 is a copy of an exchange of correspondence between counsel for Sure-Way (dated June 15, 2005) and counsel for Stericycle (dated June 13, 2005) addressing Sure-Way's failure to file its 2003 federal income tax return.

11. Exhibit JAK-19 is a copy of an exchange of correspondence between counsel for Stericycle (dated July 8, 2005) and counsel for Sure-Way (dated July 15, 2005) with respect to Stericycle's request for copies of documents to evidence Sure-Way's compliance with its QSR Manuals and related FDA regulations.

12. Exhibit JAK-20 is a copy of an exchange of correspondence between counsel for Stericycle (dated June 13, 2005) and counsel for Sure-Way (dated June 14, 2005) related to

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Stericycle's request for documents to evidence Sure-Way's compliance with the FDA's registration and listing requirements and Sure-Way's response to Stericycle's requests.

13. Exhibit JAK-21 is copies of the following documents: a letter from the State of North Dakota Office of Attorney General, dated November 14, 2001; a complaint from the Southeast Judicial District of North Dakota, captioned State of North Dakota, State Department of Health v. Sure-Way Systems, Inc.; a Consent Agreement signed by the Chief of the State of North Dakota Environmental Health Section and an "Agent" of Sure-Way Systems, Inc., believed to be Dudley Chilcott, and an Order for Judgment. These documents were provided by Sure-Way Systems, Inc. in responses to Stericycle's Supplemental Data Requests.

14. Exhibit JAK-22 is a copy of a Sure-Way Systems QSR Manual, last modified September 2003, provided by Sure-Way Systems, Inc. in responses to Stericycle's Supplemental Data Requests.

DATED this 18th day of July, 2005, at Seattle, Washington.

Jennifer A. Krebs

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Exhibit JAK-2

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ESTABLISHMENT INSPECTION REPORT

Sure-Way Systems, Inc.
310 E. Harry Bridges Blvd.
Wilmington, CA 90744
FEI: 3002911426
1/10, 13 & 14/2000 KC (924)

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SUMMARY OF FINDINGS:

This was a directed Quality System (QS) inspection of a small Class II medical device manufacturer and reprocessor of reusable sharps containers per assignment 000393 from Division of Enforcement II, Office of Compliance, CDRH, HFZ-333. The sharps containers manufactured and reprocessed by the firm are not subject to Medical Device Tracking regulations. This inspection was conducted in accordance with the Compliance Program 7382.845 – Inspection of Medical Devices. Medical Device Profile Class – PRF was covered.

This initial inspection of Sure-Way Systems, Inc. focused on the cleaning of reusable sharps containers that are returned by hospitals or laboratories after use. The inspection revealed the firm was not operating in a state of control for the reprocessing operation of sharps containers. Objectionable conditions noted on the Inspectional Observations, FDA 483, included:

1) No quality policy, quality plan and quality audit procedures;
2) No validation study for the sharps container cleaning process;
3) No written procedures for design control, change controls, cleaning process, complaints and MDRs;
4) No written acceptance criteria for incoming and finished products; and
5) No Device History Records.

A twelve-item FDA 483 was issued to the firm's management. They promised to make corrections to all observations of objectionable conditions and to respond in writing to the Los Angeles District Office by 2/15/2000.

HISTORY OF BUSINESS:

Sure-Way Systems, Inc. has been a privately-held Montana Corporation since 1983. The firm is a major medical waste hauler in Montana and Wyoming. It collects medical wastes from hospitals and laboratories and processes them to municipal solid waste. The firm's headquarters office is located at 4072 Eastside Road, Stevensville, Montana 59870. The majority shareholders and Corporate Officers are:

Mr. Gary Chilcott – President.
Mr. William Lawrence – Vice President and Director.
Mrs. Dawn Chilcott – Treasure of the Boards of Directors (Wife of Mr. Gary Chilcott).

Sure-Way Systems, Inc.
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The firm started the reprocessing business of sharps containers after moving into the Amaritime facility in Wilmington in late 1998. The firm was previously located at 2472 Chambers Road, Suite 250, Tustin, CA 92780. Amaritime Environmental Solutions, Inc. is a medical waste hauler. Sure-Way Systems, Inc. at this Wilmington facility has only [redacted] full time employees and its normal operational hours are from 8:00 a.m. – 4:30 p.m., Monday through Friday.

This firm is currently not registered with the FDA. All FDA correspondence should be addressed to Mr. Gary Chilcott - President of Sure-Way Systems, Inc. at 310 Harry Bridges Blvd., Wilmington, CA 90744. The firm has obtained their first 510(k), #K992626, from the FDA for reusable sharps containers in December 1999. It plans to replace their existing ones manufactured b[redacted] with the new design starting in March 2000.

Exhibit #1 is an interstate shipping record for a shipment o[redacted] reusable sharps containers. It includes a Purchase Order and a Packing List showing that 1625 units of 2-Gallon [redacted] reusable sharps container were picked up from [redacted] on 4/21/97 and shipped to Sure-Way System, Inc. in Montana. Sure-Way Systems, Inc. reprocesse[redacted]harps containers.

PERSON INTERVIEWED AND RESPONSIBILITIES:

The inspection of Sure-Way Systems, Inc. was not pre-announced because the firm was discovered during the inspection of Amaritime Environmental Solutions, Inc. Both Amaritime Environmental Solutions, Inc. and Sure-Way Systems, Inc. are listed on the inspection assignment from HFZ-333.

One 1/10/2000, I displayed my Credentials and issued a Notice of Inspection to Mr. Bruce H. Collins, Professional Engineer and Director. Mr. Collins was the most responsible person at the firm during the issuance of the Notice of Inspection. He accompanied me during the walk-through of the facility and provided me with information on the cleaning process of sharps containers before Mr. Chilcott returned from the field. He reports to Mr. Chilcott.

I met with Mr. Chilcott at the end of the facility walk-through on 1/10/2000. I briefed him on the purpose of my inspection and he accompanied me during the rest of the inspection. He provided me with most of the information for this report. He is the most responsible person and also one of the majority shareholders in the firm. He reports to the Board of Directors.

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Individuals at the firm participating in the inspection included:
Mr. Don Terwiske – President of Amaritime Environmental Solutions, Inc., introduced me to Mr. Collins on 1/10/00. He provided information regarding the relationship between Amaritime and Sure-Way. Mr. Terwiske is a business partner with Mr. Chilcott and also an investor of Sure-Way sharp containers business.

Mr. Patrick B. Osborn – Director of Engineering was present on the last two days of the inspection. He was involved in the design of the new sharps containers submitted to the FDA for the 510(k) Premarket Notification in 1999. He answered questions regarding the new sharps containers as well as the quality system procedures. He reports to Mr. Chilcott.

OPERATIONS:

[redacted]he firm has obtained a 510(k) for sharps containers in December 1999 and plans to replace their existing sharps containers, purchased fro[redacted]m 1997, with the new ones starting in March 2000. Exhibit #2 is a typical contract, Sharps Disposal Service Program, signed by a medical facility with Sure-Wa[redacted]

[redacted] The firm is supposed to follow the cleaning process required by Section 118295 of the California Medical Waste Management Act. exhibit #3 for reusable rigid containers for medical waste.

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Exhibit #4 is a product label used on a reusable sharps container.

Personnel who may come in contact with a contaminated device are required by the firm to have the training for blood borne pathogens. Supervisors are reportedly always on site since the firm operates only on day shift.

OBJECTIONABLE CONDITIONS & DISCUSSION WITH MANAGEMENT:

At the conclusion of the inspection on 1/14/2000, a two page Inspectional Observations, FDA-483, was issued to Mr. Gary Chilcott, President of Sure-Way Systems, Inc. Also present in the discussion was Mr. Patrick B. Osborn. Prior to the FDA-483 discussion, I provided Mr. Chilcott a Resources for FDA Regulated Businesses and a "Medical Device Inspection Evaluation" package and told him to read the enclosed letter in the package and to return the survey form in the pre-stamped envelope to University of California, Irvine.

I explained that this list represents my observations of objectionable conditions made during the inspection and that these conditions may be determined, after review by the Compliance Branch, to be violations of the Federal Food, Drug and Cosmetic Act. I read each observation listed below aloud and provided the firm an opportunity for discussion after each observation.

1. The firm has not established a quality policy, a quality plan and quality audit procedures.

Mr. Chilcott was not aware that the firm's reprocessing operation of sharps containers are subject to the FDA Quality System Regulations. As a result, the firm does not have any written procedures required by the QS Regulations.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Chilcott agreed with the observation and promised to establish a quality policy, a quality plan and quality audit procedures.

2. Document control and design change control procedures have not been established.

My review of the 510(k) submission for sharps containers revealed the firm did not maintain a design history file. Design changes were not documented during the development of the sharp containers. Mr. Osborn stated whenever there was a change in specification, he would discuss it with the appropriate people, but the change was not formally documented. He also stated the firm did not have any procedures for document and design change controls.

Annotation: Correction promised by 2/15/2000.

Discussion: Both Mr. Chilcott and Mr. Osborn agreed with the observation. They promised to establish written procedures for document and design change controls.

3. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established. Specifically, the firm has no written specifications on chemicals used in th[redacted] washer for sanitizing reusable sharps containers.

During the walk-through of the facility with Mr. Collins on 1/10/00, I noticed that the firm was using the [redacted] and [redacted] chemicals for washing sharps containe[redacted] maintains the [redacted] washer for Sure-Way and supplies both chemicals. When I was with Mr. Chilcott on 1/13/00, I found t[redacted] was replaced w[redacted] sked Mr. Chilcott what the difference between th[redacted] and [redacted] nd he said both chemicals contain [redacted] olution that is required by Section 118295 of the California Medical Waste Management Act. Mr. Chilcott could not provide me any written specifications for the cleaning solutions.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Chilcott stated that this would be good business practice to establish written specifications for the cleaning chemicals. Mr. Osborn promised to correct it by 2/15/2000.

4. The cleaning process for reusable sharp containers and transport carts has not been validated.

The firm has not performed any validation study to ensure that the use [redacted] asher, the cleaning chemicals and its operating parameters are effective to remove bioburden from used sharps

containers. The [redacted]asher is often used as a small dish washing machine in restaurants.

Annotation: Correction promised by 3/1/2000.

Discussion: Mr. Chilcott asked me what kind of tests are required to validate the cleaning process. I told him that the firm should determine the bioburden levels for returned sharps containers before and after the cleaning operation. I also suggested that the firm should develop a validation protocol and document all testing results in a validation report. Mr. Osborn stated that they might perform swab tests on returned sharps containers and transport carts in the validation.

5. Process control procedures for cleaning reusable sharps containers have not been established. Specifically, the firm has no written operating procedures and specifications for the [redacted] washer.

Since the firm has no written operating procedures and specifications for the [redacted]asher, the operating parameters including the amount of chemical used, the dwell time and the temperature of the hot water may have been changed after each service performed by different technicians from [redacted]e firm contract[redacted]maintain [redacted]asher.

6. Equipment used in the washing and decontamination process for reusable sharp containers does not meet specified requirements. Specifically, the temperature of the water used in th[redacted] washer is only [redacted]stead of [redacted]egrees Fahrenheit and the exposure to the chemical sanitizer is approximatel[redacted]ead of three minutes as required by Section 118295 of the Medical Waste Management Act.

During the inspection, Mr. Collins stated the firm follows Section 118295 of the California Medical Waste Management Act using the chemical sanitizer to wash reusable sharps containers instead of hot water because the firm's boiler cannot generate hot water reaching 180 degrees Fahrenheit. During a demonstration performed by Mr. Chilcott, I noticed the complete cycle used for washing a sharp container was less than one minute and the temperature gage of th[redacted]asher was read betwee[redacted]egrees Fahrenheit. Section 118295 of the Medical Waste Management Act requires a reusable container be exposed to hot water of at least 180 degree Fahrenheit for a minimum of 15 seconds or chemical sanitizer for a minimum of three minutes.

Annotation: Correction promised by 3/1/2000.

Discussion: Mr. Chilcott was aware that [redacted]asher was not meeting the State requirements. He stated the firm has purchased a new washer that would meet the requirements and would have it installed by 3/1/2000.

7. Schedules for the adjustment, cleaning and other maintenance of equipment have not been established. Specifically, the firm has no maintenance schedule and records for the [redacted] washer and the automated lid remover.

Mr. Chilcott could not provide any maintenance and service records for th[redacted]asher when I requested for them during the inspection. In fact, the firm did not establish any maintenance and cleaning schedules for th[redacted]asher. In addition, the automated lid remover is installed with a Hepa filter and the firm had no records on the filter replacement.

Annotation: Correction promised by 3/1/2000.

Correction: Mr. Osborn promised to develop a maintenance log for both [redacted]asher as well as the automated lid remover and to keep all maintenance records in the future.

8. The firm has not established receiving, in-process and finished device acceptance procedures.

At the time of the inspection, the firm did not have any written procedures including a sampling plan for inspecting chemical solutions and washed sharps containers.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn stated the firm would establish written procedures for receiving, in-process and finished device acceptance.

9. The firm has no Device History Records for reprocessing sharp containers. Specifically, the dates of reprocess, the quantity re-processed, the quantity released for distribution and the acceptance records.

At the time of the inspection, the firm only had records for the numbers of container and the amount

of medical waste received from hospitals, but the processing records including the dates of reprocess, the quantity re-processed, the quality released for distribution and the acceptance records were not documented.

Annotation: Correction promised by 2/15/2000.

Discussion: Mr. Osborn agreed with the observation and promised to establish Device History Records to document the re-processing by 2/15/00.

10. The firm has no complaint handling procedure and Medical Device Reporting (MDR) procedure.

Mr. Chilcott was not aware of the MDR regulation. During an interview with Mr. Keith Edward, he explained that in case there was a product complaint, a service technician would document it in a Daily Report, exhibit #5. The firm did not have a written procedure to describe what a product complaint is and the necessary steps to follow when there is a product complaint. Mr. Edward stated the firm has not received any complaints since the firm started the reprocessing of sharps containers in late 1998. Mr. Edward could not provide me the file containing the Daily Reports when I asked to review them. He said the firm did not keep them.

Annotation: Correction promised by 2/15/2000.

Correction: Mr. Chilcott promised to have the complaint and MDR procedures by 2/15/2000.

11. Procedures for identifying product throughout all stages of incoming, production and distribution are not defined. Specifically, the acceptance status of product and areas of operation are not identified.

During the walk-through of the facility, I noticed that neither the areas of operation nor the acceptance status of products including the transport carts were identified. Since the firm's operation is in a warehouse and there is no wall separating each operation, there is a possibility that someone may accidentally use a contaminated transport cart for stocking cleaned sharps containers.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn agreed to establish written procedures and to identify the areas of operation

in the facility when the firm has completed the installation of the new washer.

12. Procedures have not been defined to prevent contamination of product by certain substances. Specifically, washed sharp containers were placed upside down directly on wet floor contaminated with washing solution from a washer sanitizing reusable medical waste containers.

During the walk-through of the facility, I observed some washed sharps containers were contaminated with washing solution from a washer sanitizing reusable medical waste containers. The washed sharp containers were placed upside down directly on wet floor instead of on a rack. On 1/13/00, I verified the firm had made a voluntary correction by placing washed sharp containers on a rack.

Annotation: Correction promised by 3/15/2000.

Correction: Mr. Osborn stated written procedures would be established once the new washer was installed.

At the end of the inspection, I provided a copy of the Quality System Regulation, CFR 21 Part 820 to Mr. Chilcott for his information. He reiterated his commitment to comply and promised to respond in writing with corrective actions to the Los Angeles District by 2/15/00.

ATTACHMENTS:

1) Notice of Inspection, FDA-482 dated 1/10/00.
2) Inspectional Observations, FDA-483 dated 1/14/00.
3) Assignment 000393 from Division of Enforcement II, Office of Compliance, CDRH, HFZ-333.

EXHIBITS:

1) An interstate shipping record for a shipment o[redacted]eusable sharps containers.
2) A typical contract, Sharps Disposal Service Program, signed by a medical facility with Sure-Way.
3) Section 118295 of the California Medical Waste Management Act for reusable rigid containers for medical waste.

4) A product label used on a reusable sharps container.
5) A Daily Report.

Kelvin Cheung

Kelvin Cheung
Engineer
LOS-DO/CPK-RP

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 19900 MacArthur Blvd. #300 Irvine, CA 92612 (949) 798-7600
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Gary Chilcott	PERIOD OF INSPECTION 1/10, 13 & 14/2000 / C.F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Medical device reprocessor & manufacturer
FIRM NAME Sure-Way Systems, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 310 E. Harry Bridges Blvd.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE (Zip Code) Wilmington, CA 90744	CITY AND STATE (Zip Code) Same

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

THE OBSERVATIONS NOTED ON THIS FDA483 ARE NOT AN EXHAUSTIVE LISTING OF OBJECTIONABLE CONDUCTIONS. UNDER THE LAW, YOUR FIRM IS RESPONSIBLE FOR CONDUCTING INTERNAL SELF AUDITS TO IDENTIFY AND CORRECT ANY AND ALL VIOLATIONS OF THE GMP REGULATIONS.

1. The firm has not established a quality policy, a quality plan and quality audit procedures.

2. Document control and design change control procedures have not been established. Correction promised by 2/15/2000.

3. Procedures to ensure that all purchased or otherwise received product and services confirm to specified requirements have not been established. Specifically, the firm has no written specifications on chemicals used in th[redacted]washer for sanitizing reusable sharps containers. Correction promised by 2/15/2000.

4. The cleaning process for reusable sharp containers and transport carts has not been validated. Correction promised by 2/15/2000

5. Process control procedures for cleaning reusable sharps containers have not been established. Specifically, the firm has no written operating procedures and specifications for th[redacted]washer. Correction promised by 3/1/2000

6. Equipment used in the washing and decontamination process for reusable sharp containers does not meet specified requirements. Specifically, the temperature of the water used in th[redacted]vasher is only [redacted]nstead o[redacted]egrees Fahrenheit and the exposure to thechemical sanitizer is approximatel[redacted]nute instead of three minutes as required by Section 118295 of the Medical Waste Management Act. Correction promised by 3/1/2000

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kelvin Cheung	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kelvin Cheung, Engineer	DATE ISSUED 1/14/2000

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 19900 MacArthur Blvd. #300 Irvine, CA 92612 (949) 798-7600	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Gary Chilcott	PERIOD OF INSPECTION 1/10, 13 & 14/2000	C.F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Medical device reprocessor & Manufacturer	
FIRM NAME Sure-Way Systems, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 310 E. Harry Bridges Blvd.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Wilmington, CA 90744	CITY AND STATE (Zip Code) Same	

7. Schedules for the adjustment, cleaning and other maintenance of equipment have not been established. Specifically, the firm has no maintenance schedule and records for th[redacted]vasher and the automated lid remover. Correction promised by 3/1/2000

8. The firm has not established receiving, in-process and finished device acceptance procedures. Correction promised by 3/15/2000

9. The firm has no Device History Records for reprocessing sharp containers. Specifically, the dates of reprocess, the quantity re-processed, the quantity released for distribution and the acceptance records. Correction promised by 2/15/2000

10. The firm has no complaint handling procedure and Medical Device Reporting (MDR) procedure. Correction promised by 2/15/2000

11. Procedures for identifying product throughout all stages of incoming, production and distribution are not defined. Specifically, the acceptance status of product and areas of operation are not identified. Correction promised by 3/15/2000

12. Procedures have not been defined to prevent contamination of product by certain substances. Specifically, washed sharp containers were placed upside down directly on wet floor contaminated with washing solution from a washer sanitizing reusable medical waste containers. Correction promised 3/15/2000

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kelvin Cheung	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kelvin Cheung, Engineer	DATE ISSUED 1/14/2000

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NO.
19900 MacArthur Blvd. #300
Irvine, CA 92612
(949) 798-7600

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. Bruce H. Collins

3. DATE
1/10/00

4. FIRM NAME
Sure-Way Systems, Inc.

5. HOUR
~~4:00~~ a.m.
1:40 p.m.

6. NUMBER AND STREET
310 E. Harry Bridges Blvd.,

7. CITY AND STATE & ZIP CODE
Wilmington, CA 90744

8. PHONE # & AREA CODE
(310)522-0150

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Kelvin Cheung

10. TYPE OR PRINT NAME AND TITLE *(FDA Employee(s))*
Kelvin Cheung, Engineer

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec.704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and research data *(other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title)*. **A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.**

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F - Licensing - Biological Products and Clinical Laboratories and******

Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - ******Control of Radiation.

Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

******

(f) "The Secretary may by regulation (1) require dealers and disbributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manuracturers to preserve such information.

Exhibit JAK-3

Exhibit JAK-3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1999

Mr. Gary Chilcott, President
Sure-Way Systems, Incorporated
310 East Harry Bridges Boulevard
Wilmington, California 90744

Re: K992626
Trade Name: Sure-Way Reusable Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: October 7, 1999
Received: October 25, 1999

Dear Mr. Chilcott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

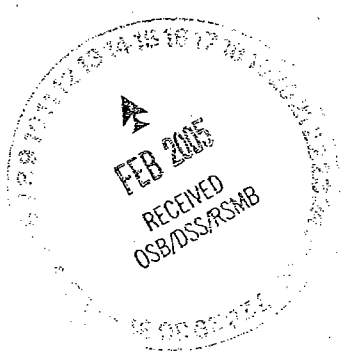

Exhibit JAK-4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
HFL-35 M3430

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

FEB 2 2 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary Chilcott, President
Sure-Way Systems, Inc.
310 E. Harry Bridges Boulevard
Wilmington, CA 90744

W/L 29-00

Dear Mr. Chilcott:

During an inspection of your facility conducted on January 10, 13 and 14, 2000, our investigator determined that your firm manufactures, reprocesses and distributes reusable sharps containers. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement a quality policy which defines the intentions and direction of your organization with respect to quality [21 CFR 820.20(a)].

2. Failure to establish and implement a quality plan which defines the quality practices, resources, and activities relevant to devices designed and manufactured by your firm [21 CFR 820.20(d)].

3. Failure to establish and implement procedures for a systematic, independent examination of your quality system at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with the quality system procedures [21 CFR 820.22].

4. Failure to establish and implement procedures to control the design of your device in order to ensure that specified design requirements are met [21 CFR 820.30(a)].

5. Failure to establish and implement procedures to control all documents required by the Quality System Regulation [21 CFR 820.40].

6. Failure to establish and implement procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].

7. Failure to develop, conduct, control, and monitor production processes to ensure your devices conform to their specifications [21 CFR 820.70 & 75]. Specifically, your firm has no documented evidence which provides a high degree of assurance that your cleaning processes for your reusable devices used as part of production meet their pre-determined specifications and quality attributes. Most disturbing is that our investigation disclosed instances where equipment used in the washing decontamination process for reusable sharp containers did not meet their specified requirements and no investigations were conducted. Additionally, your firm has no schedules for the adjustment, cleaning and other maintenance activities for your cleaning equipment.

8. Failure to establish and implement procedures for acceptance of incoming product, in-process product and finished device acceptance to ensure that each product run or lot of finished device have met its acceptance criteria [21 CFR 820.80].

9. Failure to establish and implement procedures to ensure that device history records for each batch, lot or unit are maintained to demonstrate that the device was manufactured in with the Device Master Record and Quality System Regulation [21 CFR 820.184]. Specifically, your firm does not maintain any records describing the date of manufacture, quantities manufactured, quantities released, or the acceptance records.

10. Failure to establish and implement procedures to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For

Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Thomas L. Sawyer, Director, Compliance Branch and a copy to Dannie E. Rowland, Compliance Officer at U.S. Food and Drug Administration, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

Acting District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320

Exhibit JAK-5

Exhibit JAK-5

RESPONSE TO
FDA 483 INSPECTION MEMORANDUM
(DATED JANUARY 14,2000)

FEBRUARY 28, 2000

SURE-WAY SYSTEMS INC.
310 East Harry Bridges Blvd.
Wilmington, CA 90744

RESPONSE TO
FDA 483 INSPECTION MEMORANDUM
Dated January 14,2000

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RESPONSE STATEMENT

Introduction

The following response to the FDA 483 inspection memorandum is presented in the order that various issues are addressed in the subject memorandum of inspection observations during the period 1/10,1/13, 1/14. This response describes the corrective actions taken and documents certain elements of operations and maintenance procedures, which are on file with FDA as an element of Sure-Way's recent 510(k) review presentations. These presentations to FDA, which have been reviewed and accepted, include a description of operations protocol and laboratory testing data which pertain to the next generation of reusable sharps containers and related processing equipment systems. These containers and processing systems, currently being placed into service, were shown to and demonstrated to Mr. Cheung during his inspection. The pertinent sections of our accepted FDA (510k) submittal will be attached hereto for convenience.

1. **Quality Assurance**

   a. **Quality Control Policy**

   Sure-Way's Quality Control Policy with regard to the processing of reusable sharps disposal containers is to reuse and recycle containers which are equivalent to new containers, with regard to physical condition, and which have been sanitized in accordance with state health department requirements, following the removal of all sharps contents.

   b. **Quality Control Plan**

   The Sure-Way sharps container reuse processing quality control plan involves [redacted] to State of California Health Department requirements. Following the [redacted] each container will be subjected to quality assurance (QA) inspection, as described below:

   c. **Quality Assurance Audit Procedures**

   Each container will be subjected to a two-phase QA audit procedure. The first phase [redacted]

   The second phase of QA audit is a final QA inspection by the container QA Reassembler, a[redacted]. The QA Reassembler will inspect each container visually and will return non-complying containers for further processing and will discard

damaged containers to the recycle bin for shipment to a plastics manufacturer for materials salvage and remanufacture, or for landfill disposal.

Under no circumstances will damage rejected containers be reused for sharps disposal.

References:

See Appendix No. 1 for initial FDA 510(k) submittal
See appendix No. 2 for detailed description of operation plans, Quality Control Policy, Container Sanitization Plan, and Quality Assessment Audit Procedures previously submitted.
See Appendix No. 3 for summary of 510(k) use simulation testing
See Appendix No. 4 for FDA 510(k) Clearance letter of Dec. 16, 1999
See Appendix No. 6 for description of manufacturer's quality control procedures and documentation.

2. Document and Design Change Control

a. Document Control

Document control will include both hard copy files and computer files for the following categories of required data tracking:

1) Accounts Files

Accounts files will include all pertinent information with regard to account information, such as service location, special service provisions, contracts, billing and payment records, complaints, and remediation actions.

2) Operations Files

Operations files will include recordation of daily production quantities in terms of both the number of units processed, and the total weight of sharps processed and disposed. These files will also include production records relating to manpower, utilities consumption, transportation and regulatory compliance as may be applicable

3.) Equipment Files

Equipment files will contain manufacturer's published information, including purchase dates and costs, procurement information, warranties, replacement schedules, operation and maintenance manuals, records of modifications and replacement parts

4.) Regulations and Compliance Files

These existing files include all applicable regulations, regulatory compliance plans, and all performance testing records.

b. Design Change Control Procedures

Design change control procedures shall be responsive to the following criteria:

1.) Defect Correction

The first priority of design control will relate to corrections of defective equipment, which does not satisfy minimum performance specifications, with emphasis on modifying equipment that is not capable of performing as required to comply with regulatory standards.

2.) Efficiency Improvements

Design change will be responsive to the need to improve performance of equipment which is inefficient, either in terms of the quality of product treated, or in terms of the speed or capacity of production.

3.) Customer Preference

Design change for containers will be very sensitive to the need to be responsive to satisfying the needs and preferences of the end user, or customer. The users of reusable sharps containers have had a significant influence on the design of the first generation of Sure-Way sharps containers and will have a major influence on subsequent generations of containers.

4.) Cost Considerations

Design changes will also be significantly influenced by the continuing incentive to further reduce the net cost of sharps disposal to the healthcare industry, in any way that is functionally effective and which does not impact infection control or safety considerations.

5.) Design Peer Review

Design quality control will primarily be assured by a procedure requiring peer review by second and third parties, one from the company engineering staff and one from the operations staff. All designs will require preparation of plans and specifications in sufficient detail to control manufacturing quality. These plans and specifications will be reviewed with recommendations for consideration of modifications to be reviewed by the designer with a written response to the review recommendations. Final decisions on design modifications will then be made based on a consensus of the designer and the design reviewers.

References:

See Appendix No. 5 for supplemental description and decision line diagram of document and design change management.

See Appendix No. 7 for complaint response procedures.

3. Procurement Management

a. Chemicals Procurement

The procurement of chemicals utilized for cleaning and sanitizing reusable containers shall be managed solely by the Sure-Way Operations Manager and shall be restricted to the listing of State Health Department chemicals for this specific purpose. Any deviation from this procurement standard shall be requested in writing with an explanation of the basis for the recommendation. No change from the approved list will be made without the written consent of the State Health Department.

b. Equipment Procurement

The procurement of mechanical and processing equipment shall be made using a written purchase order or contract based, on approved drawings and sufficiently detailed specifications to control equipment materials, performance assurance, warranties, and quality control of fabrication. Procurement of "off-the shelf" or catalog equipment shall require a purchase order signed by the Operations Manager.

References:
See Appendix No.7 for detailed diagram of procurement management

4. Validation of Cleaning Procedures

a. Reusable Sharps Containers Cleaning

Validation of reusable sharps container cleaning effectiveness will involve [redacted] Tests will emphasize confirmation of negative presence of pathologic bacteria and will allow for the presence of ambient levels of bacteria and the fact that the containers are not subjected to sterilization or are they hermetically sealed following processing.

Validation of cleanliness will be confirmed by the QA Reassembler for each container during reassembly, as the lids are replaced on the containers. Containers holding residual particulates will be reprocessed until clean. Containers showing staining will be immersed in a [redacted] until clean, even though the staining is not necessarily an indicator of lack of sanitization.

b. Transport Security Cart Cleaning

Validation of cleanliness of transport cart cleanliness will be primarily the responsibility of the QA Reassembler prior to the cart being filled with clean containers for reuse transport. The transport carts are not exposed to direct

contact with waste materials at any time, inasmuch as each sharps container lid is pin locked at the time of its removal from the wall in a patient room and the container is constrained in an upright position at all times while being transported in the transport cart.

References:
See Appendix No. 2, Attachment "E" for detailed discussion of cleaning validation procedures.

5. Container Cleaning Process Control

a. [redacted] Washer Operation

The following [redacted] washer operations control procedure has been established for over a year and is currently being used:

- Pull solids basket screen; clean and replace;
- Turn on power switch at least 20 minutes prior to commencement of operations in order to bring wash water up to operating temperature.
- Check to see that detergent and sanitizer chemical containers are at least ¼ full and that the automatic chemical feed pumps are operating.
- When wash water temperature exceeds 190 degrees F, commence washing operations. Actuate the pump motor switch next to the power switch;
- After sharps have been removed from containers, place containers inverted into the washing tray;
- Insert tray into the washer far enough to engage the conveyor switch and pump actuator control;
- The washing operation from this point on is automatic;
- Remove washed containers from holding tray at the exit table; inspect containers for cleanliness and stack containers inverted on the drying rack. Return rejects, if any, for another cycle of washing or manual scrubbing
- When washing run is completed, deactivate the power switch.

b. New Washer Operation

The custom designed and fabricated washer, placed in service since the time of the subject FDA field inspection, was specifically designed to wash medical waste containers. This washer is designed to wash sharps containers and general medical waste containers. Operation involves [redacted] This washer and subsequent models incorporate the following performance upgrades relative to the initial utilization of the [redacted] commercial dishwasher, as described below:

References:

See Appendix No. 2 for detailed description of container chemical process control.

6. Washer Performance Upgrade

a. Automated Chemical Feed Control

The new in-line washer utilizes digital temperature controllers in the wash and rinse tanks to maintain [redacted] to [redacted] degree F temperature via [redacted] exchangers. Conveyor speed, while adjustable, has been set at [redacted] minute. Chemical makeup of wash water is automatically controlled and monitored using [redacted] adjusted to provide the desired concentration of detergent/disinfecting chemicals.

b. Operation

- Pull emergency stop button "out"
- Observe that temperatures are between [redacted] and [redacted] degrees F on each tank's digital display
- Turn on conveyor and observe normal operation
- Turn on pumps #1 and #2 (wash and rinse)
- Sharps containers are [redacted]

[redacted]

References:
See Appendix No. 2 for detailed description of washer operation.

7. Maintenance Management

a. Tipping and Lid Removal Equipment

- **Maintenance Plan**

The maintenance of the Tipper/Lid Removal Equipment is limited. The drive units are [redacted] motors, which are permanently lubricated and require no maintenance. In the event of failure, replacement is required. Maintenance is limited to the following:

1.) An Occasional need to adjust conveyor belt tension.
2.) Conveyor shaft bearings require periodic lubrication
3.) Drain condensate water accumulation from the air supply catch bowl.

- **Maintenance Schedule**

Routine maintenance is limited to weekly lubrication of shaft bearings and condensate drainage.

- **Maintenance Records**

Routine maintenance performed will be recorded in the equipment maintenance log. Records of parts change-outs, such as a motor replacement, will also be maintained in the equipment file.

b. [redacted] Washer

- **Maintenance Plan**

The maintenance plan for the [redacted] commercial dishwasher is as prescribed by the attached excerpts from the [redacted] manual for the [redacted] Washer.

- **Maintenance Schedule**

Scheduled maintenance of the [redacted] washer is limited to a weekly check of spray nozzles to clean those which appear restricted, and to tighten or replace any that may have come loose. End plugs on the wash water distributor arms will deteriorate over several years usage and will require replacement when they eventually exhibit excessive leakage and/or come loose. As with a home dishwasher, maintenance is performed when a part fails and needs replacement. The pump may

fail in 10 or 20 years, depending on the amount of abrasive wear and the hours of usage. Abrasive wear washing sharps containers is minimal. The gearbox for the conveyor drive unit may fail also in 10 or 20 years and will eventually require replacement. The [redacted] exchanger, as with any water heater, may require replacement when it fails due to corrosion. The corrosion potential of wash water used at the Wilmington plant is quite low.

- **Maintenance Records**

As with all Sure-Way equipment, a file is maintained which will include work orders, receipts for replacement parts, such as a pump or a motor. A record of spray nozzle cleaning is not kept and is not required.

References:
See Appendix No.8 for equipment operation and maintenance procedures.

8.Sharps Container Processing Procedures

See attached reusable sharps container processing procedures protocol. These documents are an attachment to the Sure-Way State Health Department Operating Permit and an attachment to Sure-Way's recently accepted FDA 510(k) submittal.

References:
See Appendices No. 2 and No. 3 for detailed description of container processing procedures.

9. Sharps Container History Records

a. Individual Container Records

History records of each individual sharp container are not maintained. Each lot of containers to be manufactured for Sure-Way is registered by date and lot numbers which are molded into the body of each container when it is manufactured. Under the conditions of the FDA 510(k) review, and in

accordance with related [redacted] requirements, the Sure Way reusable sharps container has substantially exceeded the requirements for an approved use period of 5 years. This compliance was demonstrated as a result of directed FDA use-simulation testing based on protocol reviewed and approved by FDA. Documentation of these use-simulation tests, performed by an independent testing laboratory, is attached. Note that the critical penetration test results of the containers, following 5year use simulation, exceed the allowable standard by 300%. **See Appendix No. 3** for post use-simulation test results.

The history of use and reuse of each container is irrelevant to its suitability for reuse within the context of the approved 5-year life cycle. The durability of sharps reuse containers of the same material and wall thickness has demonstrated their durability under normal conditions of use to be in excess of 13 years. It must also be recognized that, in spite of the excellent performance of the Sure-Way container with the drop test and the penetration tests, it is possible with a sharp implement to deliberately damage the container and render it unsuitable for continued reuse. This kind of damage is not readily inflicted under the normal security surveillance of a hospital and is not the result of normal routine usage. The key point is that the suitability of the sharps container for continued reuse is confirmed each and every time that a container is processed and examined for any type of malicious or accidental abuse that would render it unsuitable for continued reuse. The Sure-Way device history record will document the removal from service of any unsuitable container and will note the nature of damage sustained and the probable cause, if known. This information will be placed into the history record along with the lot number and date of manufacture of the container.

The use-simulation testing of the new Sure-Way sharps container, as performed for the FDA 510(k) review, indicates that after 5 years of twice the normal reuse frequency, the physical strength and durability of the reused container is within [redacted] of that of a new container, retaining a penetration resistance at least [redacted] times the allowable standard for new containers.

b. Quantity of Containers Reprocessed

Inasmuch as the Sure-Way sharps disposal service is performed and billed on a per container location service, no individual container measurement of quantity is required, or is necessary. The total daily flow of sharps is measured by weight and recorded. The number of containers processed daily is also recorded.

c. Quantity of Containers Released for Distribution

Quantities of reusable sharps containers released for distribution are a matter of record and are maintained by account of each purchaser. To date there is only one purchaser of record, and that purchaser is not using the containers for

sharps disposal. Records of container distribution will be maintained permanently, recorded by lot number, along with all related sales information. Each lot's distribution will be recorded along with the date of manufacture and the date of service initiation. The recorded lot numbers and dates of manufacture will be as they are molded into each container at the time of manufacture.

References:
See Appendix No. 2 for details concerning container records.

10. Reporting Procedures

a. Complaint Handling

To date, Sure-Way has had no reported incidence of sharps container complaints. The following complaint response procedures will be utilized in the event a complaint is received:

COMPLAINT RESPONSE PROCEDURE

1. Telephonic Response
The Sure-Way Operations Manager will immediately contact the complainant. He will make an early appointment to meet with the complainant to clarify the substance of the complaint and determine its validity and cause. The operations Manager will prepare a memorandum for the complaint file describing the complaint and possible mitigation thereof.

2. Written Response
The Operations Manager will prepare a response in writing to the complainant confirming understanding of the complaint and outlining what steps will be taken to mitigate the circumstances causing the complaint, and will offer compensation or replacement of product, if there is any confirmed justification to do so. Sure-Way will not aggressively challenge the complaint unless there is a clear indication that the complaint has originated as a result of the improper activity by a competitor to stimulate the complaint. Our response to any complaint will be professional and will be based on factual information, if a challenge is presented, and will emphasize our intent to continue to provide excellent service.

3. Complaint Follow-Up
The complaint response procedure will include a tickler file reminder to re-contact complainants 30 days following an incident and to follow-up quarterly for a year.

4. **Complaint Source Corrections**
In the event a complaint discloses a product or service procedure defect, Sure-Way will take immediate action to correct the product defect or to replace defective product, and the Operations Manager will instruct all personnel to remedy any procedural problems which have generated a valid complaint. Unless a complaint is a clear fabrication, the resolution of the complaint will lean towards generosity and away from argument and wasted time.

b. Medical Device Reporting
Although Sure-Way sharps containers are a medical waste disposal system implement, and are not considered to be a "medical device", the procedures for Medical Device Reporting will be followed.

References:
See Appendix No.7 for complaint response documentation form.

11. Product Identification Procedures

a. Incoming Product
Incoming sharps product waste is identified with regard to source automatically in the procedure for service, which identifies product by security cart in which filled sharps containers are transported. These med carts and contents by size of container are entered into the daily operations log. Any unusual circumstances with regard to this handling and transport are duly noted by log entry.

b. Sharps Processing
No further identification of sharps product, once it is received and discharged to the autoclave carts and is sterilized, is required. Following sterilization, [redacted]

c. Acceptance Status
Acceptance status of waste sharps is predetermined at the time the sharps container locations are established at the hospital, clinic or laboratory. The assessment and confirmation of sources of waste is made at that time with hospital staff responsible for the management and separation of medical waste sources at their institution.

No chemo, radioactive, or other non-sharps waste is accepted at a designated sharps reception station. Any violation of this service contract condition results in notification of institutional staff responsible for the sources of waste. Any non-conforming wastes received will be separated at the time of tipping, and responsible parties will be notified immediately. This problem has not been experienced to date.

d. Operations Areas

At the present time, Sure-Way sharps operations are restricted to Southern California, which is serving as a proving ground, and will be the location used to prove the new generation of Sure-Way sharps containers, which have recently been accepted for marketing by the FDA. There is considerable interest in the quick-release lid Sure-way sharps container throughout the U.S. and Canada. Sure-Way intends no restriction to its areas of operation at this time.

References:

See Appendix No. 7 for records of operation forms.
See Appendix No. 2 for a description of container tracking procedures.

12. Contamination Protection Procedures

a. Processed Container Handling

With regard to the conditions cited in the subject FDA inspection report with regard to washed containers being placed upside-down on the floor "contaminated" by washing solution, it should be mentioned that the "contaminated" washing solution consists of water with a high level of chlorine residual and is the same water used for sanitizing the containers in the washing process. However, the suggestion of separation of the containers from the floor is appreciated and has been acted on with placement of washed containers now on a drying rack, which keeps them off the floor.

b. Planning Objectives

Maximizing separation of sanitized sharps containers from unprocessed waste sharps and other medical waste will continue to be a high priority of consideration for future plant configurations, and has had a significant impact on the revised layout of the respective waste streams in our current master plan development.

References: See Attachment No.2, Attachment E, and State of California Operations permit Application, Appendix "S" (in Attachment "E").

Exhibit JAK-6

DEPAI MENT OF ENVIRONMEI 'AL QUALITY
PERMITTING & COMPLIANCE DIVISION
Community Services Bureau
Waste Management Section

MARC RACICOT, GOVERNOR

STATE OF MONTANA

Phone: (406)444-4400
Fax: (406)444-1374

Metcalf Building
1520 E Sixth Ave
PO Box 200901
Helena, MT 59620-0901

CERTIFIED MAIL

August 10, 1999

Sure-way Systems of Montana
William Lawrence
P.O. Box 899
Deer Lodge, MT 59722

RE: Violation Letter & Inspection Report Sure-way Systems of Montana Class II Infectious Waste Treatment Facility (Lic. #358)

Dear Mr. Lawrence:

On July 22, 1999, I inspected the Sure-way Systems of Montana Class II Infectious Waste Treatment Facility for compliance with the rules and regulations governing solid waste disposal in Montana. According to ARM 17.50.526(1), whenever violations of the laws and rules governing solid waste management are noted during the course of an inspection, we are required to notify the operator of the violations observed during the inspection. A major violation was noted for failure to submit license payments when due. On July 29, 1999, the Department received past due payment for the forth quarter of fiscal year 1998 (including interest), past due partial payment for fiscal year 1999, which included first quarter 1999 (no interest paid) and a portion of second quarter fiscal year 1999. Outstanding payments remain due. Enclosed you will find a copy of the on-site observation report and the official inspection report. The latter report was based on the on-site observation report taken at the time of inspection.

The official inspection report has been separated into various sections, such as General Operation and Maintenance Plan and Ground Water Monitoring Requirements. Each section has then been further divided into "Major Violations", "Minor Violations", and "Comments". Those sections in which no violations or comments were noted have not been included in this inspection report. Under the appropriate category, I have quoted the rule or regulation which was violated and an explanation of the specific problem.

Major violations need to be corrected immediately. If left uncorrected, these problems may result in future action by the Montana Department of Environmental Quality. All violations noted in the enclosed inspection report have to be corrected in order to bring your operation into compliance. Compliance deadlines are specified under each section as needed. Materials discussed under "Comments" are only suggestions or observations,

and are not requirements of State rules and regulations.

The purpose of carrying out inspections is to protect human health and the environment by ensuring compliance with State rules and regulations. We will try to provide any assistance you may need in order to comply.. Thank you for your cooperation in this matter and please do not hesitate to contact this office if you have any questions or comments.

Sincerely,

Andrea G. Vickory
Solid and Hazardous Waste Specialist

cc: Gary Chilcott, CEO/President, Sure-way Systems, Inc., 310 Harry Bridges Blvd., Wilmington, CA 90744
Enclosures: Copy of On-Site Observation Form, Inspection Report
File: f:\cb5405\word\landfills\Sureway IWTF II 2 99 358

SOLID WASTE MANAGEMENT SITE/SYSTEM INSPECTION REPORT
(Revision 7/20/98)

Site Name: Sure-way Systems of Montana
License #: 358
Date of Inspection: July 22, 1999
Persons Present: Gary Chilcott, Tinch Ramey, Sure-way Systems
Andrea G. Vickory, DEQ

Applicable Acronyms

ARM = Administrative Rules of Montana **CFR** = Code of Federal Regulations
Department = Montana Department Environmental Quality **MCA** = Montana Code Annotated
MSWLF = Municipal solid waste landfill **MSWMA** = Montana Solid Waste Management Act
NESHAP = National Emission Standards for Hazardous Air Pollutants

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ARM 17.50.526(1) ENFORCEMENT If after an inspection the department determines that violation of the act or this subchapter is occurring, it shall notify the licensee of the nature of the violation.

General Operational and Maintenance Requirements

Major Violation: Department records indicate that fees for the most of fiscal year 1999, and the first quarter fiscal year 2000 have not been paid.

ARM 17.50.510(1) Any person who maintains or operates a solid waste management system shall maintain and operate such system in conformance with the requirements of this rule, the plan of operation and maintenance approved by the department, all local zoning, system planning, building, and protective covenant provisions, and any other legal requirements that may be in effect.

ARM 17.50.410(1)(b) ...Failure to submit payments when due shall subject the license holder to the provisions of 75-10-116, MCA.

Section 75-10-116, MCA A person who owns a solid waste disposal facility subject to a fee under 75-10-118 and fails to pay the fee in the manner provided by department rule is subject to a fine of not more than $2,000 or imprisonment not to exceed 6 months, or both, and shall reimburse the department for the amount of the fee owed and the interest calculated at a rate equal to the previous fiscal year's average rate of return on the board on investments' short-term investment pool.

Compliance Deadline: Please contact the department in writing within 15 days of receipt of this letter with a payment plan that includes a schedule of payment.

Exhibit JAK-7

Exhibit JAK-7

Sure-Way Systems, Inc.

206 Missouri St. Deer Lodge, MT 59722 phone 800-822-3929

Memorandum

To: Rick Thompson,

From: Gary Chilcott Pres/CEO

Date: 12/4/00

Re: Revised operations plan and floor plan for Sure-Way Systems Butte med. waste plant

---

Rick here is our revised plan. The new addition allows us to implement a FDA and DOT approved sharps disposal system that we developed in California and is currently in use there. The program that we are implementing here is substantially the same as the one that we had approved in California. If you have any questions please call me at 800-822-3929

Gary Chilcott

Gary Chilcott , Pres/ CEO

Sure-Way Systems, Inc.

358 County Silver Bow
Facility & # Sureway
Closure
Finan Assur
GW Corr Meas
GW Monitoring
GW Reports
Inspections
Other:
Landfarm
Liner
Methane
O & M
Run - On

DEC 0 7 2000

MONTANA
DEPT. OF ENVIRONMENTAL QUALITY
COMMUNITY SERVICES BUREAU

Exhibit JAK-8

Exhibit JAK-8

NORTH DAKOTA DEPARTMENT OF HEALTH
Environmental Health Section

Location:
1200 Missouri Avenue
Bismarck, ND 58504-5264

Fax #:
701-328-5200

Mailing Address:
P.O. Box 5520
Bismarck, ND 58506-5520

REF FILE: Sure-Way Systems, Inc. (TS-036)

April 5, 2002

DUDLEY CHILCOTT
SURE-WAY SYSTEMS INC
PO BOX 239
VALLEY CITY ND 58072-0239

Dear Mr. Chilcott:

On February 13, 2002, the Department became aware of an apparent waste disposal site located on a farm owned by Jerry Peterson Jr. The Department was informed that paper wastes generated off-site were burned and the ash disposed of. Enclosed is an interoffice memo regarding the Department's inspection of this property.

The Department advises Sure-Way Systems, Inc. that wastes generated at its facility are subject to the North Dakota Solid Waste Management Rules and must be managed accordingly.

Should you have any questions regarding this letter, please feel free to contact Chris Roob at 701-476-4141 or me at 701-328-5166.

Sincerely,

Curtis L. Erickson, Manager
Hazardous Waste Program
Division of Waste Management

CLE:lb
Enc.
CERTIFIED
cc: Jerry Peterson Jr., Valley City

I N T E R

North Dakota
Department of Health

O F F I C E

MEMO

Ref File: Sure-Way Systems, Inc. (TS-036)

To: File

From: Scott C. Hopfauf, Env. Engineer
Solid Waste Program
Division of Waste Management

Subject: Complaint of Illegal Disposal

Date: April 3, 2002

On February 13, 2002, the Department was informed that commercial wastes were disposed of in an unpermitted landfill south of Litchville, N.D.

In approximately May of 2000, paper wastes from Sure-Way Systems of Valley City were burned and disposed of in the N ½ of Section 10, Township 135 North, Range 60 West in Barnes County. The property is owned by Jerry Peterson Jr., a past employee of Sure-Way Systems of Valley City.

On March 28, 2002, Mr. Peterson and I inspected the disposal site. The site consisted of an open trench which contained typical farm waste, burn barrel ash, wood, asphalt shingles, etc. Mr. Peterson pointed out the exact location of where the burn took place. Ash residue was observed; however, no recognizable documents were observed. Metal plates which held the documents together were observed. Mr. Peterson informed me that this is all that remains of the burned material.

I informed Mr. Peterson of the exemptions in the N.D. Solid Waste Management Rules for farm wastes and that he is not allowed to accept waste from off the farm site.

I took photographs and we left the site.

SCH:lb